October 16, 2023

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

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

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

RE: Requirements Related to the Mental Health Parity and Addiction Equity Act – RIN 1210-AC11

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

The Legal Action Center and the 23 undersigned national and state organizations appreciate the opportunity to submit comments on the Department of Health and Human Services, Employee Benefits Security Administration, and the Internal Revenue Service's (the "Departments") Proposed Rules on Requirements Related to the Mental Health Parity and Addiction Equity Act (Parity Act or MHPAEA). We commend the Departments for comprehensively reviewing the regulatory standards and proposing compliance standards to improve enforcement of a critical civil rights law for individuals with substance use disorders and mental health conditions.

The Legal Action Center (Center or LAC) is a non-profit law and policy organization that fights discrimination, builds health equity, and restores opportunity for people with substance use disorders, arrest and conviction records, and HIV and AIDS. We worked with our national partners to secure enactment of the Parity Act, and we have done extensive work to enforce the Parity Act at the national and state levels. The Center convenes the Coalition for Whole Health, a national coalition of local, State and national organizations active in the law's enactment, and state parity coalitions in both Maryland and New York. On behalf of the Maryland Parity Coalition, we led advocacy efforts by substance use disorder (SUD) and mental health (MH) consumer and provider stakeholders to secure enactment of a

Parity Act compliance law in 2020 and develop strong <u>regulatory and data standards</u> referenced in the Technical Release. In New York, we conduct Parity Act policy advocacy, securing enactment of state parity standards, a Parity Reporting Act, and Parity Act compliance standards, as well as provide client assistance to individuals with MH and SUDs to address insurance-based barriers to care as part of the NY Consumer Health Access to Addiction and Mental Health Care Project (CHAMP) program.

Through our coalition, policy advocacy, and consumer assistance work, we witness first-hand the overwhelming struggle – both emotional and financial – of individuals and families who seek access to affordable MH and SUD care and the tragic consequences when such services are not readily available. We have worked with SUD and MH providers who seek admission to carrier networks only to be offered a contract rate that is a fraction of their costs of service delivery. Many individuals face far fewer barriers to accessing medical care, even for their rare and complex medical conditions, than for their SUD or MH care. As the Departments have recognized, our nation is facing an unprecedented overdose epidemic and mental health crisis, which has disparately affected Black and Native American people and other communities of color, and insurance coverage for SUD and MH care continues to be separate and disparate compared to other medical care coverage. We fully agree with the Departments' assessment: many barriers to MH and SUD treatment are grounded in discriminatory insurance practices that violate the Parity Act.

We commend the Departments for proposing comprehensive standards to root out on-going discriminatory insurance practices and those that impose a greater burden on access to MH and SUD care. We are particularly supportive of the Departments' proposals to:

- Improve definitions of key elements in the non-quantitative treatment limitation (NQTL) analysis and the evidence-based sources for defining MH benefits and SUD benefits;
- Retain a broad definition of NQTLs and expand the non-exhaustive list to include "network composition" with a more comprehensive and inter-related set of design features that may limit provider availability and access to care;
- Establish two additional tests of NQTL compliance using quantitative metrics and bar the use of discriminatory factors or evidentiary standards in the design and application of NQTLs; and
- Require analysis and reporting of outcome data for NQTL "in operation" compliance and construe evidence of disparate outcome data in network composition as dispositive evidence of a Parity Act violation (under a recommended revised threshold).

We have strong concerns, however, about the Departments' proposal to embed two exceptions in the NQTL violation tests: application of generally recognized independent professional medical or clinical standards and standards designed to detect or prevent and prove fraud, waste and abuse. We urge the Departments not to adopt either exception and to retain the regulatory status quo in which both factors are appropriately considered in relevant NQTL analyses. We are not aware of any evidence that the current analytical framework is unworkable, ties the hands of health plans/issuers to apply clinically accepted standards of care or detect or prevent fraud, waste or abuse, or results in incorrect findings of discrimination. Indeed, the Departments' regulatory commentary and description of their enforcement activities, set out in the MHPAEA Report to Congress, confirm that health plans and issuers have failed miserably in conducting complete, detailed, and accurate compliance analyses under the existing standards and continue to discriminate against individuals with MH and SUDs. They should not be afforded additional opportunities via the two far-reaching proposed exceptions to further evade compliance. We fear that the adoption of the two exceptions could completely neutralize the strong compliance standards proposed by the Department and, through codification, result in weaker standards

than the current regulations.

In addition to removing the two exceptions, we offer the following key recommendations to strengthen the proposed rules. We explain these items in greater detail below and offer additional recommendations to require health plans/issuers to ensure parity compliance in advance of offering plans, policies or contracts.

Definitions

- Instead of the exceptions to the NQTL tests, incorporate a definition of "generally accepted standards of care" and include "actions to address fraud, waste, and abuse" in the definition of "strategies" or "processes."
- Adopt a definition of "meaningful" coverage as "the full continuum of services that are consistent with generally accepted standards of care as identified by the non-profit professional society of practitioners in the specialty."

NQTLs

- o Explicitly identify "scope of services" in the list of non-exhaustive NQTLs.
- o Identify "concurrent review" in the parenthetical for medical management standards in the non-exhaustive list of NQTLs.

NQTL Tests

- Explicitly prohibit the use of Medicare fee schedules as part of the historically discriminatory plan data or information that may not be used in the "design and application" test.
- Instead of the "material difference" standard, adopt a "de minimis" standard for disparities in outcome data.
- Construe all disparate outcomes of the data analyses as violations of the Parity Act, not just those for network composition.
- Clarify that the data collection and analyses must separately assess and report outcomes for SUD benefits and MH benefits.
- o Clarify or remove the reference to accreditation standards in the outcomes data test.
- o Collect appointment wait time data for the network composition metrics.
- Add a "Construction" provision to incorporate the protective "guardrails" when applying independent professional medical and clinical standards and fraud, waste and abuse to NQTLs.

Availability of Plan Information/Disclosure

- Prohibit health plans/issuers from withholding compliance analyses based on proprietary information.
- Conform the standard for member/participant access to the comparative analysis in the disclosure provisions with that in the proposed comparative analysis standard, i.e. upon receiving a denial rather than "upon appeal."

• NQTL Comparative Analysis Requirements

- O Clarify that State regulatory authorities may request a comparative analysis for health plans for which they have jurisdiction without action by federal regulators.
- Require health plans/issuers to affirmatively reprocess claims for final determinations of a violation rather than identify the "opportunity" for members/participants to request reprocessing.

Enforcement

- o Bar plans/issuers that cannot present their parity compliance analysis at the point of sale from offering the plan/policy.
- Identify steps to enforce Internal Revenue Service penalty provisions for noncompliance.

The Departments have been exceedingly patient with highly resourced health plans/issuers, many of whom have shown a total disregard for the compliance analysis and reporting standards and continue to impose discriminatory standards that burden access to SUD and MH care. Having worked collaboratively with health plans/issuers to bring them into compliance with the Parity Act, far stronger action is needed now to address blatantly discriminatory insurance practices. The regulations have consistently barred plans/issuers from offering policies or contracts that fail to comply with the NQTL and other regulatory provisions (26 C.F.R. § 54.9812-1(h); 29 C.F.R. § 2590.712(h); 45 C.F.R. §146.136(h)): a standard observed in the breach. We urge the Departments to take all steps necessary to enforce this requirement and bar health plans/issuers from utilizing any NQTL that violates the Parity Act or for which they cannot submit a complete comparative analysis upon request. We also call on the Departments to enforce available Internal Revenue Service (IRS) penalties in all such circumstances.

Thank you for considering the following comments.

I. Purpose Section – 26 C.F.R. § 54.9812-1(a)(1), 29 C.F.R. § 2590.712(a)(1), 45 C.F.R. § 146.1369(a)(1).

We fully support the adoption of the purpose section to (1) reinforce the fundamental and original purpose of the Parity Act – to prohibit discriminatory financial requirements and treatment limitations that impose greater burdens on access to MH and SUD care – and (2) put plans/issuers on notice that enforcement of all regulatory standards will align with this singular purpose. The purpose provision establishes a clear benchmark for state and federal enforcement entities and courts that have not held plans/issuers accountable for blatantly discriminatory practices under the current regulatory standards. Finally, it may be most helpful to plan members who do not understand their parity rights and cannot self-advocate to secure their right to non-discriminatory benefit coverage and access. The regulatory purpose offers a readily understandable touchpoint by which to measure and challenge their plan's discriminatory actions.

Individuals who face barriers in accessing MH and SUD benefits rightly question the existence of a "parity law." They see their plans/issuers thwart access to care by refusing reimbursement for services recommended by their practitioner, force them to call lengthy lists of providers, while in crisis, to find even one who can deliver timely care, and pay unaffordable out-of-pocket costs to get covered benefits that should be available through a network provider. They either assume their plan is permitted to take such steps or, having no access to the underlying plan information or the ability to assess NQTL compliance, take no action. With the straightforward and concrete statement of purpose, consumers can press their plans or ask enforcement bodies to investigate these unfair practices.

II. Meaning of Terms – 26 C.F.R. § 54.9812-1(a)(2), 29 C.F.R. § 2590.712(a)(2), 45 C.F.R. § 146.136(a)(2).

A. Factors, Evidentiary Standards, Processes and Strategies

We fully support the proposed definitions of factors, evidentiary standards, processes and strategies, which provide greater clarity on the difference between factors and evidentiary standards and draw a clear distinction between "strategies" and "processes," which relate, respectively, to the plan/issuers' approach to the *design* and *application* of an NQTL. We appreciate the articulation of both member or provider actions and plan/issuer actions in the "processes" for applying an NQTL and explicitly referencing "reviewer discretion in adhering to criteria hierarchy when applying" an NQTL. The proposed definition of "strategies" appropriately includes practices that involve "deviations from generally accepted standards of care," which we recommend be defined in the regulations (see below) to ensure more evidence-based NQTL standards related to medical management, formulary design, fail first/step therapy requirements, and restrictions based on geographic location, facility type and provider specialty, and scope of services.

Additionally, we recommend that the Departments include in the definitions of "strategies" and/or "processes" actions to detect or prevent and prove fraud, waste, and abuse. We agree that plans/issues must have the ability to address fraud, waste and abuse in the delivery of MH, SUD and medical/surgical benefits. In our view, the appropriate vehicle for doing so in the parity context is through the NQTL design and application analysis, not a stand-alone exception. The Departments have identified "claim types with a high percentage of fraud" as an example of a "factor" ((a))2)), and that focus could be reinforced by including steps plans/issuers can take as a "strategy" and/or "process."

Overall, the proposed definitions will lend far greater structure to the NQTL comparative analysis and, by defining the discrete parts of each element, result in more complete analyses that will ease the burden on regulators when conducting compliance reviews and those seeking to enforce plan members' rights. Drawing a distinction between the elements involved in the design versus the application of an NQTL should also reinforce the plan/issuer's statutory obligation to assess and report both the "as written" and "in operation" components of an NQTL comparative analysis. The current lack of definition provides too much latitude to plans/issuers that recycle the same rote set of factors, processes and evidentiary standards for every NQTL without specificity and contributes to an imprecise and useless comparative analysis. We support the Departments' proposals to end that practice.

