IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

The ERISA Industry Committee,

701 8th Street N.W., Suite 610
Washington, D.C. 20001,

Plaintiff,

v.

United States Department of Health and Human Services,

200 Independence Avenue, S.W.
Washington, D.C. 20201;

United States Department of the Treasury,

1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220;

United States Department of Labor,

200 Constitution Avenue, N.W.
Washington, D.C. 20210,

Defendants.

Case No. 25-cv-136

COMPLAINT

INTRODUCTION

1. This case is about the "Parity Rule"—a final rule that fundamentally reshapes the requirements for health plans that cover diagnosis and treatment for mental health and substance use disorders. *See Requirements Related to the Mental Health Parity and Addiction Equity Act*, 89 Fed. Reg. 77,586 (Sept. 23, 2024) ("Parity Rule" or "Rule"). The Mental Health Parity and Addiction Equity Act ("MHPAEA" or the "Act") regulates these plans by requiring parity between the limits they adopt for mental health and substance use disorder ("MH/SUD") benefits and those they adopt for other types of health benefits—referred to as medical and surgical ("M/S") benefits. But Congress has repeatedly made clear that the Act is not a benefits mandate, and it therefore does not require health plans to provide any particular MH/SUD benefits, or even to provide MH/SUD benefits at all. Many employers of course willingly provide health benefits, including MH/SUD benefits, through employer-sponsored employee-benefit plans, and have done so for years. Employers offer these benefits because they recognize the importance of employee well-being and mental health, and acknowledge the growing need for greater access to services for MH/SUD conditions. By continuing to expand their MH/SUD benefits, employer plans have demonstrated a longstanding commitment to providing affordable, high-quality coverage for mental health and substance use disorders. And Congress has left it to plan sponsors to figure out how best to achieve that objective.

2. While the requirements for achieving mental health parity have evolved over the decades, the foundational policies have not changed: All that is required is parity in particular plan *terms* and their application, not parity in *access* to MH/SUD benefits, much less provision of *particular* benefits. When Congress first took action to address parity in the Mental Health Parity Act of 1996, for example, it merely required parity in the dollar limits that apply to mental health

("MH") benefits compared with M/S benefits. In 2008, the MHPAEA expanded on this model by adding parity requirements related to plan financial terms (*e.g.*, copayments and deductibles); treatment limitations (*e.g.*, limiting the number of doctor visits per year, or requiring referrals for certain services); and substance use disorder ("SUD") benefits. The 2010 and 2013 regulations that implemented these requirements did not require parity in *access* to MH/SUD benefits, and they expressly recognized that the MHPAEA does *not* mandate any benefits. And Congress stayed true to these principles when it amended the MHPAEA in the 2021 Consolidated Appropriations Act ("2021 CAA") to codify portions of the 2010 and 2013 regulations and add documentation and reporting requirements. The 2021 CAA thus left in place, unmodified, the MHPAEA provision specifying that the Act does not "requir[e]" a plan "to provide any [MH] or [SUD] benefits." 29 U.S.C. § 1185a(b)(1).

3. The most recent rule implementing the MHPAEA, the Parity Rule, is an about-face of these longstanding policies. The Parity Rule was issued on September 9, 2024 by the Department of Health and Human Services, the Department of the Treasury, and the Department of Labor (collectively, "the Departments"), with the stated goal of increasing access to MH/SUD benefits. These are noble goals, and Plaintiff The ERISA Industry Committee ("ERIC") endorses them without reservation. But the Parity Rule goes far beyond these goals in ways that will likely result in *decreased* access to MH/SUD benefits—the exact opposite of the Departments' goals. Rather than faithfully implementing the statutory requirements of the MHPAEA, much of the Parity Rule upends the regulatory and compliance framework that has evolved over decades pursuant to the limits established by Congress. The Parity Rule also imposes entirely new, ambiguous requirements that are so burdensome and unworkable that they will discourage

employers from offering MH/SUD benefits at all. Several provisions of the Rule are particularly problematic:

4. *First*, the Parity Rule's new "meaningful benefits" requirement is a stark example of the Departments' regulatory overreach. Under the Rule, plans that cover a MH/SUD condition in a benefit classification (*e.g.*, inpatient, outpatient, pharmacy) must provide "meaningful benefits" for that condition in all classifications in which M/S benefits are provided. 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). And the Rule defines "meaningful benefits" by reference to generally recognized independently formulated standards for current medical practice. So, for example, if a plan offers inpatient M/S benefits—as nearly every health plan does—and also offers inpatient MH/SUD benefits, the Departments have now arrogated to themselves authority to determine the adequacy of those inpatient MH/SUD benefits. Not only that, the Departments will now make that determination based on their own interpretation of "generally recognized" medical standards as set forth in third-party clinical literature, rather than by comparison with that plan's inpatient M/S coverage.

5. The "meaningful benefits" requirement exceeds the Departments' statutory authority because it effectively imposes a benefits mandate that the Departments lack authority to impose. As discussed above, the MHPAEA makes abundantly clear that it is *not* a benefits mandate. *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."). Until this Rule, that was also the Departments' express and longstanding position. *See*, *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

[SUD] benefits."). The "meaningful benefits" requirement flouts this limitation by effectively dictating the types of inpatient, outpatient, and pharmacy treatment that plans must cover if they cover those categories of treatment. It thus strips plan sponsors of the basic judgment about what benefits will ensure affordable, high-quality coverage, and risks deterring plan sponsors from adopting plans that cover MH/SUD treatments at all.

6. The Departments' benefits mandate is also antithetical to the Employee Retirement Income Security Act ("ERISA"), which governs the vast majority of group health plans subject to the Parity Rule. ERISA is premised on employers' voluntary adoption of benefits plans and protects their autonomy in selecting the terms of coverage, payable benefits, and other aspects of plan design that best suit their employees' wants and needs.

7. At a minimum, the Departments' refusal to acknowledge their significant course reversal—incorrectly insisting that the Parity Rule is "not intended to mandate coverage of any particular benefits," 89 Fed. Reg. at 77,635—violates the Administrative Procedure Act ("APA"). Under the APA, the Departments may change their position within the bounds of their statutory authority so long as they display awareness that they are doing so, provide a reasonable basis for the new policy, and acknowledge and account for the reliance interests engendered by their prior approach. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). But here the Departments contend that the Rule is not a benefits mandate and thus fail even to acknowledge their blatant change in approach, let alone explain it or address the significant reliance interests it upends.

8. The meaningful benefits requirement also violates the private nondelegation doctrine and the APA's notice-and-comment requirements because what qualifies as "meaningful benefits" depends on "generally recognized" medical standards developed in third-party clinical

literature. That dynamic incorporation of privately created standards into government regulations unlawfully delegates the Departments' executive power to private entities, and it also deprives regulated parties of any opportunity to comment on those standards before they are altered, in contravention of the APA's notice-and-comment requirements. And, it is arbitrary and capricious to outsource the determination of "meaningful benefits" to third parties—rather than deferring to plans sponsors' experienced judgments regarding the benefits that can be feasibly covered while keeping coverage affordable for employees.

9. *Second*, the Parity Rule's "material differences in access" standard is a similar example of agency overreach. Under the Rule, material differences in "access" as between MH/SUD and M/S benefits are presumptive evidence of a regulatory violation: "To the extent the relevant data … suggest that [a] nonquantitative treatment limitation contributes to material differences in access to [MH/SUD] benefits as compared to [M/S] benefits in a classification, such differences will be considered a strong indicator that the plan violates" the Rule. 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).

10. The "material differences in access" standard is far afield from the Departments' statutory authority to ensure parity in plan *terms* and the application of those terms. Instead, the Departments have now effectively claimed authority—granted nowhere in the MHPAEA—to regulate parity in *outcomes*. Take, for example, a common nonquantitative treatment requirement that has been included in health plans for decades: a requirement that patients obtain a referral from a generalist before seeking treatment from a specialist. Even if that same requirement applies equally to MH/SUD and M/S benefits, applying the requirement to MH/SUD benefits is now presumptively unlawful under the Rule if the requirement has a greater impact on access to

MH/SUD benefits than it has on access to M/S benefits. The Parity Rule thus risks depriving plans of many of the basic tools they use to ensure that the MH/SUD coverage they offer is both affordable and high quality.

11. In effect, the Departments have transformed the MHPAEA from a prohibition on disparate treatment of MH/SUD benefits to a prohibition on disparate impacts. But disparate-impact liability is rare under federal law, and courts do not lightly read it into federal statutes mandating equal treatment. There is nothing in the MHPAEA that states or even suggests Congress intended to create such liability here. The "material differences in access" standard thus exceeds the Departments' authority.

12. The Departments' novel assertion of authority to regulate parity in outcomes is particularly troubling, moreover, because differences in access to MH/SUD and M/S benefits often have nothing to do with plan terms or their application. They frequently derive from a wide range of causes entirely outside plans' control, such as random variability and changes to unrelated state or federal laws. A "material differences in access" standard also assumes that MH/SUD and M/S treatments are somehow statistically comparable. They are not. The Parity Rule thus arbitrarily requires plans to compare unlike and incommensurable things. In addition, the "material differences in access" standard violates the Due Process Clause's basic requirement of fair notice because it does not sufficiently define "access" or "relevant data" for purposes of measuring any "material differences."

13. These are just two examples among many. As detailed below, several other provisions of the Final Rule exceed the Departments' authority or violate the APA. The Rule imposes a vaguely defined "comparative analysis" requirement that is arbitrary and capricious and unconstitutionally vague because it requires plans to compare M/S and MH/SUD benefits without

sufficiently describing what information must be included in that analysis. 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 Departments further exceeded their authority and violated the APA's notice-and-comment and reasoned decisionmaking requirements by adding requirements not contemplated by the proposed rule that compel named fiduciaries of ERISA-covered plans to certify that they have engaged in a prudent process to select a qualified service provider to perform and report the comparative analysis that the Rule mandates and have satisfactorily monitored that service provider. 29 C.F.R. § 2590.712-1(c)(6)(vi) (DOL). And the Departments aggravated these concerns by arbitrarily and capriciously placing key portions of the Rule into effect as early as January 1, 2025—less than four months after the Rule was issued—despite the impossibility of plans updating all of their comparative analyses by that date.

