Nos. 20-17363, 20-17364, 21-15193, 21-15194

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DAVID WIT *et al.*,

Plaintiffs-Appellees,

v.

UNITED BEHAVIORAL HEALTH,

Defendant-Appellant.

GARY ALEXANDER *et al.*,

Plaintiffs-Appellees,

v.

UNITED BEHAVIORAL HEALTH,

Defendant-Appellant.

On Appeal from the United States District Court
for the Northern District of California
Nos. 14-cv-2346, 14-cv-5337, Hon. Joseph C. Spero

BRIEF OF AMICUS CURIAE ASSOCIATION FOR BEHAVIORAL HEALTH AND WELLNESS IN SUPPORT OF APPELLANT FILED WITH CONSENT OF ALL PARTIES (Cir. R. 29-2(a))

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CORPORATE DISCLOSURE STATEMENT (FRAP 26.1(a))

The following information is provided under Federal Rule of Appellate Procedure 26.1: Association of Behavioral Health and Wellness has no parent corporation and no stock.

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I. INTEREST OF AMICUS

Association for Behavioral Health and Wellness (ABHW) submits this amicus curiae brief in support of United Behavioral Health (UBH). Fed. R. App. P. 29(a).[1]

ABHW represents health plans and insurers (collectively "plans") that manage behavioral health benefits.[2] ABHW's members provide coverage to over 200 million people in the public and private sectors to treat mental health, substance use disorders, and other behavioral issues impacting health and wellness. ABHW is dedicated to advancing federal policy and educating the public on behavioral health and addiction care. ABHW focuses on achieving better health outcomes for individuals and communities by advocating for improved access and higher quality, evidence-based care.

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[1] All parties consented to the filing of this brief. No party, party's counsel, or person other than ABHW, its members, and its counsel authored the brief in whole or in part or contributed money intended to fund the brief's preparation or submission.

[2] Unless specified otherwise, this brief uses the term "plan" to refer generally to health benefit plans that provide behavioral health benefits, regardless of type (*e.g.*, group health plans, individual health insurance plans, association health plans, multi-employer plans) or funding arrangement (*e.g.*, insured, self-funded), as well as entities that provide administrative services (*e.g.*, claims administration, utilization management) to those health benefit plans (*e.g.*, third-party administrators). The principles set forth in this brief are generally applicable to such "plans" but, because plan administration, operations, and benefits vary, they might not apply to a particular plan in a particular circumstance.

The objective of this brief is to provide the Court with important context about how and why plans develop and apply clinical standards for administering and managing behavioral health benefits. This context is critical to the issues on appeal in this case.

II. INTRODUCTION

Behavioral healthcare plans, like all managed healthcare plans, "manage" their members' benefits through the process of utilization management (UM). UM means that in making coverage decisions, a health plan reviews benefit requests to determine whether a requested service is medically necessary and provided at the most appropriate level of care for the member's condition.[3] This review protects plan members from being subjected to unneeded healthcare services and therefore improves health outcomes, promotes more beneficial treatment, and prevents inefficient and inappropriate use of resources, making care better and more affordable for plan members.

Clinical coverage guidelines are essential tools in plans' UM. Federal and state laws, independent accreditation bodies, and the contracts between plans and their members recognize and assume that plans will develop and apply clinical

[3] *See, e.g.*, Cal. Health & Saf. Code § 1374.721(f)(3) (effective Jan. 1, 2021); *California Phys. Serv. v. Aoki Diabetes Research Inst.*, 163 Cal. App. 4th 1506, 1510-11 (2008).

coverage standards for UM purposes. The process by which plans develop these guidelines is rigorous, based on medical evidence and peer-reviewed science, and subject to regulatory oversight and scrutiny. In making benefits and coverage determinations, plans have not been—and should not be—required to apply the identical clinical criteria that providers use in deciding the different question of how to treat patients.

The district court's judgment conflicts with these principles. The court failed to give UBH appropriate deference and largely disregarded UM principles and the important ends achieved through that process. Instead, based on the testimony of two medical experts retained by the plaintiffs to opine on UBH's particular guidelines, the court issued sweeping findings that invalidated UBH's guidelines and dictated the specific clinical criteria plans must use when evaluating claims for behavioral health benefits. The court proclaimed that the criteria it chose to supplant UBH's existing criteria were in effect the only set of criteria reflecting "generally accepted standards of care," when in fact that is not the case. Not only did the court mandate that UBH use particular criteria to determine whether to approve future claims for benefits, but also it issued a classwide directive requiring the plan to "reprocess" 67,000 past claims using the newly mandated guidelines, without regard to whether the plan's application of its prior guidelines had caused any particular class member's claim to be denied. The court, by mandating UBH's

use of particular standards, usurped UBH's authority to undertake its own analysis of applicable generally accepted standards of care and determine a set of clinical standards appropriately suited to managing its members' benefits.