B. Mental Health Benefits, Substance Use Disorder Benefits and Medical/Surgical Benefits

We also fully support the Departments' clarification in the definitions of MH benefits, SUD benefits and medical/surgical benefits that plans/issuers must define the conditions that fall into each benefit bucket consistent with "generally recognized independent standards of current medical practice" such as the most recent version of the International Classification of Diseases (ICD). Further clarification that MH and SUD benefits include "all conditions" that are listed in the most recent version of the Diagnostic and Statistical Manual (DSM) or fall into any of the diagnostic categories listed in the mental, behavioral or neurodevelopmental disorders chapter of the ICD. We agree that state law definitions, often relics of pre-Parity Act legislation, may conflict with ICD and DSM standards and should not be the operable standard. We support the Departments' directive that autism spectrum disorders and eating disorders are MH conditions and must be covered as such.

C. Definition of "Generally Accepted Standards of Care"

Consistent with the Departments' requirement that plans/issuers use independent standards of current medical practice to prevent manipulation of benefit coverage, we urge the Departments to also include a definition of "generally accepted standards of care" – referenced in the definition of "strategies" – and tie it to criteria/guidelines from the relevant nonprofit clinical association for the relevant specialty. This additional definition would address one of the most significant "strategies" that plans/issuers use to impose greater burdens on access to MH and SUD care¹ and provide a consistent benchmark for measuring "deviations" from such standards in medical necessity and utilization review determinations.²

An increasing number of states are adopting a strong definition of "generally accepted standards of care" for MH/SUDs, including <u>Illinois</u>, <u>California</u>, <u>Georgia</u>, and <u>New Mexico</u>. We recommend the following version of these definitions:

"Generally accepted standards of care" mean standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties such as psychiatry, psychology, clinical sociology, social work, addiction medicine and counseling, and behavioral health treatment. Valid, evidence-based sources reflecting independent professional medical or clinical standards are peer-reviewed scientific studies and medical literature, recommendations of federal government agencies, drug labeling approved by the United States Food and Drug Administration, and recommendations of nonprofit health care provider professional associations and specialty societies, including, but not limited to, patient placement criteria and clinical practice guidelines.

Widely accepted nonprofit criteria include the American Society of Addiction Medicine (ASAM) criteria, which many states require state-regulated plans to use for all utilization review decisions,³ and the age-specific LOCUS (Level of Care Utilization System for Psychiatric and Addiction Services) criteria. Selection of the nonprofit clinical specialty association criteria and guidelines are essential because they are:

¹ See Wit v. United Behavioral Health, 2020 WL 6479273 (N.D. Ca. Nov. 3, 2020), aff'd in part, rev'd in part and remanded, 2023 WL 5356640 (9th Cir. Aug. 22, 2023) (affirming District Court decision that UBH violated its fiduciary duty by developing and applying level of care guidelines that placed its financial interests above plan members right to benefits consistent with generally accepted standards of care); see, e.g., L.C. v. Blue Cross and Blue Shield of Tex., 2:21-cv-00319-DBB-JCB (D.Utah, Feb. 10, 2023) (Court rejected claim that plan violated Parity Act by applying Milliman Care Guidelines' acute care criteria to a sub-acute residential treatment for MH care, unlike practice for medical/surgical benefits).

² We note that the Departments use a comparable term "independent professional medical or clinical standards" for the NQTL exception, which we strongly oppose. While either term can be used, we propose "generally accepted standards of care" to build on the Departments' reference to this element. Providing a definition for this "strategy" will facilitate its use in evaluating NQTLs related to medical management, formulary design, fail first/step therapy, treatment completion requirements, and scope of services.

³ Legal Action Center and Partnership to End Addiction: Spotlight on Medical Necessity Criteria for Substance Use Disorders (Dec. 2020), https://www.lac.org/resource/spotlight-on-medical-necessity-criteria-for-substance-use-disorders.

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

As noted below in the discussion of the proposed exceptions, the Departments' parameters for "independent professional medical or clinical standards" – standards that "must be independent, peer-reviewed, or unaffiliated with plans and issuers" – is far too weak to ensure that proprietary criteria are not used to deny prescribed care and severely limit the length of stay in more intensive levels of MH and SUD care.

III. Classification of Benefits and Coverage of MH Benefits and SUD Benefits in All Classifications in Which Medical/Surgical Benefits are Covered - 26 C.F.R. § 54.9812-1(c)(2)(ii), 29 C.F.R. § 2590.712(c)(2)(ii), 45 C.F.R. § 146.136(c)(2)(ii).

A. Adoption of "Meaningful" Coverage Standard, Examples and Definition

We support the continued use of the existing six classifications and the limitation of subclassifications to outpatient office visits and other outpatient items and services. We strongly support the Departments' proposed requirement of "meaningful" coverage of SUD and MH benefits in all benefit classifications in which medical/surgical benefits are covered and clarification that benefit coverage applies to each MH and SUD condition or disorder that is covered in any benefit classification. This proposed "meaningful" coverage is essential to address a loophole that plans/issuers have exploited to deny reimbursement of fundamental evidence-based services for MH and SUD care that would never be excluded for medical/surgical care. Such services are not experimental or investigative but are generally accepted standards of care. The inclusion of a "meaningful coverage" requirement would impose additional guardrails on plan/issuer exclusions (and their discretionary interpretation of plan "exclusions") and would also help state policy makers and advocates amend state statutory standards that may restrict the types of services that state-regulated plans are required to cover.

The Departments have appropriately included new examples related to plan/issuer exclusions of such services for autism spectrum disorders and eating disorders, i.e, applied behavioral analysis (ABA) therapy and nutritional counseling, ((ii)(C)(5) and (C)(6)). We support the inclusion of these helpful examples. We also recommend the Departments include an additional example of benefit exclusions related to the treatment of opioid use disorders (OUD). The Departments' Report to Congress confirms that plans/issuers continue to exclude coverage of opioid treatment programs (OTP) and other services in plans; an astounding practice given our Nation's opioid epidemic, disparate rates of overdose by Black and Native American people and more than fifty-years of scientific and clinical evidence of treatment effectiveness. We appreciate the Departments' enforcement efforts on this issue, and we urge the Departments to include a case example in the regulations that would reinforce a clear requirement to cover OTP services consistent with the "meaningful" coverage of SUD benefits in all classifications in which medical/surgical services are covered.

We have also seen exclusions of standard medical care for OUD in inpatient hospital services. Legal

Action Center is currently assisting a client who received withdrawal management care, including methadone administration, for his OUD in an emergency department before transfer to an inpatient hospital bed for three days. His employer-sponsored plan refused to reimburse his emergency or inpatient care for OUD, claiming the SUD benefits are excluded from his plan. In his internal appeal, we asserted that there is no evidence of a benefit exclusion in his plan, the plan exclusion clearly violates the Parity Act's "benefit coverage in all classifications" requirement, as the plan covers suboxone in the prescription drug classification, as well as the "scope of coverage" NQTL. The plan's decision in the client's first level appeal did not respond to any of the Parity Act claims and upheld its exclusion of benefits without justification. ⁴ A "meaningful" coverage standard would clearly help this client and other plan participants.

We agree with the Departments that "meaningful" coverage must be defined to establish standardized guardrails for benefit coverage. Without a definition, plans/issuers will likely interpret such requirement narrowly, resulting in plan members having no greater access to care and being forced to assert rights through appeals at best. We recommend that "meaningful" coverage be defined as the full continuum of services that are consistent with generally accepted standards of care as identified by the non-profit professional society of practitioners in the specialty. (See proposed definitions). Plan members should have a right to coverage of medically necessary services, provided in the most integrated setting, across the full continuum that the non-profit professional society of MH and SUD practitioners establish as evidence-based.

B. Relationship of "Meaningful Coverage" and "Scope of Services" NQTL.

We agree that the "meaningful" requirement proposal relates directly to the NQTL "scope of services" requirement: any limitation on the scope of services for MH or SUD benefits is an NQTL that must be compared to medical/surgical benefits to determine, under the design and application test, whether the factors and evidentiary standards as well as the processes and strategies, are comparable and not applied more stringently to MH or SUD benefits. Thus, in the above client case of excluded withdrawal management services, the plan should be required to identify the factors, evidentiary standards, processes and strategies it uses to exclude coverage of inpatient opioid withdrawal management care and demonstrate comparable and no more stringent application than its design and application "rules" for the exclusion of medical/surgical services in the inpatient classification.

Consistent with these dual analytical approaches to benefit coverage, we recommend that the **Departments explicitly include "scope of services" in the non-exhaustive list of NQTLs.** The Departments' 2013 preamble explanation of coverage of intermediate levels of care – intensive outpatient, partial hospitalization and residential care – reaffirmed that the full continuum of MH and SUD services must be covered in alignment with medical/surgical services. Yet even with that guidance, plans/issuers continue to exclude fundamental services and do not assess those exclusions as an NQTL. While the Departments' new example of a plan exclusion of residential MH and SUD treatment (with plan coverage of skilled nursing facilities and rehabilitation hospitals), affirms that this exclusion is an impermissible NQTL, ((c)(4)(viii)(L)), we believe the explicit inclusion of "scope of services" will

⁴ The plan did not respond to a second-level appeal that restated the Parity Act and other claims within the required timeframe.

⁵ We also work on state enforcement of the Parity Act in Medicaid and, in seeking to address exclusions of SUD services that are covered in medical/surgical benefits, Maryland Medicaid officials asserted that they need only to cover benefits in each classification and are not obligated to evaluate benefit exclusions as an NQTL.

significantly improve enforcement through clear regulatory language.

IV. Non-Exhaustive List of Non-Quantitative Treatment Limitations – 26 C.F.R. § 54.9812-1(c)(4)(iii), 29 C.F.R. § 2590.712(c)(4)(iii), 45 C.F.R. § 146.136(c)(4)(iii).

We fully support the Departments' reinforcement that the list of NQTLs is non-exhaustive and **we strongly support the heightened focus on network composition**. As the Departments have noted, numerous studies document the significantly higher utilization of out-of-network services for SUD and MH services than medical/surgical services. Consumer members of the Maryland Parity Coalition struggle to find MH and SUD providers in their plans' networks who can deliver timely, clinically appropriate and readily accessible care, particularly for adolescent treatment and adults with more complex MH conditions. Few can endure the time-consuming and often futile searches for providers in the midst of crisis, and out-of-network services are not affordable for most. The whole family's health deteriorates under these stressful conditions and the constant reminder of the potentially deadly consequences of drug use and untreated mental illness.

The network composition NQTL appropriately recognizes that multiple plan/issuer practices – reimbursement practices, credentialing requirements, network admission standards – contribute to network composition and inadequate levels of network providers. Two examples demonstrate the very urgent need to evaluate the intertwined plan/issuer practices that contribute to limited networks for MH and SUD care.

- One OTP director sought admission to Maryland's largest carrier's network so that his patients could use their insurance coverage rather than pay out-of-pocket. He experienced lengthy administrative delays as the carrier had no facility-based application and then lost his application multiple times. The carrier finally offered a non-negotiable rate that did not cover the cost of specific services, including counseling, required under state law. After repeatedly requesting reimbursement for required services to cover his costs, the program director determined that he could not afford to join the network. He then filed a complaint with the Maryland Insurance Administration challenging the carrier's contracting practices.⁷
- A New York provider sought to renegotiate reimbursement rates that were low at the time he joined the issuer's network and had not been increased for 10 years. The issuer refused to speak with him. The provider has considered leaving the network but is also concerned about his patients who might have to stop seeing him if he were no longer a network provider.