14. By substantially increasing administrative costs—in time and labor, as well as monetary expenditures—the Parity Rule will take valuable resources away from providing MH/SUD benefits, forcing employers to re-think the type and level of their coverage for those benefits, quite possibly causing people to lose access to, or the ability to use, the behavioral health coverage and benefits they already have. In other words, not only does the Parity Rule violate the intent of Congress in the MHPA, the MHPAEA, and the 2021 CAA, but implementing the Parity Rule could *decrease* access to MH/SUD benefits. Plaintiff wholeheartedly endorses MH/SUD parity goals, but the Rule is a textbook example of regulatory overreach that undermines those goals by undercutting access to high-quality, affordable care.

15. For all these reasons, the Rule—and at minimum the challenged provisions—must be vacated as unlawful, procedurally improper, arbitrary and capricious, and contrary to the APA.

PARTIES

16. Plaintiff The ERISA Industry Committee (ERIC) is a national nonprofit trade association with its principal place of business in Washington, D.C.

17. ERIC advocates exclusively on behalf of large employers regarding health, retirement, and compensation public policies at the federal, state, and local levels. ERIC's members are unaffiliated companies that serve as plan sponsors by offering comprehensive group health benefits to their employees in compliance with the Internal Revenue Code, ERISA, and the Public Health Service Act. Most of these plans are self insured, meaning plan sponsors design and implement the benefits with the help of a third-party administrator, but the sponsors directly bear the cost of reimbursing providers and paying for health benefits. The group health plans of ERIC's member companies insure tens of millions of workers, their families, and retirees.

18. ERIC's members traditionally go above and beyond the typical health plan offerings of other employers in order to provide access to quality care for their workers and families. They have consistently offered health plans that provide comprehensive and affordable coverage, including robust prescription drug coverage, such as coverage for gene and cell therapy and other specialty drugs. Participants often have access to concierge medicine or direct primary care, enhanced telehealth services, and other benefits not traditionally covered by health plans. On average, ERIC member companies pay 80 percent of health care costs on behalf of plan participants. ERIC's members believe in caring for the whole patient and, while not required, have willingly increased MH/SUD benefit offerings in pursuit of total patient care.

19. Many of ERIC's members have Article III standing because they are employers that offer health plans subject to the Parity Rule, meaning those members are required and will continue to be required to comply with the Parity Rule's requirements. ERIC's members have

already incurred and will continue to incur substantial costs collecting data, preparing analyses from that data, certifying those analyses, and altering any plan terms that do not conform to the Rule's requirements. And because many of these requirements apply as of January 1, 2025, ERIC's members have been forced to change many of their practices in less than four months.

20. For ERIC's members, these significant burdens will increase administrative costs, taking valuable and finite resources away from providing additional coverage and care. ERIC's members will be forced to redirect funds that otherwise would have been spent on additional benefits for employees and their families in order to defray these purely compliance-related costs. As a result, ERIC's members will likely have to either reduce access to the MH/SUD benefits they currently offer or eliminate the nonquantitative treatment limitations applicable to M/S benefits. This will increase health care costs for individuals and their families and force ERIC's members to change their benefits coverage. These injuries are directly and immediately traceable to the challenged parts of the Rule and would be remedied by a judgment vacating the Rule or, at a minimum, the challenged provisions.

21. ERIC has associational standing to bring this lawsuit on behalf of its members because at least one of its members has Article III standing, the interests that ERIC seeks to protect are germane to its organizational purpose of advocating for the interests of employers serving as plan sponsors for employee benefit plans, and neither the claims asserted nor the relief requested in this lawsuit requires the participation of individual ERIC members.

22. Defendants are the federal agencies that jointly promulgated the Parity Rule challenged in this lawsuit.

23. Defendant HHS is an executive department of the United States federal government that is headquartered in Washington, D.C.

24. Defendant Treasury is an executive department of the United States federal government that is headquartered in Washington, D.C.

25. Defendant DOL is an executive department of the United States federal government that is headquartered in Washington, D.C.

JURISDICTION AND VENUE

26. This action arises under the APA, 5 U.S.C. §§ 500 *et seq.*; the MHPAEA, 42 U.S.C. § 300gg-5; 29 U.S.C. § 1185a; 26 U.S.C. § 9812; and the Declaratory Judgment Act, 28 U.S.C. § 2201. This Court has federal question subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331.

27. The Rule is final agency action subject to judicial review as provided by the APA. 5 U.S.C. § 704.

28. Venue is proper in this Court because this is an action against agencies of the United States. Defendants HHS, Treasury, and DOL reside in this judicial district; a substantial part of the events or omissions giving rise to this action occurred in this judicial district; and no real property is involved in this action. 28 U.S.C. § 1391(e)(1).

ALLEGATIONS

I. Legal And Factual Background

A. Health Plans Provide Many Different Types Of Benefits And Adopt Limits On Those Benefits To Promote Access To High-Quality, Affordable Care

29. Many employers choose to voluntarily offer a wide variety of health benefits to attract and retain talented workers and keep their employees healthy and productive. Employer health plans thus typically include an array of benefits to ensure comprehensive and quality health coverage. This includes broad provider networks and ample coverage options for a variety of services and products.

30. The benefits offered under employer-sponsored health plans commonly include not only medical and surgical benefits (M/S), but also mental health and substance use disorder (MH/SUD) benefits. Some plans cover a select few MH/SUD benefits, and others choose to offer a wide variety to meet the various needs of their workers and families. They do so because employers widely recognize the importance of mental health and the growing need for access to MH/SUD items and services.

31. Employer-sponsored group health coverage typically is financed by contributions from the employer and its employees. Employees typically pay a monthly or yearly premium that varies based on the level of coverage provided, and contribute to reimbursement of medical providers through copayments, deductible amounts, and co-insurance. Employers and employees alike thus share an interest in selecting an appropriate level of coverage. In offering health benefits, therefore, employers adopt various financial requirements as well as quantitative and nonquantitative limitations on coverage to ensure that high-quality care remains affordable for both the employers and their employees. *See supra* ¶ 10. These limitations on benefits help ensure that large numbers of workers and their families retain access to high-quality, affordable care.

32. The vast majority of group health plans subject to the Final Rule (including all plans sponsored by ERIC's member companies) are governed by ERISA. A key feature of ERISA is that it does not "requir[e] employers to establish employee benefits plans" at all. *Lockheed Corp. v. Spink*, 517 U.S. 882, 887 (1996). Rather than "mandate what kind of benefits employers must provide if they choose to have such a plan," *id.*, ERISA leaves plan sponsors "large leeway to design … plans as they see fit," *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 833 (2003). An employer's control over plan design is critically important for a well-ordered system of employment-based benefits coverage because it allows each employer to tailor its terms of

coverage and benefit offerings to the wants and needs of its workforce. Indeed, employer autonomy in plan design is so central to ERISA that the statute contains a "broad" express-preemption provision (29 U.S.C. § 1144(a)) that nullifies all state laws that "prohibi[t] employers from structuring their employee benefit plans in a [particular] manner." *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97-98 (1983).

33. Employer-sponsored coverage—and employer autonomy over plan design—thus confers numerous advantages on employees and their families. In designing their plans, employers consider the wants and needs of their current and prospective employees, thinking through what benefits to offer to successfully recruit and retain a talented workforce. Because coverage is elective, employees may opt out from that financial contribution if they do not need coverage—such as if they are covered under their spouse's employer's plan. Further, those who opt in usually have multiple health plan options to choose from. This means they can select a level of coverage and a contribution rate that makes the most sense for them. And if circumstances change, employees can typically make a new health plan selection from the plans offered on an annual basis. In other words, employer autonomy over plan design furthers employees' health and financial well-being.

B. Congress Enacts The Mental Health Parity Act Of 1996 To Prevent Plans From Treating Mental Health Benefits Differently From Medical and Surgical Benefits

34. Congress first took action to address mental health parity in the Mental Health Parity Act of 1996 ("MHPA"). *See* Pub. L. No. 104-204, tit. VII, 110 Stat. 2874 (Sept. 26, 1996). In the MHPA and its implementing regulations, Congress and the Departments imposed mental health parity solely with respect to plan terms and the application of those terms. A plan complied with the MHPA so long as it treated M/S and MH benefits equally. Plans had no obligation to

assess—much less cure—any disparate impact that a term applicable to both M/S and MH benefits might have had on access to MH benefits.

35. The MHPA focused narrowly on requiring parity with respect to plan terms that adopt dollar limits on the amount of benefits that can be paid out over the entire duration of coverage ("aggregate lifetime limit[s]") and during a single year ("annual limit[s]"). 29 U.S.C. § 1185a(e)(1)-(2). The Affordable Care Act of 2010 has since largely eliminated these limits for most health plans, but for plans that still have them, the MHPA generally prohibits them from applying more restrictive limits on MH benefits. That is, if a plan adopts no aggregate lifetime or annual limit on M/S benefits, it generally cannot apply any such limit to MH benefits. 29 U.S.C. § 1185a(a)(1)(A), (a)(2)(A). If a plan does adopt a certain dollar limit on M/S benefits, it generally can apply a comparable limit to MH benefits so long as it does "not distinguish in the application of" that limit as between MH and M/S benefits. *Id.* § 1185a(a)(1)(B), (a)(2)(B).

36. Congress also made clear in the MHPA that it was not imposing a benefits mandate: "Nothing in the [MHPA] shall be construed … as requiring a [plan] … to provide any [MH] benefits." 29 U.S.C. § 1185a(b)(1). And the MHPA was not to be interpreted "as affecting the terms and conditions" of a plan other than with respect to the MHPA's specific parity requirements. *Id.* § 1185a(b)(2).

C. The Mental Health Parity And Addiction Equity Act Of 2008 And Its Implementing Regulations Expand Federal Parity Requirements While Maintaining The Prior Act's Equal Treatment Standard

37. The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) was Congress's next major effort to address parity in plan terms. *See* Pub. L. No. 110-343, tit. V, subtit. B, § 512, 122 Stat. 3765 (Oct. 3, 2008). In addition to extending the MHPA's parity requirements for aggregate lifetime and annual dollar limits to SUD benefits, Congress imposed MH and SUD parity requirements with respect to two additional types of plan terms: financial

requirements and treatment limitations. 29 U.S.C. § 1185a(a)(3). Importantly, the MHPAEA continued to apply the MHPA's disparate-treatment standard of liability (as opposed to a disparate-impact standard), and it made no distinctions between "quantitative" and "nonquantitative" treatment limitations.