The court's findings impose a "one size fits all" requirement impacting the entire industry, not just UBH. If not reversed, the decision will be, and already is, a guidepost for other district courts to impose their own views of proper clinical decisions on plans, depriving plans of the ability to devise appropriate standards based on rigorous application of medical evidence and peer-reviewed science and subject to regulatory oversight and scrutiny. This case creates the troubling specter of courts remanding large numbers of prior benefit decisions to plans—not so that the plans can address any standards found deficient by a court, but to require the plans to redo thousands of prior denials based on new standards unilaterally imposed by the court. Courts may cite the order here to support inserting themselves into health plan operations and directing plans how to operate and which criteria to use, both prospectively and retrospectively. This would strip plans of their statutory and contractual authority and override their ability to manage utilization of healthcare.

Courts are not attuned to the ever-evolving nuances of behavioral health conditions, generally accepted treatments, or UM needs, and thus are not a proper forum for mandating appropriate decision-making processes or standards on these

subjects. A court should not select among competing scientific evidence to decide for plans what the appropriate clinical guidelines must be. If a court determines that a plan's clinical guidelines caused the plaintiff a concrete injury and violated the terms of the ERISA plan or applicable law, the proper solution is a remand to the plan with a directive to reconsider the guideline and, if necessary, to correct it. This Court should reverse the district court and clarify the parameters of the proper role for a court when considering a challenge to a health plan's clinical guidelines.[4]

III. PLANS DEVELOP CLINICAL GUIDELINES UNDER A RIGOROUS AND ROBUST PROCESS IN ACCORDANCE WITH LEGAL REQUIREMENTS

Clinical guidelines health plans use to determine coverage and benefits are the products of rigorous processes that aim to balance numerous considerations: safeguarding the goal that plan members receive the treatment most appropriate for their condition, achieving consistency with generally accepted medical standards, and enabling the plan to manage benefits.

Plan guidelines are not developed or applied in a vacuum and are not arbitrary. Plans are subject to legislative, regulatory, and contractual standards requiring that clinical criteria applied to determine member benefits are sound, evidence-based, tested, and sufficiently flexible to respond to the variety of clinical

[4] This amicus brief focuses on the district court's decision regarding clinical guidelines. However, the court made numerous other erroneous rulings. ABHW endorses the arguments made by amicus America's Health Insurance Plans.

situations that present themselves. Even where guidelines are required to accord with generally accepted standards of medical practice, there is no single authoritative source for determining those standards, as even the court in this case observed. *See Wit v. United Behavioral Health*, No. 14-cv-02346-JCS, 2019 WL 1033730, at *14 (N.D. Cal. March 5, 2019) ("generally accepted standards of care are the standards that have achieved widespread acceptance among behavioral health professionals. *There is no single source of generally accepted standards of care*") (emphasis added). Rather, "generally accepted standards of care ... can be gleaned from multiple sources, including peer-reviewed studies in academic journals, consensus guidelines from professional organizations, and guidelines and materials distributed by government agencies." *Id.* (listing numerous additional sources of generally accepted standards demonstrated by the evidence in this case).

Clinicians, scientists, academics, and researchers can and do differ in their views and approaches to treatment. No one approach or set of clinical standards governs across the board in all contexts. And clinical standards are constantly evolving. Thus, it is appropriate for plans to develop or adopt clinical guidelines for their own use by consulting a range of sources and conducting robust discussion, vetting, and periodic updates. As discussed in Part V, the district court took this responsibility away from plans and dictated what the appropriate clinical standards must be.

A. The legal framework for development of clinical guidelines.

Federal laws and regulations specifically contemplate that plans will develop guidelines to guide coverage decisions and do not require plans to apply particular guidelines. For instance, ERISA regulations contemplate that a plan may make adverse benefit determinations based on "an internal rule, guideline, protocol, or other similar criterion." 29 C.F.R. § 2560.503-1(g)(1)(v).

The federal Mental Health Parity and Addiction Equity Act (MHPAEA) and implementing regulations set forth a specific process and parameters for plans to develop guidelines for mental health, demonstrating that no one particular set of criteria is required and that it is permissible and expected that plans develop or select the guidelines they apply. MHPAEA prohibits "more restrictive" treatment limitations on mental health benefits when compared to medical or surgical treatments and prohibits separate treatment limitations applicable to only mental health benefits.[5] 29 U.S.C. § 1185a(a)(3)(A)(ii). MHPAEA's regulations refer to "processes, strategies, evidentiary standards, or other factors" used to develop non-quantitative treatment limitations on mental health benefits, including "[m]edical management standards limiting or excluding benefits based on medical necessity

[5] This case does not present an issue under MHPAEA, but the provisions of that statute, as well as other laws cited in this section, are instructive on the point that plans have authority to determine their own guidelines.

or medical appropriateness," and require that those processes be comparable to those used for other medical conditions. 29 C.F.R. § 2590.712(c)(4)(i), (ii).