One NY client's case demonstrates the unacceptable burdens of a self-funded plan's inadequate network on consumers. Our client, who struggled for years with an OUD, was unable to work until he obtained

⁶ Jane Ehrenfeld, "Lost in the Storm: My 10-year old daughter thinks she should be dead. When I tried to help her, I saw how deep our national crisis really is." Slate (June, 11, 2023) https://slate.com/technology/2023/06/child-teen-mental-health-crisis-therapy-help.html.

⁷ Remarkably, following a **2.5 year review**, the MIA did not issue a substantive decision on his claim. It explained that the issuer had not filed a complete Parity Act comparative analysis, in connection with a separate state requirement, and that the insurance department continued to work with the issuer to bring it into compliance with the Parity Act. It is unclear why the MIA could not make a determination of compliance on the merits of this case. While it informed the provider of the right to appeal, there was no substantive decision to appeal.

methadone treatment through Medicaid and stabilized his health condition. Now, employed full-time, he cannot afford his treatment under his private insurance plan. His employer-sponsored self-funded plan does not maintain an adequate network of OTPs and, instead, arranged care through a single case agreement with an out-of-network (OON) provider. That approach has not provided equitable coverage because our client must pay \$115 each week for treatment, a prohibitively high cost, that he would not have to pay a network provider. He is now considering leaving his job so that he can resume Medicaid coverage and continue his treatment; an unacceptable option that is directly related to his plan's inadequate network and OON reimbursement practices. Both examples reflect the multiple plan/issuer network composition practices that must be assessed to address the burden on access to SUD and MH care.

Finally, we recommend two revisions to the list of NQTLs. First, given the significant reliance on "concurrent review" to limit the length of stay in more intensive levels of MH and SUD care, we recommend that "medical management standards" identify "concurrent review" in the parenthetical along with prior authorization. Sec. (c)(4)((iii)(A)). Second, as noted above, we urge the Departments to explicitly include "scope of services" to ensure greater accountability for limitations imposed on the coverage of MH and SUD benefits.

V. NQTL Tests -- 26 C.F.R. § 54.9812-1(c)(4), 29 C.F.R. § 2590.712(c)(4), 45 C.F.R. § 146.136(c)(4).

We fully support the Departments' proposal to establish two additional tests of Parity Act compliance – "no more restrictive standard" and "outcomes data standard" and to strengthen the existing "design and application" test. We agree that a violation of any one of these tests should constitute a Parity Act violation, as required under (c)(4).

We have strong concerns, however, about adopting the proposed "material difference" benchmark for finding a conclusive violation or strong indicator of an in operation violation for the NQTL. A "material difference" standard would establish a far higher bar than either the "no more restrictive" or "no more stringent" statutory standard (NQTL comparative analysis standard). We recommend that the Departments adopt a "de minimis" difference standard to align with the Act's statutory standards. We also strongly oppose the two proposed exceptions and, as discussed below (point VI), urge the Departments not to adopt either exception for any of the three tests and instead maintain the status quo of addressing both as NQTLs.

A. No More Restrictive Standard

Subject to removal of the exceptions, we commend the Departments for adopting and adapting the "substantially all/predominant value" standard for NQTL compliance, which, as noted, more closely mirrors the statutory standard. This test has resulted in a high level of parity compliance for financial requirements and quantitative treatment limitations and will disallow NQTLs that are either applied almost exclusively to SUD and MH benefits (e.g. limitations based on court-ordered treatment, likelihood of improvement, network credentialing standards that require specific insurance coverage for SUD and MH practitioners or include specific and unique questions about SUD or MH treatment participation by practitioners of those services) or impose a more burdensome variation of the limitation compared to the medical/surgical benefits. While the "design and application" test could catch many of these discriminatory standards, the "no more restrictive standard" is a streamlined test that will not require the more complicated comparative analysis of the processes, strategies, evidentiary standards, and factors that are used to design and apply the NQTL. That approach helps members/participants who

do not have access to detailed plan documents or the capacity to conduct a comparative analysis, which generally requires the assistance of counsel.

We envision this test as being particularly useful for specific NQTLs that have a numerical component for purposes of application, such as the concurrent review example in (c)(4)(i)(c) and Example 1. We frequently hear that plans/issuers impose concurrent authorization requirements for residential SUD care that require daily or very frequent submission of patient information and interaction with the plan/issuer's utilization management staff or peer-to-peer reviews. The administrative burden is timeconsuming, costly, not aligned with the reality of patient care and recovery, and often results in poor discharge planning and continuity of care. 8 Daily/very frequent concurrent review requirements could very well violate the "predominant variation" test, as noted in Example 1. Similarly, providers of residential treatment and other more intensive levels of care often report that plans/issuers apply an "unwritten," yet standard, cap on the number of days of care that will be authorized for an episode of care regardless of the patient's condition. For example, plans may communicate to providers during concurrent review that no further days will be authorized, thus deterring the provider from even requesting ongoing care, despite the patient's need. Such "length of stay" caps too often become the default even when a patient's condition merits additional services; providers acquiesce, anticipating the futility of appeals with the plan/issuer, as they and patients cannot cover the cost of services. The "no more restrictive" test offers a way to investigate such caps that evade analysis as a quantitative treatment limitation. A third example involves the intensity of authorization or concurrent review procedures which, for example, may require detailed responses to multiple questions for SUD or MH care but limited, pro forma questions for medical/surgical benefits. We appreciate the Departments' examples of this test (Examples 1, 2, 3, 8, 9 and 10) and urge the Departments to identify additional examples of NQTLs for which this test would streamline a compliance analysis.

Finally, we also support the Departments' definition of "restrictive" for purposes of the NQTL analysis and the standard for determining the portion of medical/surgical benefits that are subject to the specific NQTL based on plan payment.

B. Design and Application Standard

Subject to the removal of the exceptions, we fully support the "design and application" standard and commend the Departments for explicitly barring the use of discriminatory factors and evidentiary standards (or underlying processes and strategies) in designing or applying the NQTL. We also agree that the standard for identifying information that "discriminates" is sufficiently broad to capture a wide range of factors and evidentiary standards currently in use by plans/issuers.

That said, we believe this standard could be significantly strengthened by incorporating the Departments' preamble guidance that this standard would prohibit plans/issuers from relying on "historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA's requirements where the use of such data results in less favorable treatment of mental health and substance use disorder benefits." 88 Fed. Reg. at 51573. Legal Action Center is currently investigating a clear example of the use of historical data not

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⁸ Providers often cite administrative burden as a reason for not participating in health plan/issuer networks. Frequent concurrent review ignores that patients with serious MH and SUD conditions will not make noticeable improvement over a single day or even a week.

subject to the Parity Act that the City of New York uses to determine the out-of-network reimbursement rate for all employee benefit plans: **the reimbursement rate in effect in 1983 – 25 years before enactment of the Parity Act.** The 1983 reimbursement rate standard was not subject to the Parity Act and, while it applies to reimbursement for medical/surgical benefits as well as MH and SUD benefits, we expect that the rate results in less favorable treatment for MH and SUD services. City employees with MH and SUD conditions should not be required to prove on a case-by-case basis that this benchmark violates the Parity Act. As proposed, the City should be barred from using the benchmark.

To ensure that plans/issuers do not rely on any historical data that has not been subject to the Parity Act, we urge the Departments to add the following language to (c)(4)(ii)(B)(3):

Information is considered to discriminate against mental health or substance use disorder benefits if it is historical plan data or historical information from a time when the plan or coverage was not subject to this [part] or it is biased or not objective, in a manner that results in less favorable treatment of the mental health or substance use disorder benefits....

We also note that the proposed standard would appropriately bar plans/issuers from using Medicare fee-for-service rates as the benchmark (evidentiary standard) for setting reimbursement rates for either network or OON providers. While many plans/issuers rely on the Medicare fee schedule to claim compliance, Medicare is not subject to the Parity Act and its rates include and perpetuate historically discriminatory standards.

First, the statute includes a discriminatory rate setting standard for licensed clinical social workers, licensed professional counselors and marriage and family therapists. These licensed professionals are reimbursed at 75% of the Physician Fee Schedule while comparable licensed non-physician practitioners who deliver medical/surgical services (e.g. occupational therapists, physical therapists, physician assistants, nurse practitioners, and clinical nurse specialists) are paid at 85% of the Physician Fee Schedule.⁹

Second, the Centers for Medicare and Medicaid Services (CMS) has long recognized that the relative value unit (RVU) methodology for establishing Medicare rates results in a "systemic undervaluation of work estimates for behavioral health services" and has observed that "any potential systemic undervaluation could serve as an economic deterrent to furnishing these kinds of services and be a contributing factor to the workforce shortage." According to CMS, primary care and counseling services for MH and SUDs are among the services most affected by their methodology, which undervalues the practice expenses incurred in the administrative labor, office expenses and all other expenses incurred by practitioners who bill the psychotherapy codes. ¹² To the extent plans/issuers use

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⁹ Meredith Freed, Juliette Cubanski and Tricia Neuman, "FAQs on Mental Health and Substance Use Disorder Coverage in Medicare (Jan. 18, 2023), https://www.kff.org/mental-health/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.

¹⁰ Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs: CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies, 88 Fed. Reg. 52262, 52320, 52366 (Aug. 7, 2023); *see also*, Marua Calsyn and Madeline Twomey, "Rethinking the RUC: Reforming How Medicare Pays for Doctors' Services" (July 13, 2018), https://www.americanprogress.org/article/rethinking-the-ruc/ (identifying the undervaluing of cognitive services, such as those involved in MH and SUD counseling patients, compared to procedure-based services, and the underlying flaws in the process for establishing RVUs).

¹¹ *Id.* at 52367.

¹² Id. at 52367-68.

Medicare as an evidentiary standard to establish reimbursement rates, they perpetuate embedded inequities that must be eliminated. To allow the use of Medicare as a benchmark is totally inconsistent with CMS's essential conclusion that the Medicare fee schedule is not equitable for MH and SUD services. We urge the Departments to reinforce this in the final regulations, disallowing the use of Medicare as an evidentiary standard.

We appreciate the Departments' inquiry about the use of Medicare as a benchmark for evaluating outcomes data related to reimbursement rate setting. We have addressed the merits of using Medicare to evaluate reimbursement practices for specific provider types below and in the Legal Action Center's Technical Release comments. The use of a Medicare benchmark to identify reimbursement disparities for specific provider types that bill MH, SUD and medical/surgical services, respectively (e.g. physicians) can be instructive, particularly given CMS's confirmation of the likely impact on network participation as a result of the fee schedule's structural undervaluation. That does not mean, however, that Medicare is an appropriate evidentiary standard for reimbursement rate setting, as the fee schedule is based on historical data that is not subject to the Parity Act.