38. "[F]inancial requirements" under the MHPAEA are plan cost-sharing terms like "deductibles, copayments, coinsurance, and out-of-pocket expenses." 29 U.S.C. § 1185a(a)(3)(B)(i). Congress barred plans from imposing any "separate cost-sharing requirements that are applicable only with respect to [MH/SUD] benefits," and mandated that a plan's financial requirements for MH/SUD benefits must generally be "no more restrictive than the predominant financial requirements" that apply to M/S benefits. *Id.* § 1185a(a)(3)(A)(i). So, for example, if the predominant cost-sharing requirement that applies to inpatient, out-of-network M/S benefits is a 15 percent coinsurance rate, the plan generally cannot apply a higher coinsurance rate to inpatient, out-of-network MH/SUD benefits.

39. The second type of plan term addressed by the MHPAEA—treatment limitations—"include[s] limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." 29 U.S.C. § 1185a(a)(3)(B)(iii). The MHPAEA imposes the same parity requirements on treatment limitations that it imposes on financial requirements: there can be "no separate treatment limitations that are applicable only with respect to [MH/SUD] benefits," and a plan's treatment limitations on MH/SUD benefits must generally be "no more restrictive than the predominant treatment limitations" that apply to M/S benefits. *Id.* § 1185a(a)(3)(A)(ii).

40. The Departments adopted interim regulations implementing the MHPAEA in 2010, *see Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and*

Addiction Equity Act of 2008, 75 Fed. Reg. 5410 (Feb. 2, 2010), followed by final regulations in 2013, *see Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Technical Amendment to External Review for Multi-State Plan Program*, 78 Fed. Reg. 68,240, 68,280 (Nov. 13, 2013). Those regulations introduced for the first time a new distinction between two types of treatment limitations: quantitative and nonquantitative ("QTLs" and "NQTLs," respectively). The regulations defined QTLs as treatment limitations that "are expressed numerically," such as annual limits on the number of doctor visits. 75 Fed. Reg. at 5431; 78 Fed. Reg. at 68,267. And they defined NQTLs as limitations that "otherwise limit the scope or duration of benefits for treatment." 75 Fed. Reg. at 5431; 78 Fed. Reg. at 68,267. Examples of NQTLs include requirements for a referral from a primary care provider for certain services; limitations on medically unnecessary, experimental, or investigative treatments; other plan exclusions on coverage, such as exclusions based on a failure to complete a course of treatment; and standards for a provider's admission to the plan's network. 75 Fed. Reg. at 5436; 78 Fed. Reg. at 68,282.

41. With respect to QTLs, the 2010 and 2013 regulations—like the statute itself—impose the same parity requirements that apply to financial plan terms: QTLs for MH/SUD benefits generally cannot be more restrictive than the QTLs that apply to M/S benefits. For example, if a plan adopts an annual limit of 50 outpatient visits for M/S treatments, the plan cannot adopt an annual limit of fewer than 50 outpatient visits for MH/SUD treatments. 75 Fed. Reg. at 5412, 5431, 5433-34; 78 Fed. Reg. at 68,267, 68,269, 68,277.

42. But the Departments imposed "different parity standards" for NQTLs. 78 Fed. Reg. at 68,245. The regulations mandated that a plan cannot adopt NQTLs on MH/SUD benefits in a given classification "unless, under the terms of the plan as written and in operation, any processes,

strategies, evidentiary standards, or other factors used in applying the [NQTL] to [MH/SUD] benefits in the [given benefits classification] are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the [NQTL] to [M/S] benefits in the classification." 75 Fed. Reg. at 5436; 78 Fed. Reg. at 68,282. For example, if a plan requires prior authorization for both M/S and MH/SUD inpatient benefits, yet "[i]n practice," inpatient benefits for M/S conditions "are routinely approved for seven days," whereas inpatient benefits for MH/SUD conditions are routinely approved "only for one day," that would be—according to the Departments—a lack of parity. 78 Fed. Reg. at 68,282.

43. Like the underlying statute, the MHPAEA's 2010 and 2013 NQTL regulations at most required parity in the "operation" of plan terms—that is, how plan terms are implemented or applied—and not parity in the *effects* that result from plans' equal implementation of comparable terms. Nothing in the 2010 or 2013 regulations—unlike the Parity Rule—went so far as to require parity in *access* to MH/SUD benefits, much less did they mandate any particular benefits. Indeed, the preamble to the 2013 final rule stated that "[d]isparate results alone do not mean that the NQTLs in use do not comply with these [parity] requirements." 78 Fed. Reg. at 68,245-46. The Departments also expressly recognized that "[t]he statute does not mandate coverage for either [MH] or [SUD] benefits," 75 Fed. Reg. at 5420, and made clear that "nothing in th[e] regulations requires a plan or issuer to provide any [MH] or [SUD] benefits," 78 Fed. Reg. at 68,251; *see also id.* at 68,246 ("[T]he Departments d[o] not intend to impose a benefit mandate through the parity requirement that could require greater benefits for [MH] conditions and [SUD] disorders than for [M/S] conditions.").

D. The 2021 Consolidated Appropriations Act Codifies The Different Criteria For NQTL Parity But Still Imposes A Disparate-Treatment Liability Standard

44. In its 2020 amendments to the MHPAEA, enacted as part of the 2021 CAA, Congress codified the NQTL parity criteria in the 2010 and 2013 regulations. *See* Pub. L. No. 116-260, div. BB, tit. II, § 203, 134 Stat. 1182, 2903-10 (Dec. 27, 2020). As amended, the MHPAEA now provides that plans must "perform and document …. and make available to the [Departments] … comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to [MH/SUD] benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to [M/S] benefits in [a given] benefits classification." 29 U.S.C. § 1185a(a)(8)(A)(iv).

45. The 2020 amendments also require plans to submit the following information alongside their comparative analyses: (1) "[t]he specific plan or coverage terms or other relevant terms regarding the NQTLs, … and a description of all [MH/SUD] and [M/S] benefits to which each such term applies in each respective benefits classification"; (2) "[t]he factors used to determine that the NQTLs will apply to [MH/SUD] benefits and [M/S] benefits"; (3) "[t]he evidentiary standards used for th[ose] factors …., when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to [MH/SUD] benefits and [M/S] benefits" and (4) "[t]he specific findings and conclusions reached by the [plan] with respect to the health insurance coverage, including any results of the [comparative] analyses … that indicate that the plan or coverage is or is not in compliance." 29 U.S.C. § 1185a(a)(8)(A)(i)-(iii), (v).

46. To enforce these new requirements (and the MHPAEA's existing requirements), Congress spelled out a stringent enforcement regime offering plans little opportunity to contest

any determinations of noncompliance. For example, plans must submit their comparative analyses to the Departments "upon request." 29 U.S.C. § 1185a(a)(8)(A). If, upon "review[ing] the comparative analyses," the relevant agency makes an initial determination that the plan "is not in compliance," the plan must come into compliance within just "45 days." *Id.* § 1185a(a)(8)(B)(iii)(I)(aa). After this 45-day period, "if the [agency] makes a final determination that the plan … still is not in compliance," then the plan must notify plan enrollees of the purported noncompliance within 7 days. *Id.* § 1185a(a)(8)(B)(iii)(I)(bb). That is, within a week of a unilateral determination by potentially a lone government employee, an employer (or its plan administrator) must tell employees that the company is supposedly violating the law.

47. Congress still, however, did not purport to impose a disparate-impact liability standard, whether for NQTLs or any other plan terms. Nor did Congress repeal or otherwise modify the provision specifying that the MHPAEA does not "requir[e]" a plan "to provide any [MH] or [SUD] benefits." 29 U.S.C. § 1185a(b)(1).

II. The Parity Rule

A. The Departments Propose Sweeping Changes To The Regulatory Framework Governing Parity For Mental Health And Substance Use Disorders

48. The Parity Rule significantly upends the decades-old statutory and regulatory framework governing MH/SUD parity. The Departments first introduced what would become the Parity Rule in a notice of proposed rulemaking issued on July 25, 2023 and published in the Federal Register on August 3, 2023. *Requirements Related to the Mental Health Parity and Addiction Equity Act*, 88 Fed. Reg. 51,552 (Aug. 3, 2023) ("Proposed Rule"). The 60-day comment period ran through October 2, 2023, *id.* at 51,552, but was subsequently extended to October 17, 2023, 89 Fed. Reg. at 77,589.

49. Although the Proposed Rule purported to implement the amendments to the MHPAEA in the 2021 CAA, the Departments instead proposed changes that would overhaul longstanding requirements and interject several new, vague, and even undefined standards. The most problematic provisions include the following:

50. "Meaningful Benefits" Requirement. The Departments proposed a requirement that, in effect, would require many plans and issuers to provide *coverage* for certain mental health conditions and substance use disorders. Specifically, "if a plan or issuer provides any benefits for a mental health condition or substance use disorder in any classification of benefits, benefits for that mental health condition or substance use disorder must be provided in every classification in which [M/S] benefits are provided." 88 Fed. Reg. at 51,586. And as proposed, such benefits for mental health conditions or substance use disorders must be "***meaningful benefits***." *Id*. (emphasis added). The Departments did not provide a definition of "meaningful benefits" but instead asked for comment on "whether and how to define" the term. *Id.*

51. "Material Differences in Access" Standard. The Departments proposed that any "***material differences***" in "***access***" to MH/SUD benefits (as measured by outcomes-based data) would constitute presumptive evidence of noncompliance with the MHPAEA—in effect, the very sort of disparate-impact parity standard that Congress has long declined to impose. Specifically, if "relevant data … show material differences in access" to MH/SUD benefits "as compared to" M/S benefits, those differences "would be considered a strong indicator that the plan or issuer violat[ed]" the MHPAEA. 88 Fed. Reg. at 51,568, 51,627. Despite proposing this entirely new liability standard, the Departments offered little to no clarity on the meaning of either "material differences" or "access," nor did the Departments provide meaningful guidance on what constituted "relevant data."

52. Comparative Analysis Requirements. Compounding those problems, the Departments proposed onerous and unclear requirements for how plans were to analyze and report compliance with the new "material differences in access" standard. The Proposed Rule largely echoes the CAA's comparative analysis requirements, *see supra* ¶ 44, but offered little guidance on what specific information plans must provide. 88 Fed. Reg. at 51,561. It instead used vague and insufficiently defined terms, including the terms at the heart of the comparative analyses—*i.e.*, "material differences" and "access." For example, the Proposed Rule required plans to provide a "detailed explanation of material differences in outcomes that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to [MH/SUD] benefits and [M/S] benefits," *id.* at 51,593, but the lack of any clear definition of "material differences" left the scope of this reporting requirement entirely opaque.

53. ERISA Plan Fiduciary Certification Requirement. The Department of Labor also proposed that plans "subject to ERISA" "would be required to include a certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the comparative analysis to be in compliance with the content requirements of these proposed rules." 88 Fed. Reg. at 51,593; *see id.* at 51,651.