C. Outcomes Data Standard

Subject to the removal of the exception, we strongly support the proposed requirement that plans/issuers collect and evaluate outcomes data to assess (1) the impact of NQTLs on access to MH and SUD benefits and (2) whether the NQTL complies, in operation, under the "no more stringent" and "design and application" tests. As the Departments have highlighted, plans/issuers rarely conduct and/or share such analyses, which are essential to assess in-operation compliance for many NQTLs. We urge the Departments to clarify in (c)(4)(iv) that all data collection and analyses must assess and report outcomes for SUD benefits separately from MH benefits rather than collapse SUD and MH data. As we note in the Center's Technical Release comments, research has demonstrated that different levels of disparity exist for SUD benefits and MH benefits compared to medical/surgical benefits, and both measures must be captured separately to ensure appropriate remedial responses. We recommend that (c)(4)(iv)(A) be revised to state:

When designing and applying a nonquantitative treatment limitation, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health **benefits**, and substance use disorder **benefits**, and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether the limitation, in operation, complies with paragraph's (c)(4)(i) and (ii) of this section **separately for mental health benefits and substance use disorder benefits**.

We also agree that the Departments should issue guidance on the outcome measures that would require the use of uniform and standardized definitions, methodologies, and templates by all plans/issuers

¹³ Milliman, "Addiction and Mental Health vs. Physical health: Widening Disparities in Network Use and Provider Reimbursement," at 19 - 20 (Nov. 19, 2029) (out-of-network utilization for SUD care "especially stark" and increased between 2013-2017 compared to med/surg services; SUD out-of-network utilization nearly four times the out-of-network utilization rate of MH services delivered in outpatient facilities and nearly double for office visits; relative SUD reimbursement declined over five-year period while MH reimbursement increased based on Medicare-allowed level); Wendy Yi Xu, et. al, "Cost Sharing Disparities for Out-of-Network Care for Adults with Behavioral Health Conditions," JAMA NETWORK OPEN (Nov. 6, 2019) doi:10.1001/jamanetworkopen.2019.14554 (patients with drug use and alcohol use disorders had higher utilization of and cost-sharing payments for out-of-network care than individuals with MH conditions or other chronic health conditions).

for the collection and analysis of each data point. Absent uniform and standardized guidelines, plans/issuers will likely submit incomplete and biased data that will undermine regulatory oversight and prevent consumers from comparing coverage of MH and SUD benefits across plans. Additionally, we urge the Departments to issue guidance on outcome data for NQTLs in addition to network composition metrics. As noted below, prior authorization and concurrent review standards pose substantial barriers to SUD and MH care, and discriminatory practices can be readily assessed through outcomes data.

1. Outcomes Measures for NQTLs Other Than Network Composition

We agree that outcomes data related to claims submission and denials for MH, SUD and medical/surgical services (separately analyzed) should be reported and also recommend that the Departments expand the required data points to include other readily quantifiable utilization management outcomes that may reveal discriminatory care and claims processing practices. In Maryland, for example, issuers are required to report:

- Number of prior authorization (PA) requests and number denied;
- PA requests that are subject to fail-first requirements;
- Number of requests for concurrent review, number approved and denied; and
- Number of retrospective reviews of medical necessity, number approved and denied.¹⁴

The Departments have also identified additional data points in the preamble discussion of the comparative analysis, including rates of appeal for adverse benefit determinations (upheld and overturned). While such data would be captured in some states under the proposed standard, we believe all plans/issuers should be required to report these key utilization metrics.

We also urge the Departments to adopt metrics that will evaluate administrative burden imposed on MH and SUD providers, which affects both access to care (e.g. more time spent on administrative utilization management tasks reduces the number of patients seen) and provider participation in networks. ¹⁵ For example, an examination and comparison of the number and portion of services and prescription drugs that require PA and concurrent review can reveal whether MH and SUD providers have heightened and disparate utilization management obligations. The frequency of concurrent review for services and prescription drugs and the placement of drugs on formulary tiers are also reflective of access burdens.

Additionally, we note that the proposed rule would require data collection and analysis of metrics required by private accreditation standards. We urge the Departments to either remove this standard entirely or clarify the specific accreditation standards that require outcomes data to allow for an assessment of such data points. Accreditation standards, unlike State statutory or regulatory requirements, are proprietary and not publicly available without a significant cost. Accordingly, they cannot be assessed to ensure that they are valid data points and appropriately considered as part of the in

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¹⁴ *See* Maryland Insurance Administration, Mental Health Parity Workgroup, Data Supplement 1, https://insurance.maryland.gov/Consumer/Pages/workgroups.aspx.

¹⁵ See, e.g., Heather Saunders, Madeline Guth, and Gina Eckart, "A Look at Strategies to Address Behavioral Health Workforce Shortages: Findings from a Survey of State Medicaid Programs (Jan. 10, 2023), https://www.kff.org/mental-health/issue-brief/a-look-at-strategies-to-address-behavioral-health-workforce-shortages-findings-from-a-survey-of-state-medicaid-programs/; Amer. Hospital Assoc., "Commercial Health Plans' Policies Compromise Patient Safety and Raise Costs (2022), https://www.aha.org/white-papers/2022-07-28-commercial-health-plans-policies-compromise-patient-safety-and-raise-costs

operation analysis. We are also aware of the <u>URAC Mental Health Parity Accreditation</u> program. Those standards are not publicly available and have no bearing on whether a plan complies with the Parity Act, under the proposed regulations. We are concerned that incorporating accreditation standards as a specific outcomes data point may inadvertently undermine the regulatory process by lending greater weight to accreditation processes than is appropriate and allow for reliance on a process and decisions that are proprietary and non-transparent in nature. At a minimum, if outcomes data that are required under accreditation standards are to be a part of the outcomes data analysis process, we urge the Departments to include detailed information about the metrics in the forthcoming guidance.

2. Network Composition Outcomes Data

We support the Departments' targeted requirement that plans/issuers report a range of outcomes data related to network composition, as significant gaps in provider networks for SUD and MH providers have imposed the greatest burdens on access to care and affordability. As we have detailed in the Legal Action Center's Technical Release comments, we urge the Departments to explicitly require collection of appointment wait time data as part of the network adequacy metrics and recommend inclusion of that data point, along with time and distance data, in (c)(4)(iv)(A)(2). This metric is essential to assess the true breadth of the plan/issuer's network and, importantly, will account for providers who are taking new patients (which may be more difficult to ascertain through a travel distance/time metric, generally ascertained through geo-mapping rather than direct contact with providers). In our tracking of network adequacy in Maryland, issuers have routinely satisfied travel distance metrics for MH, SUD and medical services but fail to meet appointment wait time metrics for MH and SUD benefits. It makes little difference that a provider is accessible within a reasonable travel distance if a timely appointment is not available.

We also commend the Departments for requiring an assessment of provider reimbursement rates compared to billed charges. A comparison to billed charges is the most accurate reflection of the current market rates, and, as noted in the above OTP provider example, a plan/issuer's failure to cover a provider's cost of services prevents them from joining a network. Additionally, the "billed charges" benchmark should not be replaced by a reliance on Medicare rates for SUD and MH benefits. As noted above, Medicare has adopted discriminatory reimbursement rates for non-physician MH and SUD practitioners; the fee-for-service schedule is based on RVUs that structurally devalue MH and SUD counseling services; and Medicare rates are not subject to the Parity Act. Additionally, Medicare does not cover and, thus, does not provide a benchmark rate for many SUD and MH services that are required under an evidence-based continuum of care, including SUD and MH residential services, SUD outpatient community-based services in substance use disorder treatment facilities (other than OTPs) and a range of credentialed professionals. Nor does it cover adolescent services. Accordingly, a Medicare benchmark should not be permitted as an evidentiary standard for reimbursement rate setting.

That said, as we noted in our Technical Release comments, a comparison of a plan/issuer's reimbursement rate to the Medicare fee-for-service schedule may be appropriate for specific services

¹⁶ See Legal Action Center and Partnership to End Addiction, "Spotlight on Network Adequacy Standards for Substance Use Disorder and Mental Health Services," (May 2020), https://www.lac.org/resource/spotlight-on-network-adequacy-standards-for-substance-use-disorder-and-mental-health-services.

¹⁷ Legal Action Center, "The Path to Parity: Applying the Parity Act to Medicare to Improve Access to Substance Use Disorder and Mental Health Care (June 2022), https://www.lac.org/assets/files/Path-to-Parity-MAPP-2022.06.14.pdf.

and/or practitioners to independently identify disparities should a plan wish to conduct an additional analysis. For example, assessing reimbursement rates for physicians who bill specific Evaluation & Management (E&M) codes allows for an apples-to-apples comparison of reimbursement for physicians who deliver psychiatric care and those delivering other medical services. A comparison of a plan/issuer's reimbursement for OTPs to the Medicare rate may be instructive for remedial purposes, as CMS has taken significant steps to assess the cost of OTP care delivery to individuals with opioid use disorder and has increased the Medicare reimbursement since implementation of the benefit in 2020 accordingly. Finally, a comparison of a plan's psychotherapy rates, while problematic based on the structural undervaluing of these services and a discriminatory percentage reduction for specific practitioners, could reveal even greater reductions in reimbursement for MH and SUD services by a plan/issuer. These should be supplementary – not primary – analyses of compliance.

Finally, as one additional component of the network composition metrics, we recommend that the Departments require the collection and evaluation of total out-of-pocket (OOP) payments by plan members/participants for out-of-network MH, SUD and medical/surgical benefits as an analogue to outof-network utilization rates. Research has demonstrated a significantly disparate cost burden on individuals who access SUD and MH benefits compared to medical services for other chronic conditions based on out-of-network service utilization. 18 This data should be captured so that plans/issuers can be required to address these disparities by increasing reimbursement rates for providers of in and out-ofnetwork services, ensuring that the consumer pays no greater cost for services than the in-network cost, ¹⁹ or other remedial measures. The Center's comments on the Technical Release set out the recommended analysis of OOP payments by members.

3. Material Difference Standard

We commend the Departments for adopting more robust and mandatory requirements to respond to outcome data disparities for MH benefits and SUD benefits. We agree that disparities should be dispositive of a parity violation for NOTLs related to network composition and recommend the same finding for all other NOTLs. We are concerned that anything short of a violation determination will be difficult to enforce and to verify that a carrier has, in fact, taken steps to address the disparities. Most importantly, even though the proposed regulation would require documentation of mitigation efforts in plan/issuer compliance reports, members/participants would have no way of knowing what actions have been taken and whether they effectively address the access problem.

We also oppose the use of a "material difference" standard as the threshold for finding a violation or implementing remedial measures. Although we appreciate the Departments' recognition that "material

¹⁸ Xu, et. al, supra note 13, "Cost Sharing Disparities for Out-of-Network Care for Adults with Behavioral Health Conditions," (higher cost sharing and out-of-network (OON) rates for MH and SUD conditions relative to other chronic conditions; individuals with MH conditions had cost sharing for OON care \$341 higher than those with diabetes, individuals with alcohol use disorders \$1138 higher and drug use disorders \$1242 higher than individuals with diabetes; and Zirui Song, et al., Out-of-Network Spending Mostly Declined in Privately Insured Populations With A Few Notable Exceptions From 2008 to 2016, 39 HEALTH AFF. 1032 (June 2020), doi: 10.1377/hlthaff.2019.01776 (noting the sizable difference in out-ofnetwork spending across various professional services, with psychiatric services having the highest level of approximately 30% and remaining at this level over the 8-year study period; out-of-network spending for medical services remained stable or declined over the study period with the exception of hospitalist services, pathologist services and laboratory tests). ¹⁹ As of July 2022, eighteen (18) states have adopted a standard that protects consumers from high out-of-pocket costs when a plan's network does not include providers that can deliver covered services. Legal Action Center, Survey of State Balance Billing Standards State Data (on file at Legal Action Center).

difference" must be defined to facilitate enforcement, this threshold is fundamentally inconsistent with the "no more restrictive" and "no more stringent" statutory standards. Neither standard requires a "material difference" to establish an in operation violation, and the plain language of the statute means that "any" difference in the outcome for SUD and MH compared to medical/surgical benefits violates the Act. Indeed, the "reference point" for members/participants is whether they face any greater burden in accessing MH and SUD care than medical care, because they pay for those benefits and should have access with no greater burden. That is the promise and meaning of "parity."

We recommend that that the Departments adopt a "de minimis" difference standard and define the term as a "minimal" or "negligible" difference. The plan/issuer should have the burden of demonstrating that any disparity in outcomes data meets the "de minimis" standard to avoid remedial action, as they are barred from offering policies and contracts that violate NQTL or other standards. 26 C.F.R. § 54.9812-1(h), 29 C.F.R. § 2590.712(h), and 45 C.F.R. §146.136(h).

While the use of a statistical test has the appeal of establishing a "bright-line" quantifiable value, plan members should not be required to employ expert statisticians to make use of this important test and confirm the plan/issuer's data. We also question whether any single quantitative metric is appropriate for all NQTLs, which may differ based on what is being measured. Even a small disparity in reimbursement rates that precludes SUD and MH providers from joining a network will have significant consequences for plan members who cannot afford OON costs. Should the Departments retain the material difference standard, we urge you to consult with expert health economists on the appropriate analytical tools and statistical test.

VI. NQTL Exceptions and Definition of Discrimination - 26 C.F.R. § 54.9812-1(c)(4)(v), 29 C.F.R. § 2590.712(c)(4)(v), 45 C.F.R. § 146.136(c)(4)(v).

The Departments appropriately recognize that plans/issuers must use appropriate evidence-based standards in designing and applying NQTLs and should adopt practices that will permit detection or prevention of fraud, waste and abuse in the delivery of MH, SUD and medical/surgical benefits. We do not agree, however, that a regulatory exception for either the "professional medical or clinical standards" or "fraud, waste, and abuse detection/prevention" is either consistent with the statute or needed to improve enforcement of the Parity Act. We anticipate both exceptions will (1) be exploited to impose new burdens on access to care and (2) create additional proof problems for members/participants when an exception is invoked, as they will have to, first, show discrimination in the plan/issuer's application of the exception and, if successful, prove a violation under one or more tests, even though data to do so may not exist because the plan/issuer would have been immunized from conducting all or part of the comparative analysis. In other words, invoking an exception appears to significantly disrupt or obviate the entire NQTL requirement. No justification has been provided to support a radical departure from the status quo consideration of these elements as part of the design and application comparative analysis.

We urge the Departments not to adopt the exceptions and also to strengthen the proposed regulations by adding several provisions to reinforce the importance of adhering to evidence-based standards of care and a proper consideration of strategies and processes that address "fraud, waste and abuse." First, as noted above, we have proposed:

• the adoption of a definition of "generally accepted standards of care" (as an alternative to the analogous term "professional medical or clinical standards") to create uniformity in a

- plan/issuer's assessment of "deviations from generally accepted standards of care" (which the rule includes in the proposed definition of "strategy"); and
- the inclusion, in either the "strategies" or "processes" definition, of "actions to address fraud, waste and abuse" to reinforce the Departments' identification of the factor "claims types with a high percentage of fraud" in that definition.

Additionally, to the extent the Departments wish to reinforce non-discrimination guidelines for these two specific factors, which we fully support, we propose to incorporate those standards in a new construction provision that sets out the non-discrimination requirements. The Departments' proposed guardrails (e.g. impartial application of and no deviation from medical and clinical standards and narrowly designed fraud, waste and abuse standards that are based on objective and unbiased data), should certainly govern plan/issuer practices in the context of the existing comparative analysis framework.

We recommend the following language:

- (v) <u>Construction</u>: Independent professional medical or clinical <u>Generally accepted standards of care</u> and standards to detect or prevent and prove fraud, waste, and abuse. (A) To satisfy the standards —qualify for the exceptions—in paragraphs (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(iv)(D) of this section, for <u>generally accepted standards of care</u>, independent professional medical or clinical standards, a nonquantitative treatment limitation must impartially apply <u>generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care)—to medical/surgical benefits and mental health <u>benefits</u> or substance use disorder benefits, <u>as defined in this part</u>, and may not deviate from those standards in any way, such as by imposing additional or different requirements.</u>
- (B) To <u>satisfy the standards</u> <u>qualify for the exceptions</u> in paragraphs (c)(4)(i)(E) and (c)(4)(ii)(B) of this section to detect or prevent and prove fraud, waste, and abuse, a nonquantitative treatment limitation must be <u>reasonably</u> designed to detect or prevent and prove fraud, waste, and abuse, based on indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data, and also be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits.

We offer additional rationale for not adopting the two exceptions.

1. Independent Professional Medical and Clinical Standards

The professional medical and clinical standards exception is an unexpected reprise of the 2010 interim final regulation standard – "recognized clinically appropriate standards of care" – that the Departments removed in the 2013 final rule. In doing so, the Departments explained:

[C]ommenters raised concerns that this exception could be subject to abuse and recommended the Departments set clear standards for what constitutes a "recognized clinically appropriate standard of care." For example, commenters suggested a recognized clinically appropriate standard of care must reflect input from multiple stakeholders and experts; be accepted by multiple nationally recognized provider, consumer, or accrediting organizations; be based on independent scientific evidence; and not be developed solely by a plan or issuer. Additionally, since publication of the interim final regulations, some plans and issuers may have attempted to invoke the exception to

justify applying an NQTL to all mental health or substance use disorder benefits in a classification, while only applying the NQTL to a limited number of medical/surgical benefits in the same classification. These plans and issuers generally argue that fundamental differences in treatment of mental health and substance use disorders and medical/surgical conditions, justify applying stricter NQTLs to mental health or substance use disorder benefits than to medical/surgical benefits under the exception in the interim final regulations.²⁰

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

HHS convened a technical expert panel on March 3, 2011 to provide input on the use of NQTLs for mental health and substance use disorder benefits. The panel was comprised of individuals with clinical expertise in mental health and substance use disorder treatment as well as general medical treatment. These experts were unable to identify situations for which the clinically appropriate standard of care exception was warranted—in part because of the flexibility inherent in the NQTL standard itself.²¹

The Departments appropriately recognized that the current framework offers the necessary flexibility to apply clinically appropriate standards of care. Nothing has changed over the past 10 years to support this retreat, and, indeed, Congress did not adopt this or other exceptions in establishing NQTL compliance and reporting standards under the Consolidated Appropriations Act of 2021. **We urge the Departments to not revisit this flawed standard.**

We also view this exception as unworkable in practice. While the Departments have stated that the application of this exception to an NQTL under any one of the three tests (no more restrictive, design and application or outcomes data) would not affect the plan/issuers obligation "to comply with the requirements for which the exception or exceptions do not apply," (88 Fed. Reg. at 51578), we are troubled that an exception's application to an NQTL under one test will have the same preclusive effect, in practice, for all tests.

We are also concerned that the exceptions will literally preclude a full Parity Act analysis for in operation violations. For example, plans/issuers would not be required to comply with the outcomes data provision if they impartially applied independent medical or clinical standards. Those data, however, are evidence of an "in operation" violation under the "no more restrictive" and "design and application" tests and would no longer be available or fair game to demonstrate a violation of (c)(4)(i) and (ii). That proof preclusion is completely inconsistent with the proposed (c)(4)(iv)(A) regulatory provision, which states:

[A] plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on access to mental health and substance use disorder benefits and medical/surgical benefits, and *consider the impact as part of the plan's or issuer's analysis of whether the limitation, in operation, complies with paragraphs*

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²⁰ Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 78 Fed. Reg. 68240, 28245 (Nov. 13, 2013).

²¹ *Id.* at 78 Fed. Reg. 28245, n. 17.

(c)(4)(ii) and (ii) of this section. (emphasis added).

Similarly, under the "no more restrictive test" it appears that a plan/issuer could apply an NQTL to MH or SUD benefits without satisfying the "substantially all" requirement by asserting one of the exceptions. The proposed regulation states:

Notwithstanding paragraphs (c)(4)(i)(A) through (D) of this section, a plan or issuer that applies a non-quantitative treatment limitation that [applies one of the exceptions consistent with (c)(4)(v)(A) or (B) of this section] to mental health or substance use disorder benefits in any classification will not be considered to violate this paragraph (c)(4)(i) with respect to such nonquantitative treatment limitations.

This eliminates evidence that could be used under the "design and application" test to assess whether an NQTL is "comparable" and "no more stringently" applied. Under the financial requirement/quantitative treatment limitation (FR/QTL) analytical framework from which the proposed standard has been adapted, satisfaction of the "substantially all" test translates to a finding of "no separate" FR/QTL for MH or SUD benefits, and the satisfaction of the "predominant value" test translates to a "no more restrictive" FR/QTL. The "no separate" and "no more restrictive" tests map on to the "comparable" and "no more stringent" NQTL standards.

With such far-reaching implications, we envision significant loopholes that will undermine the NQTL analysis, notwithstanding the Departments' clear intention otherwise. Should the Departments wish to codify this exception in the final regulations, we urge the Departments to clearly explain how the exception will not swallow the rule.

Finally, the proposed framework for determining whether a plan/issuer's medical or clinical standards pass muster – standards that are "independent, peer-reviewed, or unaffiliated with plans and issuers" – is not sufficiently strong to prevent the use of proprietary clinical standards that have been influenced by plan/issuer financial interests. The definition of "generally accepted standards of care" that we and others have offered would rely on standards that meet each of the above requirements and avoid financial conflicts of interest through the reliance on criteria from the nonprofit professional association for the relevant specialty.

2. Standards to Detect or Prevent and Prove Fraud, Waste and Abuse

Like the medical and clinical standards exception, we expect that plans/issuers will invoke the fraud, waste and abuse exception broadly and, notwithstanding the proposed requirement in (c)(4)(v)(B), provide no showing that the requirement is based on objective and unbiased data. The Legal Action Center has assisted a provider in New York who identified that a commercial insurer who contracts with a third-party administrator for its MH and SUD benefits uses a program to analyze claims to detect fraud, waste, and abuse, and subsequently requires providers who are flagged in the system to submit substantial, burdensome documentation with their claims. It does not appear that a comparable program or analysis exists for medical/surgical benefits or the supplemental documentation required of such providers. MH and SUD providers will be hard-pressed to challenge the application of the exception or examine the merits.