54. January 1, 2025 Applicability Date. The Departments proposed that the rule would apply "on the first day of the first plan year beginning on or after January 1, 2025." 88 Fed. Reg. at 51,596. The Departments noted that the "new requirements may take time for plans and issuers to implement" but—at least on July 25, 2023 when the Proposed Rule was released—the Departments thought January 1, 2025 would "strike an appropriate balance" and provide enough time for implementation. *Id.*

B. Commenters Strenuously Object To Key Provisions Of The Proposal

55. The Departments received over 9,500 comment letters in response to the Proposed Rule. 89 Fed. Reg. at 77,589. While commenters expressed widespread support for the goal of achieving mental health parity, key aspects of the Proposed Rule were opposed by a wide range of interested parties, including health insurance carriers and third-party administrators, self-funded health plans, employers and other plan sponsors, and associations representing those groups.

56. Indeed, commenters challenged all of the requirements discussed above, and more. Commenters repeatedly faulted the proposal for going beyond the Departments' statutory authority and for departing from prior agency interpretations of the MHPAEA without explanation. Commenters also generally objected to the Departments' failure to provide clear notice of the bounds of permissible conduct. Absent more specificity, commenters stated they could not provide meaningful or productive comments.

1. The "Meaningful Benefits" Requirement

57. Commenters strongly opposed the proposed "meaningful benefits" requirement as fundamentally inconsistent with the applicable statutes and existing regulatory framework and constituting a broad—and indefensible—incursion into plans' choices of what treatments to offer. Commenters were particularly concerned that the Proposed Rule was effectively a benefits mandate that would require coverage of numerous (or even all possible) treatments for a given mental health condition or substance use disorder. Commenters expressed concern that the requirement was unauthorized by statute and would be a significant revision to the existing regulations. For example, commenters explained that Congress—and the Departments' own longstanding regulations—required parity in the financial and treatment limitations that plans adopt for the MH/SUD benefits that *are* offered, but did not require that particular benefits must be offered. Commenters asserted that the Departments' interpretation is thus unlawful because

agencies have only the powers given by Congress, and the presumption is that Congress intends to make major policy decisions.

58. Commenters also opposed the requirement on policy grounds. They explained, for example, that because the meaningful benefits requirement unlawfully expands coverage, it risks undermining plans' efforts to provide high-quality, safe, and effective medical care. Commenters further asserted that if the Departments intended to keep the meaningful benefits requirement, they should issue another proposal with a clear definition of "meaningful benefits" on which commenters could provide meaningful input.

2. The "Material Differences In Access" Standard

59. Commenters also strenuously objected to the proposal that "material differences" in "access" to MH/SUD benefits, as evaluated through outcomes-based data, would be presumptive evidence of noncompliance. Industry commenters asserted that this standard is contrary to law, highly unclear, unworkable in practice, and effectively a disparate-impact test.

60. Specifically, commenters noted that the MHPAEA provides no basis for considering outcomes-based data, and that this requirement is a departure in policy, as the Departments previously acknowledged that outcomes are *not* dispositive of compliance with parity requirements. Both in the 2013 final rule and in subsequent agency guidance, the Departments flatly rejected recommendations to apply identical outcomes-based tests and requirements for QTLs and NTQLs, explaining that "[d]isparate results alone do not mean that the NQTLs in use do not comply with these [parity] requirements." 78 Fed. Reg. at 68,245-46. Instead, the Departments had considered whether the "processes, strategies, evidentiary standards, and other factors" for MH/SUD benefits are comparable to and no more stringent than for M/S benefits. *Id.*

61. Commenters also requested clarity regarding the definition of the "material differences in access" standard. And commenters recommended that, to the extent that the

Departments proceeded with this new standard, the Departments should provide an exhaustive list of outcomes data that plans and issuers must analyze. The Proposed Rule included a requirement that plans and issuers evaluate "any other relevant data"; plans and issuers sought more certainty regarding *what* data are required.

62. Commenters further noted that there are multiple practical difficulties and irrationalities with this standard. Commenters explained that it was arbitrary to consider material differences in access as presumptive evidence of a parity violation because disparate outcomes can occur despite equal treatment of MH/SUD benefits—for example, providers may refuse to join networks, only accept cash, or refuse to submit claims with insurers, and States may limit provider competition. Commenters also pointed out the difficulty and unfairness of comparing MH/SUD and M/S treatments, since they are fundamentally unalike. Similarly, commenters noted that NQTLs affecting the scope or duration of benefits—for example, the requirement that treatment be medically necessary—often cannot be expressed numerically or be mathematically compared, so any "material differences" in access cannot be objectively identified. In addition, commenters suggested that the presumption should apply both ways: If the existence of a material difference in access results in a presumption of noncompliance, then the *lack* of such a difference logically should result in a presumption of compliance.

3. The Comparative Analysis Requirements

63. Commenters vigorously opposed the proposed comparative analysis requirements on the basis that they are too vague and non-specific to provide notice as to what is required. For example, commenters explained that the requirements amounted to an unbounded universe of plan terms, strategies, and processes that would need to be analyzed and compared, raising the concern that the Departments would deem the comparative analyses deficient if plans did not correctly anticipate *what* they would need to analyze.

64. Other commenters objected to the requirements on the ground that the lack of specificity invites inconsistent enforcement among the Departments and thus asked for a model template so plan sponsors can understand and develop the NQTL comparative analysis.

4. The ERISA Plan Fiduciary Certification Requirement

65. Commenters strongly opposed the Department of Labor's proposal to require ERISA plan fiduciaries to certify compliance with the comparative analysis requirement. Commenters noted that the Department of Labor was flouting Congress's intent because Congress specifically chose *not* to impose a certification requirement for the NQTL comparative analysis, despite imposing various certification requirements in other parts of the 2021 CAA. And some commenters asserted that the Department of Labor had deviated from its requirements under other provisions of ERISA providing that plan sponsors are not subject to fiduciary certifications where they receive disclosures in their capacity as fiduciaries. *See*, *e.g.*, 29 U.S.C. § 1108(b)(2).

66. Other commenters protested that the certification requirement was unreasonably burdensome. They explained that third-party service providers typically perform a plan's comparative analysis, and that fiduciaries would lack the requisite technical knowledge to assess whether the analysis complies with the Departments' regulations. To comply with the requirement, fiduciaries would effectively be required to hire yet *another* service provider to independently review the work done by the service provider performing the analysis. Commenters explained that this would create inefficiencies and higher costs that would end up diverting resources away from covering MH/SUD benefits. They also explained that the certification requirement could expose fiduciaries to additional liability from service providers and plan beneficiaries in the event the Departments deem a comparative analysis noncompliant. Even short of litigation, commenters noted, the certification requirement would strain contract negotiations between plan sponsors and third-party service providers. Plan sponsors would likely seek

insulation from liability in the event the service provider completes a comparative analysis that the Departments deem noncompliant; conversely, service providers would likely seek insulation from liability on the theory that it is the fiduciary's ultimate obligation to certify compliance.

5. The January 1, 2025 Applicability Date

67. Finally, numerous commenters objected to the Proposed Rule's January 1, 2025 applicability date. Commenters explained that, given the complexity of the industry, the plans at issue, and the Proposed Rule, it is not feasible for employers to digest and implement the substantial operational changes in just a few short months.

68. Some commenters also explained how the January 1, 2025 applicability date was especially problematic in connection with specific new requirements of the Proposed Rule. For example, commenters noted that the new definition of "material" will make it challenging for plan sponsors to comply in such a short time, and that the meaningful benefits requirement would likewise raise practical difficulties.

69. Due to the expected implementation difficulties—which the Departments acknowledged in the Proposed Rule[1]—several commenters requested at least a year or two between finalization of the rule and its applicability date, as well as an implementation period in which compliance would be measured based on good-faith efforts. This would allow stakeholders the time needed to attempt to meet the new standards.

[1] 88 Fed. Reg. at 51,596 ("[T]he Departments also recognize that new requirements may take time for plans and issuers to implement.").

C. The Final Rule Retains Many Objected-To Provisions And Imposes An Entirely Different—And Therefore Unforeseen—ERISA Fiduciary Certification Requirement

70. On September 9, 2024—11 months after the notice-and-comment period ended—the Departments promulgated the Final Rule. While the Departments made some changes to the Proposed Rule, many changes either did not sufficiently address commenters' core concerns or made the requirements even *more* arbitrary and unlawful, including at least one arbitrary addition to the Rule that was nowhere forecast in the Proposed Rule.

71. The Departments adopted the proposed "meaningful benefits" requirement. Although the Departments rejected commenters' arguments that this requirement imposes a benefits mandate and thus failed to acknowledge that it represents a significant reversal of longstanding agency policy, *see* 89 Fed. Reg. at 77,634, the definition that the Departments gave to "meaningful benefits" makes even clearer that the requirement is such a mandate. The Departments explained that "meaningful benefits" requires plans to cover "core treatments" for MH/SUD benefits in classifications where the plan covers "core treatments" for M/S benefits. *Id.* And rather than deferring to plans' experienced judgments about which treatments to cover to meet the specific needs of covered employees, the Departments defined that "core treatments" term by reference to "generally recognized independent standards of current medical practice"—*i.e.*, standards determined by third parties without any consideration of employers' and employees' particular needs. *Id.*

72. The Departments also adopted the "material differences in access" standard and the comparative analysis requirements, and rejected commenters' concerns that a disparate-impact standard of liability contravenes the MHPAEA. 89 Fed. Reg. at 77,610, 77,615. The Departments did not meaningfully address commenters' concerns about the arbitrariness of a "material difference in access" standard, including the lack of clarity as to what qualifies as a "material

difference" in "access," and what "relevant data" plans should collect and assess as part of their comparative analyses to evaluate compliance with that vague standard. Indeed, despite acknowledging that "some of the required content for comparative analyses are described broadly and therefore could lead to the Departments and applicable State authorities taking different approaches in determining what constitutes a sufficient comparative analysis," 89 Fed. Reg. 77,640, the Departments nonetheless deemed these "broad descriptions" to be "necessary." *Id.* The Departments even declined to provide an example of an adequate comparative analysis, as one commenter had requested. *Id.*

73. The Department of Labor did not adopt the Proposed Rule's requirement that ERISA plan fiduciaries certify that the comparative analysis complies with the Departments' regulations. Instead, the Rule imposed a completely different regime never contemplated by the Proposed Rule: It requires ERISA plan fiduciaries to certify that they have engaged in a "prudent process" to select a third party—a "qualified service provider"—to perform the comparative analysis. 89 Fed. Reg. at 77,648. The Rule also newly requires the fiduciaries to certify that they "have satisfied their duty to monitor" the qualified service provider. *Id*. Although DOL claimed that it was imposing this new requirement in response to commenters' concerns about the proposed certification requirement, it did not adequately explain how a *different* certification requirement addressed those concerns. DOL failed, for example, to address commenters' concerns that *any* certification requirement was unauthorized by the statute and "would increase compliance costs … without increasing access to benefits." 89 Fed. Reg. at 77,647. Meanwhile, commenters had no direct opportunity to address the unique problems raised by the new requirements—for example, the prospect that a single noncompliant comparative analysis by a third-party that

services thousands of plans could force all those plans to negotiate higher fees with new service providers unfamiliar with the plan's design.

74. The Departments inexplicably retained the proposed January 1, 2025 applicability date for many provisions despite their delay in promulgating the Final Rule. Indeed, the Final Rule was not promulgated until September 9, 2024—more than 13 months after the Proposed Rule was issued and 11 months after the comment period closed. Those provisions include the revised definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" that expand insurers' and sponsors' obligations under the MHPAEA. 89 Fed. Reg. at 77,652-53 & n.127. They also include the ERISA plan fiduciary certification requirement and other portions of the comparative analysis requirements, such as the vague and unclear provisions purporting to implement the statutory requirement that plans evaluate and demonstrate comparability and stringency of NQTLs as written and in operation. *Id.* At the same time, the Departments "acknowledge[d] the challenges to plans and issuers of implementing some of the requirements," 89 Fed. Reg. at 77,652, and thus imposed a later applicability date of January 1, 2026 for the "meaningful benefits" requirement, the "material differences in access" standard and associated requirements regarding the evaluation of relevant data, and related portions of the comparative analysis requirements, *id.* at 77,652-53. But the Departments did not provide any extension for the other obligations and refused to provide a good-faith compliance period.

III. Key Provisions Of The Parity Rule Are Contrary To Law And Violate The Administrative Procedure Act

75. Several provisions of the Parity Rule—including the January 1, 2025 applicability date—should be set aside because they are unlawful and contravene the APA in multiple ways. To be sure, Plaintiff shares the Departments' goal of parity for—and expanded access to—

MH/SUD benefits. But the Departments' approach to achieving that goal exceeds the Departments' statutory authority and violates the APA.

A. The "Meaningful Benefits" Requirement Contravenes The Statute And Is Arbitrary And Capricious In Multiple Respects

76. Under the Parity Rule's "meaningful benefits" requirement, if a plan covers a MH/SUD condition in a benefit classification, it must provide "meaningful benefits" for that condition in all classifications for which M/S benefits are provided. 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). To provide "meaningful benefits," the plan must cover a "core treatment" for a covered MH/SUD condition in every classification where the plan covers a "core treatment" for a M/S procedure. *Id.* A "core treatment" is a standard treatment, as defined by "generally recognized independent standards of current medical practice." *Id.*

77. This "meaningful benefits" requirement is unlawful for three reasons: (1) it exceeds the Departments' statutory authority by imposing a benefits mandate that the statute expressly forbids; (2) it arbitrarily changes the Departments' position without acknowledgment or explanation; and (3) it arbitrarily outsources the definition of "core treatment" to third parties.

1. The "Meaningful Benefits" Requirement Exceeds The Departments' Statutory Authority

78. The "meaningful benefits" requirement exceeds the Departments' statutory authority under the MHPAEA because it effectively imposes a benefits mandate that the Departments have no power to impose. Nothing in the Act mandates that plans provide any particular MH/SUD benefits. Indeed, the Act affirmatively states that "[n]othing in this section shall be construed … as requiring a group health plan … to provide any [MH/SUD] benefits." 29 U.S.C. § 1185a(b)(1). The Departments themselves have repeatedly recognized that the MHPAEA does not mandate benefits. *See* 75 Fed. Reg. at 5420 ("The statute does not mandate

coverage for either [MH] or [SUD] benefits."); 78 Fed. Reg. at 68,246 ("The Departments did not intend to impose a benefit mandate through the parity requirement that could require greater benefits for [MH/SUD conditions] than for [M/S] conditions."); *id.* at 68,251 ("[N]othing in these regulations requires a plan or issuer to provide any [MH/SUD] benefits. Moreover, the provision of benefits for one or more [MH/SUD conditions] does not require the provision of benefits for any other condition or disorder.").

79. Congress knows how to impose a benefits mandate when it wants to do so. In the Affordable Care Act, Congress directed certain health plans to include coverage for "essential health benefits," including "[m]ental health and substance use disorder services." Pub. L. No. 111-148, tit. 1, subtit. D, pt. I, §§ 1301-1302, 124 Stat. 119, 162-65 (Mar. 23, 2010); *see also id.*, tit. 1 subtit. C, pt. I, § 1201, 124 Stat. at 161. And even that law did not command plans to offer any particular MH/SUD benefits.

80. The Parity Rule's "meaningful benefits" provision is precisely what Congress forbade under the MHPAEA: a mandate that plans provide benefits for MH/SUD conditions. Plans must provide benefits that are "meaningful" for MH/SUD conditions in all benefit classifications in which M/S benefits are provided. To satisfy that mandate, plans must cover "core treatments" for MH/SUD conditions. So, for example, if a plan offers inpatient M/S benefits and also offers inpatient MH/SUD benefits, the Departments now claim the authority to determine whether the inpatient MH/SUD benefits are adequate—all based on their own interpretation of generally accepted medical standards drawn from third-party clinical literature. That is a benefits mandate in both letter and substance, because it effectively dictates the types of inpatient, outpatient, and pharmacy treatments that plans must cover if they cover those categories of treatment, stripping plans of their judgments about what benefits ensure affordable, high-quality coverage.

81. The meaningful benefits requirement also contravenes the fundamental premise of ERISA (which governs the overwhelming majority of plans subject to the Final Rule) that employers must have "large leeway" in how they design plan terms governing coverage and benefits. *Black & Decker Disability Plan*, 538 U.S. at 833; *see supra* ¶ 6.

82. A mandate to provide "meaningful benefits" for MH/SUD conditions across health plans is the type of economically significant regulation that, under the major questions doctrine, Congress does not authorize by implication. *See West Virginia v. EPA*, 597 U.S. 697, 723 (2022).

2. The "Meaningful Benefits" Requirement Is Arbitrary And Capricious Because It Constitutes An Unexplained Change Of Position

83. Even if the Departments had authority to tell plans *what* benefits they must provide when they elect to cover MH/SUD benefits, the Departments' inaccurate refusal to acknowledge that such a requirement amounts to a benefits mandate prevented them from satisfying the requirements of reasoned decisionmaking. The requirement is thus arbitrary and capricious in violation of the APA.

84. The APA requires that, "[w]hen an agency changes its existing position," it "must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" *Encino Motorcars*, 579 U.S. at 221 (quoting *Fox*, 556 U.S. at 515). The Rule flouts that requirement because although the Departments have long disclaimed any power or intention to mandate benefits under their authority to enforce the MHPAEA, *see supra* ¶¶ 5, 78-80, the Rule reverses course without explaining or even acknowledging the change. Instead, the Departments incorrectly insist that the "meaningful benefits" requirement is "not intended to mandate coverage of any particular benefits" at all. 89 Fed. Reg. at 77,635.

85. The Departments' failure to "display awareness that [they are] changing position," *Fox*, 556 U.S. at 515—let alone to "supply a reasoned analysis for the change," *Motor Vehicle*

Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 30 (1983)—makes the "meaningful benefits" requirement arbitrary and capricious under the APA.

3. The "Meaningful Benefits" Requirement Is Unlawful And Arbitrary And Capricious Because It Requires Plans To Provide Coverage Based On Third-Party Clinical Literature

86. The "meaningful benefits" requirement separately violates the nondelegation doctrine and the APA's notice-and-comment requirements, and is arbitrary and capricious, because it outsources the definition of "core treatment" to third parties. What constitutes a "core treatment" is central to whether a plan complies with the Parity Rule. To provide "meaningful benefits," a plan must cover a "core treatment" for a covered MH/SUD in each classification in which the plan provides benefits for a "core treatment" for a M/S procedure. And under the Rule, "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." 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). This definition effectively leaves it to the third-party authors of clinical literature to decide the "core treatment" standards that the Department will then use to determine whether plans have complied with the "meaningful benefits" requirement. *See* 89 Fed. Reg. at 77,634 ("[I]n determining a core treatment for a condition or disorder in this context, [plans and issuers] should rely on current evidence-based medical and clinical information.").

87. This dynamic incorporation of standards that are authored by private third parties violates the nondelegation doctrine. A private entity generally "may not wield governmental power, especially not without express and unambiguous congressional authorization." *Consumers' Rsch. v. FCC*, 109 F.4th 743, 778 (5th Cir. 2024), *cert granted sub nom. FCC v. Consumers' Rsch.*, 2024 WL 4864036 (U.S. Nov. 22, 2024). The "dynamic incorporation" of

"privately created standard[s] … threaten[s] constitutional norms by effectively delegating the agency's statutory authority" to parties that are not vested with any legislative or executive power. Emily S. Bremer, *Incorporation by Reference in an Open-Government Age*, 36 Harv. J.L. & Pub. Pol'y 131, 185-86 (2013).

88. The dynamic incorporation of privately created standards that are changed over time also contravenes the APA's notice-and-comment requirements. The APA requires agencies to "give interested persons an opportunity to participate in [a] rule making." 5 U.S.C. § 553(c). Agencies are thus required to "conduct a notice-and-comment rulemaking" whenever they seek to change regulatory standards. Bremer, *supra*, at 137. "By permitting automatic modifications to administrative regulations without the agency conducting a rulemaking, dynamic incorporation"—such as in the Parity Rule—"robs the public of the opportunity to examine and comment on changes to the incorporated material." *Id.* at 186.

89. At a minimum it is arbitrary and capricious to leave plans at the mercy of third-party clinical literature—and the Departments' interpretation of that literature—in determining what qualifies as a "core treatment." Plan sponsors are uniquely positioned to determine and justify the coverage needs of their employees, which may differ from the population at large. And forcing plans to defer to the clinical literature could pose significant challenges for sponsors of self-insured plans that want to customize their plans. These sponsors will have to rely on third-party clinical data to guide any custom exclusion or limitation on the MH/SUD benefits that the plan seeks to adopt. Compounding the problem, the Departments have created a regime under which plans will be forced to make changes to coverage any time the third-party authors of clinical literature happen to update their standards. Because these interferences with plan expertise and

plan design are unwarranted and represent a failure of reasoned decisionmaking, the "meaningful benefits" requirement is arbitrary and capricious.