Similarly, as set out above, the application of the fraud, waste and abuse exception in either the more restrictive or design and application test will invariably undermine a challenge of the NQTL in the other

test. At best, the adoption of this exception will result in time-consuming disputes about the permissibility of the specific fraud, waste and abuse practice and obfuscate the plan/issuer's underlying discriminatory practice. Even if one fraud, waste, abuse practice is disallowed, we envision the plan/issuer simply coming back with another variation that will require repeated examination of whether it is meets the narrowly tailored, basis in objective and unbiased data requirements. No patient or provider has the resources to undertake such challenges. We strongly urge that the Departments not to adopt this exception as it will truly swallow the NQTL rule.

VII. New Examples - 26 C.F.R. § 54.9812-1(c)(4)(viii), 29 C.F.R. § 2590.712(c)(4)(viii), 45 C.F.R. § 146.136(c)(4)(viii)

We appreciate the development of additional NQTL examples to address common violations of the Parity Act and provide guidance on the application of the newly proposed standards. Based on our objections to the adoption of the two exceptions, we urge the Departments to revise the examples that reference those exceptions and develop a conclusion that is based on an analysis under one or more tests and without regard to the exceptions. We also note that Example 5, which pertains exclusively to the application of an exception, should be removed.

Apart from these revisions, we are particularly appreciative of the examples that address restrictive concurrent review and peer-to-peer review requirements, disparate percentage reductions for reimbursement of non-physician MH and SUD practitioners, medication authorization requirements that do not comply with the ASAM criteria, and the exclusion of MH and SUD residential treatment, which translates into a scope of coverage limitation.

VIII. Effect of Final Determination of Noncompliance - 26 C.F.R. § 54.9812-1(c)(4)(vii), 29 C.F.R. § 2590.712(c)(4)(vii), 45 C.F.R. § 146.136(c)(4)(vii)

We support the Departments' strong regulatory standard in (c)(4) that a plan/issuer's failure to meet any one of the NQTL tests renders the limitation in violation of the statute and prohibits the plan/issuer from imposing the limitation. We urge the Departments to identify the steps they and state regulators will take to enforce this standard in a meaningful way. While the Departments have begun to identify real consequences for NQTLs for which a final determination of noncompliance is issued by the Secretary ((c)(4)(vii), this standard should be strengthened and expanded, to the extent possible, to address the multitude of NQTLs that will not be reviewed or have a final determination under the proposed compliance analysis and review procedures based on limited federal and state enforcement resources.

One starting point is to identify measures to enforce the existing regulatory provision that bars plans/issuers from offering policies and contracts that violate any provision of the Act. 26 C.F.R. § 54.9812-1(h), 29 C.F.R. § 2590.712(h), and 45 C.F.R. § 146.136(h). This standard clearly contemplates that plans/issuers conduct a thorough NQTL analysis prior to offering the plan and on an on-going basis to ensure compliance. The Departments have abundant evidence from their compliance reviews that compliance analyses are not conducted or available, as required under the Parity Act. (29 U.S.C. §1185a(a)(8), and 42 U.S.C. § 300gg-26(a)(8)). To achieve compliance, plans/issuers that cannot present their parity analysis at the point of sale should be barred from offering the plan/policy.

More immediately, to strengthen this provision, we urge the Departments to revise (c)(4)(vii) replacing "may" with "shall" to bar the plan/issuer from imposing the NQTL until it has taken appropriate action

to remedy the violation to the Secretary's satisfaction. While we understand the Departments' hesitancy to require the immediate cessation of every non-compliant limitation without consideration of surrounding circumstances, we envision no other way to incentivize plans/issuers to take parity compliance seriously, correct deficiencies, and cover and reimburse the MH and SUD services members/participants have a right to receive. This outcome is equitable considering existing standards have long barred plans/issuers from even offering policies and contracts that violate any provision of the Act. Non-compliant practices – many extending from the initial offer of the plan – should not be reinforced by allowing for additional delay in remedying a violation, particularly when the health and well-being of individuals with MH and SUDs are jeopardized. Second, we urge the Departments to add provisions that the Departments will work with the Internal Revenue Service to assess penalties allowed by the Parity Act.

Third, State regulators should have the same authority as federal regulators to order the immediate cessation of non-compliant NQTLs. The HHS and IRS regulations limit this authority to final determinations made by the Secretary, even though State departments of insurance have primary authority to enforce the Parity Act for state-regulated plans. Requiring a referral to federal regulators for remedial action is not efficient, particularly given the limited federal agency resources available to conduct compliance reviews.

IX. Availability of Plan Information – 26 C.F.R. § 54.9812-1(d), 29 C.F.R. § 2590.712(d), 45 C.F.R. § 146.136(d)

We support the Departments' affirmation in the disclosure provision that members/participants have a right to receive the plan/issuer's comparative analysis, including all supportive information required under the proposed comparative analysis provision, either upon request (ERISA governed plans) or as part of a claim's appeal process (HHS and ERISA governed plans and all state-regulated plans). Based on our client representation and caselaw, ²² plans/issuers often refuse to respond to multiple requests for plan documents related to parity compliance of challenged NQTLs (much less respond to Parity Act claims themselves in administrative grievance procedures). We urge the Departments to revise the disclosure provision to reaffirm the Departments' long-standing guidance that plan documents related to the Parity Act compliance analysis cannot be withheld based on claims of proprietary or commercially valuable information.²³ We recommend that the following language be added at the end of (d)(3):

Information required to be disclosed under this subsection shall not be withheld on the basis that the information is proprietary or has commercial value.

We note that the trigger for access to the comparative analysis in 146.136(d)(3) is different from that in 146.137(e) insofar as a member/participant would have access to the comparative analysis "upon appeal of an adverse benefit determination" as opposed to having access as soon as they "have received an adverse benefit determination." **We strongly urge the Departments to eliminate this inconsistency**

²² See, e.g., N.E. v. Blue Cross Blue Shield of North Carolina, 1:21CV684, 2023 WL 2696834 *11 (M.D. N.C. Feb. 24, 2023) (plan's failure to provide requested documentation related to Parity Act claim on multiple occasions bars it from seeking dismissal of Parity Act claim as too conclusory and vague).

²³ Dept. of Labor, Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) at 30, https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf; and FAQs About Affordable Care Act Implementation (Part XXIX) and Mental Health Parity Implementation, Q. 12, (Oct. 23, 2015), https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxix.pdf.

and conform the disclosure provision in (d)(3) to the standard in (e) so that members/participants can have information, at the time of the denial, that is needed to assess whether to raise a parity compliance claim in an internal grievance/appeal. In our experience, members/participants must often file an internal grievance challenging a carrier practice without any plan information related to the design and application of the challenged practice. This places members/participants at a significant disadvantage, undoubtedly preventing some from asserting a parity claim, rendering parity claims more speculative, and delaying the appeal process in an effort to get essential plan information (which is often not disclosed). The statutory disclosure provision in no way limits the procedural posture or timeframe at which the comparative analysis may be disclosed. See 29 U.S.C. § 1185a(a)(4), and 42 U.S.C. § 300gg-26(a)(4).

Finally, we urge the Departments to develop standards that would require the imposition of penalties that are available under existing Internal Revenue Service standards, 26 U.S.C. §4980D, based on the failure to disclose parity compliance information upon request.

X. Nonquantitative Treatment Limitations Comparative Analysis Requirements – 26 C.F.R. § 54.9812-1, 29 C.F.R. § 2590.712-1, 45 C.F.R. § 146.137

We strongly support the Departments' detailed description of the information plans/issuers are required to gather, examine and submit, upon request, to the Departments or any applicable state regulator. We particularly support the inclusion of information related to the "no more restrictive" and outcomes data analyses. Should the Departments adopt one or both proposed exceptions – which we urge you not to do – it is imperative that plan/issuer's comparative analysis identify the application of the exception to any NQTL and include a detailed analysis to demonstrate that the exception meets the non-discrimination guardrails set out in (c)(4)(v).

We also urge the Departments to explicitly reference in subsection (b) "any applicable State authority" to ensure clarity that plans' comparative analysis must be made available to state regulators upon request. The relevant sentence should read: "Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary or to any applicable State authority, upon request, in the manner required by paragraphs (d) and (e) of this section." While this statutory requirement is referenced in (e), some insurers have refused to provide the required parity compliance analysis to the applicable State authority upon request if the relevant Secretary has not also requested the analysis. We also note that, to the extent the Parity Act does not require State insurance regulators to adopt the statutory compliance review standards and timelines (as reflected in subsection (d)), we recommend that the Departments work closely with State insurance authorities to incentivize and facilitate the implementation of comparable review and notification standards so that all insured members/participants have the same substantive rights and processes regardless of the source of insurance.

Finally, we fully agree that plan members/participants must receive prompt and plain language notification of final determinations of non-compliance. The proposed notification is not sufficient, however, to protect consumer rights. We recommend that the Departments strengthen the required notification by requiring the plan/issuer to explain "any opportunity" for claims reprocessing, we urge the Departments to place an affirmative obligation on them, as part of the corrective action plan, to identify affected members/ participants, reprocess any claims, and notify those determined to have been impacted by the non-compliant NQTL with the final reprocessing resolution and/or timeframe for resolution. Plan members are not well positioned to navigate the reprocessing procedure and relevant

materials are more likely to be in the possession of the plan/issuer and provider. We commend the Departments for appropriately shifting the burden away from consumers throughout this proposed rule, and we urge a consistent approach here.

XI. Departments' Request for Information – Ways to Improve Mental Health and Substance Use Disorder Benefits Though Other Consumer Protection Laws

We welcome the Departments' interest in using other consumer protection laws to improve access to MH and SUD benefits. We offer the following suggestions.

A. Incentivizing Third-Party Administrators (TPAs)

We share the Departments' concern that TPAs are often responsible for plan design and administration (and resulting Parity Act violations) and must be incentivized to comply with the Act, including ensuring that plan sponsors receive all relevant plan information and data required for NQTL analyses. While the Department of Labor (DOL) has requested statutory authority to impose civil penalties on plans sponsors and TPAs, pending Congressional action, we urge the Department to use ERISA's strong protections to hold TPAs accountable as ERISA fiduciaries and co-fiduciaries. Under 29 U.S.C. 1132(a)(5), DOL may bring legal action against any fiduciary that violates the Parity Act, including TPAs, as incorporated into ERISA through 29 U.S.C. 1185a. Further, under 29 U.S.C. 1134, DOL is granted the power, "in order to determine whether any person has violated or is about to violate any provision of this subchapter," including the Parity Act, and to "make an investigation" and to "inspect such books and records and question such persons as he [the Secretary] may deem necessary to enable him [the Secretary] to determine the facts relative to such investigation." Thus, DOL may investigate TPAs for acts or practices that violate the law and can sue to enjoin such practices. Finally, DOL is authorized under 29 U.S.C. 1135 to "prescribe such regulations as he finds necessary or appropriate to carry out the provisions of this subchapter." We urge DOL to use its substantial authority and discretion to ensure that TPAs have adopted policies and procedures that are parity compliant.