B. The "Material Differences In Access" Standard Is Contrary To The Statute, Arbitrary And Capricious, And Violates Due Process

90. The Parity Rule treats any "material differences in access" between MH/SUD benefits and M/S benefits as presumptive evidence of a violation. Specifically, "[t]o the extent the relevant data … suggest that [a] [NQTL] contributes to material differences in access to [MH/SUD] benefits as compared to [M/S] benefits in a classification, such differences will be considered a strong indicator that the plan violates" the Rule. 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).

91. This "material differences in access" standard is unlawful for three reasons: (1) it exceeds the Departments' statutory authority by effectively imposing disparate-impact liability, even though the statute merely requires parity in plan terms and the application of those terms; (2) it hinges on the meaning of ambiguous terms that the Parity Rule fails to define with sufficient specificity; and (3) it arbitrarily treats differences in access as indicative of a plan's lack of parity and relies on the assumption that MH/SUD benefits are comparable to M/S benefits.

1. The "Material Differences In Access" Standard Exceeds The Departments' Statutory Authority

92. A standard that turns on "material differences" in "access" to MH/SUD benefits imposes disparate-impact liability, in contravention of the statutory text and history.

93. The Departments purported to ground this new standard in the statute's requirement that the "financial requirements" and "treatment limitations" for MH/SUD benefits must be "no more restrictive" than the "predominant" limitations applied to "substantially all" M/S benefits. 29 U.S.C. § 1185a(a)(3); *see* 89 Fed. Reg. at 77,614-15. But "financial requirements" and "treatment limitations" are plan *terms*, so this provision simply requires that the applicable plan

terms for MH/SUD—on their face and in application—be "no more restrictive" than for M/S benefits.

94. Indeed, in every iteration of the statute since 1996, *see supra* ¶¶ 2, 34-47, Congress has consistently imposed disparate-*treatment* liability—that is, the statute forbids plans from treating MH/SUD benefits differently in the financial requirements and treatment limitations they adopt for those benefits and in the application of those requirements and limitations. To be sure, the 2020 amendments mandated parity in the "operation" of NQTLs. *See* 134 Stat. at 2901, 2908 (requiring parity "as written and in operation" for the NQTLs). But this simply reinforced that plans cannot evade parity requirements by guaranteeing parity on paper and then applying those terms differently to different types of benefits. Nothing in those amendments demanded parity in *access* to MH/SUD benefits, nor did those amendments mention—much less establish—a "material differences in access" standard. *See* 134 Stat. at 2900-08.

95. 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. And courts typically do not read disparate-treatment liability as encompassing disparate-impact liability. *See Raytheon Co. v. Hernandez*, 540 U.S. 44, 52 (2003) ("This Court has consistently recognized a distinction between … disparate treatment and … disparate impact."); *Adams v. Fla. Power Corp.*, 255 F.3d 1322, 1326 (11th Cir. 2001) (prohibition on "disparate treatment" did not entail prohibition on "disparate impact"). The "material differences in access" standard thus exceeds the Departments' authority by imposing a standard of liability that contravenes the statutory scheme.

2. The "Material Differences In Access" Standard Is Arbitrary And Capricious And Violates Due Process Because It Fails To Define Key Terms

96. The "material differences in access" standard provides insufficient notice of what constitutes a presumptive violation. Under the Parity Rule, if "*relevant data* … suggest that [a

NQTL] contributes to *material differences* in *access* to [MH/SUD] benefits as compared to [M/S] benefits," that is presumptive evidence of a violation. 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) (emphases added).

97. Yet both parts of the "material differences in access" standard—"material differences" and "access"—are vague and insufficiently defined. The Departments acknowledged that multiple commenters requested clarity on what would constitute material differences in access, 89 Fed. Reg. at 77,614-15, but it provided little additional guidance. The Rule suggests, at most, that an NQTL will be considered to contribute to material differences in access where "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." 26 C.F.R. § 54.9812-1(c)(4)(iii)(B)(2) (Treasury); 29 C.F.R. § 2590.712(c)(4)(iii)(B)(2) (DOL); 45 C.F.R. § 146.136(c)(4)(iii)(B)(2) (HHS). But the Rule does not flesh out what constitutes a "negative impact," nor does it explain the circumstances under which a negative impact will be considered "likely." And the Rule does not provide any clear definition of "access."

98. Similarly, the Parity Rule fails to clearly define the "relevant data" that plans must "collect and evaluate" to determine whether there are material differences in access. 26 C.F.R. § 54.9812-1(c)(4)(iii)(A) (Treasury); 29 C.F.R. § 2590.712(c)(4)(iii)(A) (DOL); 45 C.F.R. § 146.136(c)(4)(iii)(A) (HHS). Again, the Departments acknowledged that commenters requested clarity on what data would be considered "relevant," but "decline[d] to provide a list of all relevant outcomes data required to be collected and evaluated by the plans and issuers at this time." 89 Fed. Reg. at 77,611-12. All the Rule says is that "relevant data *could include*, as appropriate, *but are not limited to*, the number and percentage of claims denials and *any other data* relevant to the

[NQTL] required by State law or private accreditation standards." 26 C.F.R. § 54.9812-1(c)(4)(iii)(A)(1) (Treasury); 29 C.F.R. § 2590.712(c)(4)(iii)(A)(1) (DOL); 45 C.F.R. § 146.136(c)(4)(iii)(A)(1) (HHS) (emphases added). The short and explicitly non-exhaustive nature of this list effectively and unreasonably shifts the burden to the regulated party to determine the data it must collect.

99. This failure to define the essential terms of the "material differences in access" standard is particularly arbitrary because the Parity Rule did define other key (and otherwise-vague) terms, including "evidentiary standards," "processes," and "strategies." 26 C.F.R. § 54.9812-1(a)(2) (Treasury); 29 C.F.R. § 2590.712(a)(2) (DOL); 45 C.F.R. § 146.136(a)(2) (HHS).

100. The Parity Rule's failure to sufficiently define "material differences," "access," and "relevant data" also violates the Fifth Amendment's Due Process Clause. Due process requires "clarity in regulation": that is, agencies must provide regulated entities "fair notice of what [i]is forbidden." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253-54 (2012). The Departments' refusal to provide clear definitions of terms that bear significantly on plan liability flunks this fair-notice standard.

3. The "Material Differences In Access" Standard Is Arbitrary And Capricious Because Differences In Access Do Not Necessarily Mean Lack of Parity

101. Even if the Departments had sufficiently defined the terminology that is central to the "material differences in access" standard, it still would be arbitrary and capricious for the Departments to treat those differences as presumptive evidence of a parity violation. Differences in access to MH/SUD—even "material" ones—may well have nothing to do with plan terms, how restrictive those terms are, and how those terms are applied, and instead may be a function of random variability, provider or member behavior, changes to unrelated state or federal laws, or

other factors that are entirely outside a plan's control. For example, a patient may not be able to take advantage of MH/SUD benefits because of a shortage of providers in the area, or even because of regional variations on clinical practices. *Cf.* 26 C.F.R. § 54.9812-1(c)(4)(iii)(C)(2), (4); 29 C.F.R. § 2590.712(c)(4)(iii)(C)(2), (4) (DOL); 45 C.F.R. § 146.136(c)(4)(iii)(C)(2), (4) (HHS). The Departments' "reli[ance] on factors which Congress [did] not inten[d] [them] to consider" in assessing parity renders the "material differences in access" standard arbitrary and capricious. *State Farm*, 463 U.S. at 43.

102. The Departments acknowledged the comments explaining that differences in access to different benefits may be outside a plan's control, 89 Fed. Reg. at 77,614, but said little to address those concerns. Instead, the Departments pointed to "subregulatory guidance that disparate results are a red flag or warning sign of noncompliance," and chided plans for "mistakenly consider[ing] the 2013 final regulations as granting freedom" to focus on ensuring equal treatment of MH/SUD benefits rather than ensuring equal access to those benefits, 89 Fed. Reg. at 77,615—even though those 2013 regulations had clearly stated that "[d]isparate results alone do not" signal a parity violation, 78 Fed. Reg. at 68,245.

103. The arbitrariness of this standard is compounded by its incorrect assumption that MH/SUD and M/S treatments—and the respective data related to those treatments—are comparable. There are inherent differences between MH/SUD and M/S treatments that make a comparison in "access" to those benefits a futile exercise. For example, there are many more prescription drugs for M/S conditions than for MH/SUD conditions. As a result, even if a plan applies NQTLs equally as between M/S and MH/SUD prescription drug benefits, those limitations might apply to a higher percentage of MH/SUD drug benefits. That data point, on the surface, could be taken as evidence of restricted access to MH/SUD benefits, even though it simply means

there are fewer prescription drugs for MH/SUD conditions in the first place—a medical reality that has nothing to do with parity in plan terms or their application. By insisting that two very different categories of benefits have no material differences in access, the Parity Rule arbitrarily treats unlike things alike.

104. Although the Departments acknowledged that commenters had raised this concern, *see* 89 Fed. Reg. at 77,617 ("clinical differences between mental health conditions, substance use disorders, medical conditions, and surgical procedures may sometimes drive apparent differences in data outcomes"), their response was inadequate. They insisted on placing the burden on plans to explain whether any differences in access are "attributable to generally recognized independent professional medical or clinical standards," and only if the Departments accept the plans' explanation will such differences be deemed permissible. *Id.* In other words, the Departments will assume that incommensurable things are commensurable unless the plans can show otherwise.

105. Finally, the Departments' new regulatory standard is unfairly tilted against the plans because it is a one-way ratchet. Under the Parity Rule, material differences in access are presumptive evidence of a violation, but the Rule declines to say that a *lack* of material differences in access is presumptive evidence of compliance. Commenters raised this concern, but the Departments did not address it. *See* 89 Fed. Reg. at 77,614-17.

C. The Comparative Analysis Requirements Are Arbitrary And Capricious And Violate Due Process

106. The Parity Rule requires plans to undertake a comparative analysis for every NQTL adopted for MH/SUD benefits, in order to evaluate their compliance with the Rule's "material differences in access" standard and to report these analyses to the Departments. This comparative analysis must include a description of the NQTL, an identification of the factors used to design the limitation, a description of how the factors were used in the design, a demonstration of the

comparability to M/S benefits as written, a demonstration of the comparability to M/S benefits in operation, and the conclusions of the analysis. *See* 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). These requirements are arbitrary and capricious and violate due process.

107. They are arbitrary and capricious, first, because they do not sufficiently specify what the comparative analysis must entail. The Rule fails to specify what information plans must provide, resulting in an unbounded universe of plan terms, conditions, strategies, and processes that must potentially be included in the comparative analysis.

108. Compounding the problem, the comparative analysis requirements incorporate vague and undefined terms. For example, the Parity Rule requires plans to explain and discuss "any material differences in access," yet—as explained—fails to sufficiently define "material differences" or "access." 26 C.F.R. § 54.9812-2(c)(5)(iv)-(v) (Treasury); 29 C.F.R. § 2590.712-1(c)(5)(iv)-(v) (DOL); 45 C.F.R. § 146.137(c)(5)(iv)-(v) (HHS); *see supra* ¶¶ 96-98. Similarly, the Rule requires plans to report on any material differences in access "that persist despite reasonable actions that have been or are being taken," but does not adequately define what "actions" count as reasonable. 26 C.F.R. § 54.9812-2(c)(5) (Treasury); 29 C.F.R. § 2590.712-1(c)(5) (DOL); 45 C.F.R. § 146.137(c)(5) (HHS). The Rule provides a few examples of reasonable action, but unhelpfully states that reasonable action is "not limited to" those examples. 26 C.F.R. § 54.9812-1(c)(4)(iii)(C); 29 C.F.R. § 2590.712(c)(4)(iii)(C) (DOL); 45 C.F.R. § 146.136(c)(4)(iii)(C) (HHS). Absent clear definitions of these terms, plans are left without clarity regarding the exact nature of their reporting obligation.

109. Indeed, in response to concerns raised by commenters about these unclear and ill-defined requirements, the Departments conceded that "some of the required content for

comparative analyses are described broadly and therefore could lead to the Departments and applicable State authorities taking different approaches in determining what constitutes a sufficient comparative analysis." 89 Fed. Reg. at 77,640. The Departments claimed that their "broad descriptions" were nonetheless "necessary to ensure that these final rules set forth a single set of content elements that are flexible enough to apply to the wide variety of different NQTLs imposed by plans," *id.*, but that gesture at flexibility is no substitute for placing reasonable bounds on what information plans must provide; the vast breadth of divergent matters covered by a regulatory term is an indictment of the term, not a justification for refusing to define key regulatory terms. This hopeless lack of clarity—and the Departments' *conceded* risk of inconsistent enforcement—makes the comparative analysis requirements arbitrary and capricious.

110. For the same reasons, the comparative analysis requirements also violate the Due Process Clause: They fail to specify what the comparative analysis requires, they incorporate vague terms, and the broad wording creates a risk of inconsistent enforcement across agencies.

D. The ERISA Plan Fiduciary Certification Requirement Violates The Statute, Was Adopted In Violation Of The Departments' Notice-And-Comment Obligations, Is Arbitrary And Capricious, And Violates Due Process

111. The Parity Rule requires the fiduciaries of ERISA-covered plans to "select … qualified service providers to perform … [the] comparative analysis," and to certify that "they have engaged in a prudent process" in making these selections. 29 C.F.R. § 2590.712-1(c)(6)(vi) (DOL). As part of this requirement, the fiduciaries must also certify that they have "satisfied their duty to monitor those service providers … with respect to the performance … of such comparative analysis." *Id.* The finalized certification requirement is unlawful for four reasons: (1) it exceeds the Department of Labor's statutory authority; (2) it is not a logical outgrowth of the Proposed Rule; and (3) it arbitrarily and capriciously burdens ERISA fiduciaries; and (4) it violates due process.

1. The Certification Requirement Exceeds The Department of Labor's Statutory Authority

112. DOL purports to ground the certification requirement in a provision of the 2021 CAA stipulating that a "plan or issuer shall perform and document comparative analyses of the design and application of NQTLs," including "the specific findings and conclusions reached by the group health plan." 29 U.S.C. § 1185a(a)(8)(A)(v); *see* 89 Fed. Reg. at 77,647-48. The provision mentions no fiduciary certification requirement. 29 U.S.C. § 1185a(a)(8)(A).

113. Congress knew how to impose certification requirements—the 2021 CAA included multiple such requirements. *See, e.g.*, CAA, Pub. L. No. 116-260 § 904(b)(6), 134 Stat. 2132-33 (broadband provider must furnish certification); *id.* § 404(a), 134 Stat. 2055 (passenger air carrier or contractor shall provide certification). But it chose not to include a certification requirement for fiduciaries in the MHPAEA context. *See* § 203, 134 Stat. 2900-18. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983). Adding a certification requirement where Congress wished there to be none exceeds DOL's authority and is unlawful for that reason alone.

2. The Certification Requirement Violates The APA Because It Is Not A Logical Outgrowth Of The Proposed Rule

114. "To comport with the APA's notice-and-comment requirements, an agency's final rule must be a logical outgrowth of the version set forth in its notice of proposed rulemaking." *Brennan v. Dickson*, 45 F.4th 48, 68-69 (D.C. Cir. 2022). The Parity Rule's certification requirement is not a logical outgrowth of the Proposed Rule.

115. The Proposed Rule would have required plan fiduciaries to certify compliance with the comparative analysis. *See* 88 Fed. Reg. at 51,593. In the final Parity Rule, however, the

fiduciaries must instead certify that they have prudently selected third-party "qualified service providers" to undertake and document the analysis, and have dutifully monitored those service providers. 29 C.F.R. § 2590.712-1(c)(6)(vi).

116. A change from a proposed rule to the final rule "is a 'logical outgrowth' … only if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). But because the Proposed Rule never suggested that plans would be required to make a certification about the qualifications of those service providers, or certify that they have satisfactorily monitored those service providers, comment on the finalized certification requirement was not possible. *See* 89 Fed. Reg. at 77,647-48.

117. DOL thus failed to provide proper notice about the fiduciary certification requirement that it ultimately imposed, in violation of the agency's notice-and-comment obligations under the APA. *See* 5 U.S.C. § 553. With proper notice, parties would have explained to the Departments that the new certification requirement fails to alleviate the concerns that commenters had with the proposed certification requirement, and that the new requirement raises several unique problems of its own. *See infra* ¶¶ 118-21.

3. The Certification Requirement Is Arbitrary And Capricious And Violates Due Process Because It Unreasonably Burdens Fiduciaries And Fails To Give Fiduciaries Fair Notice Of What Constitutes A "Qualified" Service Provider

118. The Rule's certification requirement imposes many of the same unreasonable and unnecessary burdens as the proposed certification requirement. If anything, the finalized certification requirement is *more* unreasonable because it imposes a host of additional burdens on plans, and fails to provide fair-notice.

119. Commenters had raised concerns that the Proposed Rule's certification requirement would impose undue burdens on fiduciaries, including that fiduciaries would effectively be forced to hire a second service provider to review the work done by the service provider that actually performs the comparative analysis, and that it would increase fiduciaries' litigation exposure and strain their relations with service providers, all of which would increase plan costs and divert resources away from covering MH/SUD benefits. The Departments "acknowledged" those objections, *see* 89 Fed. Reg. at 77,647-48, but the new certification requirement will impose many of the same burdens, and thus the Departments failed to address commenters' concerns and "offered no reasoned response." *Ohio v. Env't Prot. Agency*, 603 U.S. 279, 293 (2024). For example, because fiduciaries (which include employer plan sponsors) themselves lack the requisite technical knowledge to assess compliance with the comparative analysis requirements, they still would be forced to hire a third-party service provider to assess whether the service provider conducting the comparative analysis is sufficiently qualified to perform that analysis, and to monitor the work of that original service provider. In addition, the finalized certification requirement will lead to the same friction (and increased litigation) between plan sponsors and service providers that the proposed requirement would have caused: fiduciaries will seek contract language that insulate them from liability regarding their certification in the event the service provider is deemed unqualified or submits a faulty comparative analysis, and service providers will seek insulation from liability in light of the fiduciary's ultimate responsibility to make the certification. The upshot of all this, as with the proposed certification requirement, is higher plan costs and diversion of resources from MH/SUD benefits, which renders the finalized certification requirement just as unreasonably burdensome. The Departments' "fail[ure] to consider" these

"important aspect[s] of the problem" itself renders the certification requirement arbitrary and capricious. *State Farm*, 463 U.S. at 43.

120. Indeed, the Departments' laser-focus on imposing *some* certification requirement reflects a failure to give sufficient consideration to the clear alternative (proposed by commenters) of imposing no certification requirement at all. Plan fiduciaries already have preexisting duties of loyalty and prudence under ERISA. *See* 29 U.S.C. § 1104(a). Accordingly, in the absence of any certification requirement, they would still have duties to ensure that plans are complying with any lawful regulatory requirements; all the certification requirement adds is increased costs, strained relations between fiduciaries and service providers, increased litigation, and—ultimately—diversion of plan resources away from MH/SUD benefits. The Departments' failure to give adequate consideration to the "obvious and less drastic alternative" of imposing no certification requirement is arbitrary and capricious. *Yakima Valley Cablevision, Inc. v. FCC*, 794 F.2d 737, 746 (D.C. Cir. 1986); *accord Louisiana v. U.S. Dep't of Energy*, 90 F.4th 461, 476 (5th Cir. 2024).

121. The new certification requirement also will impose its own unique set of unreasonable burdens on plan fiduciaries. For example, because a given service provider often performs comparative analyses for thousands of plans at a time, all those plans may be forced to find new service providers if at any time their original service provider is deemed unqualified, in turn requiring plans to find different service providers who may charge higher fees because they need to familiarize themselves with the plan design and the plan's NQTLs. Indeed, the Rule fails to specify any criteria or threshold for what makes a service provider qualified or unqualified—which renders the finalized certification requirement not only arbitrary and capricious but also unconstitutionally vague in violation of due process. If, for example, the service provider is deemed to have performed a single deficient comparative analysis for a single plan, will that render

the provider not "qualified" to perform comparative analyses for the thousands of other plans it serves? The problem is further exacerbated by the Departments' enforcement regime, under which plans have little meaningful opportunity to challenge a finding of noncompliance. *See supra* ¶ 46. Does a single finding of noncompliance suffice to render a service provider unqualified, even though a plan may vigorously disagree with that finding and may have had no meaningful opportunity to challenge the finding? The Departments' finalized certification requirement raises these and a host of other unanswered questions—none of which the Departments addressed because commenters had no opportunity to comment on that requirement.