Second, plan sponsors can ensure through contract requirements that TPAs and pharmacy benefit managers provide all relevant plan information to conduct NQTL analyses, including timely updates on plan administration that may affect Parity Act compliance and assistance in conducting the NQTL analysis prior to the offer of plans or benefit changes. To make this standard practice, we urge the Departments to require, in the proposed rule, that plan sponsors insert Parity Act compliance provisions in their TPA and pharmacy benefit manager contracts. We note that CMS has encouraged State Medicaid officials to include "provisions in their [Medicaid] managed care contracts to report on the outcome of the parity analysis to ensure that parity is achieved and can be overseen appropriately." States, such as Ohio, have developed contract standards that require Medicaid managed care organizations to submit a parity compliance report to state officials, using a standardized template, in advance of making any benefit coverage revisions to allow for a compliance review prior to implementation. HHS utilized a similar approach in 2001 when it required health care entities covered by HIPAA (mainly health care providers and health insurers) to include HIPAA-related provisions in their contracts with outside entities that handle patient information on behalf of covered entities.

²⁴ CMS, An Implementation Roadmap for State Policymakers Applying Mental Health and Substance Use Disorder Parity Requirements to Medicaid and Childrens' Health Insurance Program, at 14 (Jan. 18, 2017), https://www.medicaid.gov/sites/default/files/2019-12/parity-roadmap.pdf.

²⁵The Ohio Dept. of Medicaid, Ohio Medicaid Provider Agreement for Managed Care Organization, https://medicaid.ohio.gov/static/Providers/ProviderTypes/Managed+Care/Provider+Agreements/2023 02 MCO Final.pdf.

Without such business associate agreements, ²⁶ HIPAA's privacy and security protections would have been undermined if businesses handling patient information for billing, accounting, legal, IT, or other purposes could simply ignore HIPAA. These agreements contractually require the outside entities to carry out the HIPAA obligations of the covered entities and help them with compliance. Comparable requirements for parity protections would incentivize TPAs to comply with the Parity Act and ensure plans/issuers have access to all of the information they need to comply as well.

B. Implementing Provider Nondiscrimination Provisions

LAC appreciates the Departments' interest in suggestions to enhance access to MH and SUD benefits through implementation of the Public Health Services (PHS) Act section 2706(a). Many of the issues that the Departments have sought to address concerning both network composition and restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan of coverage could simultaneously be addressed through the provider nondiscrimination provisions. We respectfully request that the Departments specify in regulations implementing PHS Act section 2706(a) that plans/issuers, including third party administrators, are prohibited from:

- Excluding any type of MH or SUD providers from their networks, assuming the provider type is licensed or certified by the State in which they are practicing to deliver care. For example, if certified drug and alcohol or addiction counselors or peer support specialists are authorized under state law to treat patients and bill insurers, then plans/issuers may not exclude these provider types.
- Limiting the types of services that MH or SUD providers can deliver to enrollees, assuming those services are within the scope of practice of their licensure or certification.
- Requiring the delivery of specific MH or SUD services by designated types of providers or facilities – such as physicians or hospital settings – if the service can be delivered by MH or SUD providers under their licensure or certification.
- Reimbursing MH or SUD providers at a lower rate than physicians or any other medical provider for delivering the same covered services to enrollees. This includes ensuring the MH or SUD community-based or office-based providers are reimbursed at a rate that is equitable to services in other settings of care, such as hospitals.
- Applying credentialing standards or admission practices to MH or SUD providers that are not applied to any other providers;
- Requiring MH or SUD providers to submit more documentation for claims or reimbursement of covered services than what is required for any other providers;
- Taking longer to reimburse MH or SUD providers for covered services than any other providers;
- Requiring more frequent audits of claims or reimbursement of MH or SUD providers than any other providers.

By explicitly incorporating these provisions into the provider nondiscrimination regulations, providers will more easily be able to identify discriminatory practices and have greater knowledge of their rights, and enrollees will have greater access to MH and SUD care.

Dept. of Health and Human Services, Business Associate Contracts, https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html.

C. Standards Related to Provider Directories

LAC appreciates the Departments request for information on ways the Departments can improve the coverage of and enhance access to MH and SUD benefits through their implementation of the provider directory requirements under Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A–5(a) and (b), particularly in underserved or rural areas where they may be limited access to the internet. The Centers for Medicare and Medicaid Services (CMS) have recently proposed regulations that would require an independent entity to conduct annual secret shopper surveys of Medicaid managed care organizations for provider directory accuracy for outpatient MH and SUD providers, as well as several other provider types. *See* "Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality," 88 Fed. Reg. 28092, 28101-02 (proposed May 3, 2023). We applaud CMS for this proposal, and we urge the Departments to use this opportunity to establish greater consistency across plans and financing systems by requiring comparable independent secret shopper survey requirements of provider directories in plans under the Departments' jurisdiction.

Inaccurate provider directories often mask another significant parity problem: inadequate networks. We appreciate the Departments' substantial proposals to heighten the scrutiny around network adequacy as an NQTL and ensure enrollees have sufficient access to network providers. To the extent plans are using their network directories to measure their own network adequacy, we believe that substantial directory inaccuracies are often indicative of network inadequacies. In such cases, nearly half of the states permit plan members to receive out-of-network services and pay no more than they would pay for a network provider. We, therefore, urge the Departments to similarly hold enrollees harmless from out-of-network costs if they accessed care from a non-network provider when their plan networks are inadequate to meet their needs, not just when they rely on inaccurate information or when they fail to receive the information. See, e.g., Cal. Health & Saf. Code § 1374.72(d) (2021).

We also request that the Departments issue regulations that put an affirmative obligation on plans or issuers to pay for claims such that the enrollee would pay no more than the in-network cost sharing rate when either (1) the information the patient received about the network status of a provider was incorrect, or (2) the patient did not receive the requested information from the plan within the 1 business day requirement. Plan participants already struggle to get the care they need, and putting the onus on enrollees to know these rights and appeal denials is overly burdensome and unfair when the plan or issuer has failed to meet its legal obligations. The process of researching their rights or appealing denials based on incorrect or missing information is especially burdensome for enrollees in underserved or rural areas where there may be limited access to the internet. Thus, plans should pay the balance of these claims, rather than relying on enrollees to dispute or appeal the additional charges they should not have incurred.

D. Telehealth Services to Improve Access to MH and SUD Services

Telehealth is an important service delivery modality for MH, SUD and other medical services post-pandemic for individuals who want to use this modality and for whom it is available and accessible. Although we are not familiar with how the Departments' guidance affected service delivery and access, our Technical Release comments identify standards that are essential if telehealth is to be counted for satisfaction of travel time and distance or appointment wait time metrics associated with network adequacy. We certainly agree with the Departments' requirement in Frequently Asked Questions

(FAQs) 43 that plans/issuers must comply with the Parity Act for coverage of telehealth services, including financial requirements, reimbursement rate setting, credentialing and admission of network providers, and network adequacy metrics among other NQTLs.

As we set out in more detail in the Technical Release comments, specific safeguards are necessary to ensure the broad availability of in-person services for individuals with MH and SUDs and the use of telehealth as a supplement to, not replacement for, in-person services. We urge the Departments to take these safeguards into account in any future standards:

- telehealth services must be clinically appropriate;
- telehealth delivery must be available and accessible to members;
- the provider must offer comparable in-person services; and
- the member must have the right to select the mode of service delivery.

While consumers continue to use telemedicine services more frequently for MH care than other medical services (and SUD care to a lesser degree than MH) post-COVID pandemic, ²⁷ research demonstrates that the majority of patients received **in-person care** for MH and SUD even at the height of the pandemic. ²⁸ Telemedicine utilization varies based on age, geographical location, access to broadband, comfort level with technology and digital literacy, ²⁹ highlighting the need to honor patient preference and needs in determining whether telemedicine services are, in fact, clinically appropriate, available and accessible to a plan member. ³⁰ Research has demonstrated that patients value the choice in how to receive MH and SUD care, and experience a greater therapeutic relationship when they have that choice. ³¹ To allow plans/issuers to count telehealth service delivery without considering a patient's preference and need for in-person care on a periodic or regular basis over the course of care would not accurately reflect the adequacy of the network and would exacerbate existing inequities in care access.

E. Claims Appeals and External Review Rules

We appreciate the Departments' request for recommendations to strengthen the internal claims and appeals and external review process regulations to improve access to MH and SUD services. As a

²⁷ See FAIR Health Telehealth Tracker, https://www.fairhealth.org/fh-trackers/telehealth (last visited Aug. 30, 2023) As of May 2023, mental health diagnoses rank first among the top five diagnoses in all four regions across the United States with substance use disorder diagnoses ranking among the top five in two of four regions (and at no greater rate than the three other identified medical conditions).

²⁸ KFF and Epic Research found that, for the period March-August 2021, **over one-half of MH or SUD services were delivered in-person regardless of the specific condition.** Telehealth service delivery accounted for 29% of visits for both opioid and alcohol-related disorders and 33% - 43% of services for a range of MH conditions. Justin Lo, et al., *Telehealth Has Played an Outsized Role Meeting Mental Health Needs During the COVID-19 Pandemic* (Mar. 15, 2022), https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/#.

³⁰ Research by NCQA concluded that "equitable and innovative care delivery should always place the patient at the center, thus, the design of technology and digital tools that facilitate care delivery must prioritize patient preference and needs." NCQA, The Future of Telehealth Roundtable: The Potential Impact of Emerging Technologies on Health Equity (2022) at p. 10. Individual patient factors and considerations, such as digital literacy, English proficiency, visual, cognitive, intellectual, mobility and functional needs, comfort level with sharing video, and socio-economic status, all contribute to a patient's care decision. *Id.* at pp. 10-11.

³¹ Jessica Sousa et al., *Choosing or Losing in Behavioral Health: A Study of Patients' Experiences Selecting Telehealth Versus In-Person Care*, Health Affairs (Sept. 2023), https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00487.

preliminary matter, greater enforcement of existing standards is needed to ensure claimants are afforded a fair and full review of their claims, as required under federal claims procedures. See 29 C.F.R. § 2560.503-1 and 2590.715-2719. We routinely raise Parity Act violations as part of our clients' internal appeal and external review procedures, and, as part of those proceedings, request relevant NQTL documents and comparative analyses. The plan/issuer frequently ignores our document requests entirely and, in other matters, produces a document dump without allowing for timely review and, since implementation of the comparative analysis requirement, fails to include the comparative analysis. Additionally, the plan/issuer generally ignores our Parity Act claims in issuing its determination in internal and external reviews. This violates a consumer's right to a full and fair review of their claim(s) and undermines the ability to file other administrative actions and/or litigation. One solution would be to require the plan/issuer to attach its relevant comparative analysis to any adverse determination related to MH and SUD benefits.

We are currently in a dispute with a self-insured plan that ignored our Parity Act claims in the first level internal review and repeatedly missed required deadlines for responding to a second level internal review that reasserted those claims. When the reviewer finally provided an informal response (pending its official second level determination), it noted that it could not address our exclusion of SUD benefits claim because it was not in possession of relevant pharmacy plan information that it needed to confirm that the plan covered SUD medications in one classification and, thus, was required to cover SUD benefits in all classification in which medical benefits are covered. In the meantime, the hospital has pursued collections against our client for the pending unpaid claims. As noted below, meaningful enforcement mechanisms are needed to penalize plans/issuers who blatantly ignore a claimant's legal claims.

We recommend several revisions to the claims procedures standards that could assist consumers in accessing MH and SUD services.