E. The January 1, 2025 Applicability Date That Governs Many Of The Parity Rule's Provisions Is Arbitrary And Capricious

122. The Parity Rule stipulates that many of its provisions apply as of January 1, 2025, not even four months after the Rule was issued. *See* 26 C.F.R. § 54.9812-1(i)(1) (Treasury); 29 C.F.R. § 2590.712(i)(1) (DOL); 45 C.F.R. § 146.136(i)(1) (HHS); *see also* 89 Fed. Reg. at 77,652. This January 1, 2025 date applies to key provisions, such as the new definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits." 26 C.F.R. § 54.9812-1(a)(2) (Treasury); 29 C.F.R. § 2590.712(a)(2) (DOL); 45 C.F.R. § 146.136(a)(2) (HHS). It also applies to other crucial provisions of the Rule, such as the ERISA plan fiduciary certification requirement and other portions of the comparative analysis requirements, such as the broad and unclear provisions purporting to implement the statutory requirement that plans evaluate and demonstrate comparability and stringency of NQTLs as written and in operation. *See*, *e.g.*, 26 C.F.R § 54.9812-2(c)(4)-(5) (Treasury); 29 C.F.R. § 2590.712-1(c)(4)-(5), (6)(vi) (DOL); 45 C.F.R. § 146.137(c)(4)-(5) (HHS).

123. This applicability date is arbitrary and capricious because it affords too little time for plans to alter their analysis of NQTLs. For example, the Parity Rule requires plans to include

among "mental health benefits" all services to treat behavioral health conditions, according to the individual's ICD and DSM based diagnosis. 26 C.F.R. § 54.9812-1(a)(2) (Treasury); 29 C.F.R. § 2590.712(a)(2) (DOL); 45 C.F.R. § 146.136(a)(2) (HHS). Accordingly, services that plans might have previously classified as M/S—like speech therapy, occupational therapy, physical therapy, or even surgery after a self-inflicted injury—must be recategorized as for MH or SUD disorders. Plans must therefore perform new comparative analyses for these terms for the first time, and depending on the results of those analyses, may need to adjust those terms. Further, to the extent a plan has relied on QTLs and NQTLs applicable to these services as part of its comparative analyses for other MH/SUD terms, the plan may need to redo those comparative analyses as well. Reclassifying services as "mental health benefits" also has claim processing implications, and may require plans to apply different cost-sharing to services newly characterized as "mental health benefits." It is not reasonable to expect plans to change their practices regarding "mental health benefits," or to take all necessary steps to comply with other provisions forcing similarly extensive alterations, in less than four months.

124. The unreasonableness of the January 1, 2025 applicability date is compounded because the vast majority of employer-sponsored group health plans operate on a calendar year basis and thus set plan terms, premiums, and perform other actuarial analyses for a given year based on what benefits will be covered the following year. Plans make these determinations many months in advance of open enrollment, which occurs at the end of each year. Indeed, open enrollment for 2025 was already taking place during the four months between when the Rule was issued and the January 1 applicability date. If coverage provisions for 2025 need to be changed pursuant to the Rule's comparative analyses, it will likely be too late for plans to alter their 2025 plan terms or premiums, meaning that plans will be undercompensated for the services they

provide. An applicability date of January 1, 2026 or later would have prevented disruption to 2025 premiums and ensured that plans had sufficient time to set premiums for 2026 that accounted for any changes to coverage required by the Rule.

COUNT I
(Without Statutory Authority And Contrary To Law)
(Against All Defendants)

125. Plaintiff incorporates the above allegations by reference.

126. The APA requires a court to "hold unlawful and set aside" any "agency action … found to be … not in accordance with law" or to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C).

127. The Parity Rule's "meaningful benefits" is not in accordance with law, and exceeds the Departments' statutory authority, because it mandates benefits, contrary to the MHPAEA's stipulation that it is not a benefits mandate. *See* 29 U.S.C. § 1185a(b)(1).

128. The Rule's "material differences in access" provision is not in accordance with law, and exceeds the Departments' statutory authority, because Congress did not impose a disparate-impact standard for evaluating parity between MH/SUD and M/S benefits. The MHPAEA requires only parity in plan terms and the application of those terms to MH/SUD and M/S benefits. *See* 29 U.S.C. § 1185a(a).

129. The Rule's ERISA plan fiduciary certification requirement is not in accordance with law, and exceeds the Department of Labor's statutory authority, because Congress did not authorize or mandate any such certification requirement in its 2020 amendments to the MHPAEA, despite mandating certain certifications in other parts of those same amendments. *See, e.g.*, CAA, Pub. L. No. 116-260 § 904(b)(6), 134 Stat. 2132-33; *id.* § 404(a), 134 Stat. 2055.

130. Accordingly, the Parity Rule is in excess of statutory jurisdiction, authority, or limitations, and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(A), (C).

COUNT II
(Arbitrary And Capricious)
(Against All Defendants)

131. Plaintiff incorporates the above allegations by reference.

132. The APA requires a court to "hold unlawful and set aside" any "agency action … found to be … arbitrary, capricious" or "an abuse of discretion." 5 U.S.C. § 706(2)(A).

133. The Parity Rule's "meaningful benefits" requirement is arbitrary and capricious in multiple respects, including because it (1) constitutes an unacknowledged and unexplained change of position by the Departments; and (2) outsources the definition of "core treatment"—the central component of the requirement—to third-party authors of clinical literature, rather than allowing plans to determine what qualifies as a core treatment.

134. The Rule's "material differences in access" standard is arbitrary and capricious in multiple respects, including because it (1) relies heavily on vague terms—"material differences," "access," and "relevant data"—which it fails to define with sufficient specificity; (2) treats mere differences in access between MH/SUD and M/S benefits as indicative of a plan's lack of 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.

135. The Rule's comparative analysis requirements are arbitrary and capricious in multiple respects, including because they fail to specify what information plans must provide to the Departments and fail to define key terms with sufficient specificity.

136. The Rule's ERISA plan fiduciary certification requirements is arbitrary and capricious because it unreasonably and unnecessarily burden fiduciaries and will cause plans to incur greater, unjustified costs and fees, and fails to give fiduciaries sufficient notice of what renders a service provider sufficiently "qualified" to perform a comparative analysis.

137. The Rule's January 1, 2025 applicability date that governs many of the Parity Rule's provisions is arbitrary and capricious because it leaves plans too little time to take the steps necessary to come into compliance with the Rule's requirements and will have harmful consequences for plans and beneficiaries alike.

138. Accordingly, the Parity Rule is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law, in violation of 5 U.S.C. § 706(2)(A).

COUNT III
(Notice And Comment)
(Against The Department Of Labor)

139. Plaintiff incorporates the above allegations by reference.

140. The APA further requires that before an agency promulgates a new rule, it must publish "notice" of the "proposed rule making … in the Federal Register" and "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b)-(c).

141. The APA also requires a court to "hold unlawful and set aside" any "agency action" that is made "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

142. The Rule conflicts with these notice-and-comment requirements because it defines "meaningful benefits" with reference to third-party clinical standards that are created and altered over time by private parties. This dynamic incorporation of private standards into government regulations thus deprives regulated parties of the opportunity to comment on regulatory changes before they are made.

143. In addition, "[t]o comport with the APA's notice-and-comment requirements, an agency's final rule must be a logical outgrowth of the version set forth in its notice of proposed rulemaking." *Brennan v. Dickson*, 45 F.4th 48, 68-69 (D.C. Cir. 2022).

144. By promulgating a rule that requires fiduciaries to certify that they have prudently selected a third-party "qualified" service provider to perform the comparative analysis and have dutifully monitored the service provider's work, the Department of Labor violated the APA's notice-and-comment rulemaking requirement. 5 U.S.C. § 553.

145. This certification requirement is not a logical outgrowth of the Proposed Rule because the Proposed Rule would have instead required that fiduciaries certify compliance with the comparative analysis requirements. Regulated parties thus had no meaningful opportunity to comment on the Department's about-face, including the host of unique problems and unanswered questions that the finalized certification requirement raises.

146. Accordingly, the Parity Rule was promulgated without observance of procedure required by law, in violation of 5 U.S.C. § 706(2)(D).

COUNT IV
(Due Process)
(Against All Defendants)

147. Plaintiff incorporates the above allegations by reference.

148. The APA requires a court to "hold unlawful and set aside" any "agency action … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

149. The Parity Rule's "material differences in access" standard fails to define with sufficient specificity the open-ended terms that determine compliance with that standard, including "material differences," "access," and "relevant data." This failure to provide fair notice to regulated parties about what conduct is required violates the Fifth Amendment's guarantee of due process.

150. The Rule's comparative analysis requirements violate due process because they fail to provide fair notice of what plans are required to include in a comparative analysis and

incorporate vague and undefined terms, including "material differences," "access," and "reasonable action[s]."

151. The Rule's ERISA plan fiduciary certification requirement violates due process because it fails to give fiduciaries fair notice of what constitutes a "qualified" service provider—thus leaving fiduciaries at sea when determining whether they can certify that a particular service provider is "qualified."

152. Accordingly, the Rule is contrary to constitutional right, power, privilege, or immunity. 5 U.S.C. § 706(2)(B).

COUNT V
(Non-Delegation)
(Against All Defendants)

153. Plaintiff incorporates the above allegations by reference.

154. The APA requires a court to "hold unlawful and set aside" any "agency action … found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

155. The Parity Rule's "meaningful benefits" requirement is an unconstitutional delegation of the Departments' executive power to private parties because it defines "meaningful benefits" by reference to third-party clinical standards developed (and changed over time) by private entities. This dynamic incorporation effectively vests private parties with legislative and executive power, in violation of the Constitution.

156. Accordingly, the Rule is contrary to constitutional right, power, privilege, or immunity. 5 U.S.C. § 706(2)(B).

PRAYER FOR RELIEF

157. Plaintiff prays that this Court:

a. Declare that the Parity Rule's "meaningful benefits" requirement, "material differences in access" standard, comparative analysis requirements, ERISA plan fiduciary certification requirement, and January 1, 2025 applicability date violate the APA; hold those provisions invalid, contrary to law, arbitrary and capricious, and otherwise unlawful; and for these reasons set aside and vacate the Parity Rule or in the alternative the challenged provisions;

b. Issue a permanent injunction prohibiting Defendants from implementing, administering, acting upon, or enforcing the Parity Rule, or in the alternative the challenged provisions, against Plaintiff or its members;

c. Award Plaintiff costs and reasonable attorneys' fees as appropriate; and

d. Grant Plaintiff such further and other relief as the Court deems just and proper.

Dated: January 17, 2025

Respectfully submitted,

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