- Denials of benefits and adverse benefit determinations should inform members/participants in plain language that the plan is subject to the Parity Act (as applicable) and that the Act bars discriminatory coverage of MH and SUD benefits and identify resources that can explain their parity rights.
- Denials of benefits for MH and SUD benefits should explain how the denial complies with the Parity Act and, as the Departments have suggested, how any specific NQTL has been applied in their benefit determination.
- Denials of benefits should inform the member/participant that they have a right to receive the comparative analysis upon request, consistent with the proposed comparative analysis requirements (26 C.F.R. § 54.9812-2(e), 29 C.F.R. 2590.712-1(e), and § 45 C.F.R. § 146.137(e)(2)) and provide clear instructions on how to receive the comparative analysis, including the contact, phone number, email, and address for requests.
- Provisions related to the qualifications of individuals who respond to internal grievances and external reviews, including internal review organizations (IROs), must ensure that relevant individuals have knowledge about and experience in conducting Parity Act reviews so that they can respond effectively to such claims.

We appreciate the Departments' query about requiring a plan/issuer to identify a patient's eligibility for a lower level of care when the requested level is denied. We have no objections to establishing this requirement as long as it is done in the context of a documented denial of the requested level of care.

We are concerned that plans/issuers frequently extinguish the appeal rights of the member/participant to the prescribed level of care in the course of communications – often in the context of a prior authorization request or concurrent review in which a plan/issuer indicates that they will not cover the requested level of care, resulting in the provider accepting coverage/reimbursement for a lower level of care and obviating a formal denial for the requested level.

Finally, we urge the Departments to put in place meaningful enforcement mechanisms to ensure that plans/issuers fulfill their obligation to provide participants/beneficiaries with legally required information, upon request, and respond to any and all legal claims of a Parity Act violation. We believe meaningful consequences must include automatic reversal of any adverse benefit determination associated with the request or legal claim. A potential mechanism is directing IROs or external reviewer to automatically reverse adverse benefit determinations when plans fail to provide claimants with any information requested during the internal and/or external appeals process or issue a substantive determination on a legal claim. Otherwise, the claims' procedure requirements to provide information are toothless, and the internal grievance and external appeal process is a meaningless alternative to litigation.

F. Minimum Value Rules

LAC supports the Departments' proposal to consider amending the minimum value (MV) rule so that it would apply separately and independently to medical/surgical benefits and to MH and SUD benefits. We urge the Departments to apply the MV rule separately and independently to MH benefits and to SUD benefits as well, consistent with the Parity Act. Research has demonstrated that, while patients pay higher out-of-pocket (OOP) costs for both MH and SUD treatment than other medical services, the OOP expenditures for SUD care substantially exceed those for MH care. 32 Adopting a separate MV requirement would help ensure that the MH and SUD benefits under employer-sponsored plans meet one objective standard of affordability and also provide valuable data on whether plans are providing MH and SUD services of comparable value to other medical services. This does not appear to be the case based on Milliman's analysis of the distribution of health care costs between MH, SUD and medical/surgical care for preferred provider plans (PPOs). The portion of plan costs for SUD care for the period 2013-2017 (excluding prescription drugs) ranged from 0.7% of health care plan spending to 1%, despite the opioid epidemic that escalated during this period. MH care costs exceeded those for SUDs, ranging from 2.2% to 2.4%, yet clearly inadequate to address even pre-COVID needs. The percentage of total healthcare spending for MH and SUDs was 5.2% in 2017 compared to 94.8% for medical/surgical services.³³

We also support the Departments' proposal to consider amending the MV rule to require substantial coverage of MH and SUD benefits. The Departments' current guidance and regulations define "substantial coverage" as coverage of inpatient hospitalization services and physician services. While these benefits capture the most costly range of services for medical/surgical care, ³⁴ they fail to capture the majority of services and providers that plan participants need and access for MH and SUD treatment. Consistent with our previous comments on "meaningful" coverage of MH and SUD benefits in the parity classifications, we recommend that "substantial coverage" be defined to incorporate the full continuum of services that are consistent with generally accepted standards of care as identified by the

³² See Milliman and Xu, supra note 13.

³³ Milliman, *supra* note 13 at p. 17.

³⁴ See IRS, "Notice 2014-69," https://www.irs.gov/pub/irs-drop/n-14-69.pdf.

non-profit professional society of practitioners in the specialty.

G. Coverage of MH and SUD Crisis Services As Essential Health Benefits

LAC appreciates the Departments request for information on coverage of behavioral health (MH and SUD) crisis services as part of the essential health benefit (EHB) categories and within the context of MHPAEA. With the transition to 988, there is a vital need for health insurance coverage of wrap around crisis response services. Mobile crisis response services and crisis receiving and stabilization services must be covered after someone contacts 988, in the same way emergency responder services and emergency department visits are covered after someone contacts 911. These MH and SUD crisis response services are also uniquely important because they allow individuals with MH and SUD – especially Black and brown individuals – to get help from trained clinicians, rather than encounter law enforcement who may misunderstand, if not penalize them for their conditions. Unnecessary encounters with law enforcement often result in stigma and harm to the caller, emergency department boarding, or criminalization.

We urge the Departments to clarify in regulations that MH and SUD crisis response and stabilization services fall into the emergency services EHB, as well as the emergency classification of benefits under the Parity Act. Plan/policy limitations on coverage of crisis services based on the location of service delivery or the provider that delivers the service would be considered an NQTL that cannot be designed or applied more restrictively for MH and SUD services. Requiring equitable coverage of MH and SUD crisis services will ensure that people can call 988 and receive the support and treatment they need and not pay higher costs – and receive more appropriate care – than they would if they called 911. Consistent with the requirements for medical emergency services, the Departments should also clarify that mobile crisis and stabilization services are:

- Reimbursed by insurers for any health emergency condition in which a prudent layperson would have believed an emergency existed;
- Reimbursed at in-network cost-sharing levels, as an emergency service, regardless of the provider's network status;
- Not subject to prior authorization; and
- Not subject to balance billing.³⁷

While we support coverage of mobile crisis and stabilization services, and doing so at parity, we have concerns about requiring insurance coverage of call/text/chat center services. Greater and more stable funding for call/text/chat center services is needed, but privacy and confidentiality concerns for those reaching out in a crisis may conflict with traditional insurance billing practices and deter those in crisis from getting the support they need. Individuals should be able to call 988 without fear of cost-sharing or of other family members on their plan learning of their call. The vast majority of individuals who call 988 do not need subsequent crisis response or stabilization services, so their insurance status or type

³⁵ Legal Action Center, "Ensuring 988 Achieves its Promise" (Apr. 12, 2023), https://www.lac.org/news/ensuring-988-achieves-its-promise.

³⁶ KFF, Behavioral Health Crisis Response: Findings from a Survey of State Medicaid Programs (May 25, 2023) https://www.kff.org/mental-health/issue-brief/behavioral-health-crisis-response-findings-from-a-survey-of-state-medicaid-programs/.

³⁷ *See* Kennedy Forum, Ensuring Coverage of Behavioral Health Emergency Services, https://www.thekennedyforum.org/app/uploads/2022/12/BH-Emergency-Servies-Brief.pdf

should not dictate the immediate help they receive through 988.

It is critical that these centers prioritize the caller's needs, not insurance coverage, and the caller should have the right to decide when, to whom, and how their information is shared, and the quantity of information shared, throughout the continuum of MH and SUD crisis services. Confidentiality is vital because some of the follow-up services may involve Social Services agencies, which could trigger disclosures of sensitive MH and/or SUD patient information to child welfare and law enforcement entities – causing negative consequences for the individual (e.g., loss of child custody, arrest, and prosecution). Nonetheless, we urge the Departments to continue to work with Congress and other federal agencies, as well as State and local agencies, to ensure these 988 centers receive adequate and sustainable funding.

While 988 call/text/chat center services are now available across the country, it is the wraparound mobile crisis response and stabilization services that are woefully lacking, especially in rural and underserved areas. By requiring coverage of these wraparound crisis services as an EHB emergency service and with comparable and no more restrictive coverage than medical services under the emergency classification of the Parity Act, the Departments can strengthen parity across the MH and SUD health care continuum.

H. Align Parity Act Regulations in Medicaid with Final Private Insurance Rules

We appreciate the September 29th request for comments by the Center for Medicaid & CHIP Services on processes to assess Parity Act compliance in Medicaid and the Children's Health Insurance Program (CHIP), and we urge HHS to move quickly to update the Parity Act regulations for the Medicaid managed care, CHIP and Alternative Benefit Plans (APB). While CMS's recently proposed rules on Medicaid Managed Care Access, Finance and Quality (CMS-2439-P) and Medicaid Access (CMS-2442-P) took important steps to address limitations in the Medicaid program, both missed important opportunities to address discriminatory access to MH and SUD care and better align Medicaid parity standards with those in private insurance.

We have been particularly concerned that the comparative analysis requirements, adopted for private plans under the Consolidated Appropriations Act of 2021, do not apply to Medicaid or CHIP managed care organizations (MCOs) and that existing regulatory standards that require State Medicaid authorities and MCOs to conduct compliance reviews have been largely ignored. States that have issued compliance analyses generally conduct cursory and incomplete analyses or fail to identify any violations, and, as we have seen in Maryland, make erroneous findings of compliance. Unlike DOL and HHS in the private insurance context, CMS has issued virtually no public guidance on the enforcement of the Parity Act in the Medicaid program and CHIP since its initial toolkit in January 2017. The Legal Action Center submitted detailed comments on the two Medicaid rules that identify multiple actions needed to improve parity enforcement based, in large part, on enforcement efforts by DOL and HHS.³⁸

The Administration has taken important steps to adopt consistent consumer protections and requirements across financing systems and must not allow a stronger set of Parity Act rules for individuals in individual and group plans, but a weaker set of rules for individuals in Medicaid managed care, CHIP, and ABPs. This is particularly critical given that these plans serve lower-income individuals and

³⁸ The Legal Action Center's comments on Medicaid Managed Care Access, Finance and Quality are available <u>here</u> and our comments on Medicaid Access are available <u>here</u>.

families who are disproportionately Black, Latino, Native American, and from other marginalized and underserved communities. Many of the entities that serve as Medicaid MCOs also operate in the state-regulated insurance markets and serve as TPAs for employer-sponsored plans. HHS must also finally hold state Medicaid agencies accountable for strong oversight, given most states' completely inadequate Parity Act enforcement efforts.

Thank you for considering our views. We are happy to answer questions and assist in any way.

Sincerely,

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American Association on Health and Disability

Institutes for Behavior Resources, Inc.

IC&RC (International Certification & Reciprocity Consortium)

James Place, Inc.

Key Point Health Services, Inc.

Lakeshore Foundation

Maryland Area Health Education Center West (AHEC West)

Maryland Association for the Treatment of Opioid Dependence

Maryland Heroin Awareness Advocates

Medicare Rights Center

National Association of Addiction Treatment Providers

National Council on Alcoholism and Drug Dependence-Maryland (NCADD-Maryland)

National Disability Rights Network (NDRN)

No Health without Mental Health (MHMH)

Ohio Council of Behavioral Health & Family Services Providers

Partnership to End Addiction

Second Chance Opportunities, Inc.

TASC, Inc. (Treatment Alternatives for Safe Communities)

The Hope Institute of America, LLC

Treat Me Please

Treatment Communities of America

WestCare Foundation

Voices of Hope Maryland