An example in the regulation shows that a hypothetical plan complies with MHPAEA if it employs the same process of expert clinical consultation when developing guidelines for both mental health and other medical conditions, which must be "based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved." *Id.* § 2590.712(c)(4)(iii) (Example 4). In another example, the regulation explains that a plan complies with MHPAEA where its design of medical management techniques is comparable for mental and medical/surgical benefits and considers "cost of treatment; high cost growth; variability in cost and quality; elasticity of demand; provider discretion in determining diagnosis, or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; and claim types with a high percentage of fraud" and "[t]he evidence considered in developing its medical management techniques includes consideration of a wide array of recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials). This evidence and how it was used to develop these medical management techniques is also well documented by the plan." *Id.* (Example 8).

Thus, under MHPAEA, plans "have the flexibility ... to take into account clinically appropriate standards of care when determining whether and to what extent medical management techniques … apply to … mental health and substance use disorder benefits, as long as the processes, strategies, evidentiary standards, and other factors" are applied comparatively to other medical benefits. 78 Fed. Reg. 68240, 68245 (Nov. 13, 2013). MHPAEA does not mandate the use of particular standards.

The Department of Labor publishes a Self-Compliance Tool for ERISA plans highlighting the clinical consultation and diverse evidence-based sources that plans may use when developing mental health level of care guidelines and providing detail on the guideline development process. It does not mandate particular criteria. Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (Tool), *available at* https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.[6] The tool explains a plan "may consider a wide array of factors in designing medical management techniques for both

[6] *See also* CMS Parity Compliance Toolkit Applying Mental Health and Substance Use Disorder Parity Requirements to Medicaid and Children's Health Insurance Programs at 45-52 (requesting detailed information on processes, standards, and strategies involved in Medicaid plans' formulation of non-quantitative benefit limits), *available at* https://www.medicaid.gov/sites/default/files/2019-12/parity-toolkit.pdf.

MH/SUD benefits and medical/surgical benefits," identifying the same factors as the MHPAEA regulation. (Tool at 20.) In considering these factors, plans may consult (among other things):

- Internal claims analysis;
- Medical expert reviews;
- State and federal requirements;
- National accreditation standards;
- Internal market and competitive analysis;
- Medicare physician fee schedules; and
- Evidentiary standards, including any published standards as well as internal plan or issuer standards, relied upon to define the factors triggering the application of [a non-quantitative treatment limitation] to benefits.

(Tool at 24.)

State law also provides requirements. California's statutory scheme provides that plans may draft and enforce their own medical necessity standards if "consistent with criteria or guidelines that are supported by clinical principles and processes. *These criteria and guidelines shall be developed* pursuant to Section 1363.5." Cal. Health & Saf. Code § 1367.01(b) (emphasis added); *see also id.* § 1367.01(f); Cal. Ins. Code § 10123.135(b), (f)(2).

Section 1363.5 in turn states:

> The criteria or guidelines used by plans, or any entities with which plans contract for services that include utilization review or utilization management functions, to determine whether to authorize, modify, or deny health care services shall:
>
> (1) Be developed with involvement from actively practicing health care providers.
>
> (2) Be consistent with sound clinical principles and processes.
>
> (3) Be evaluated, and updated if necessary, at least annually ….

Cal. Health & Saf. Code § 1363.5(b).[7]

Other states' licensing requirements make clear that no one set of UM criteria is mandated. For instance, in Vermont, "review agents" must apply for a license by, among other things, listing the titles, sources, and descriptions of "all clinical review criteria, including those that are proprietary" and attesting that the criteria "are informed by generally accepted medical or scientific evidence and consistent with generally accepted practice parameters as recognized by health care professions in the same specialties as typically provide the procedure or treatment" and "have been reviewed and updated at least annually, taking into account input

[7] After the *Wit* decision was issued, the California Legislature enacted S.B. 855, effective January 1, 2021, specifically referencing *Wit* in the statute's preamble. S.B.855 amended the California Health and Safety Code and Insurance Code to restrict and impair plans' ability to manage care for mental health and substance use disorders, instead requiring them to adopt a single standardized definition of "medical necessity" for those services. This legislation contradicts longstanding California statutes placing responsibility to develop or adopt criteria on plans themselves.

from practicing mental health care providers." This requirement "shall not be construed to require review agents to make modifications to nationally-recognized guidelines." Licensing Requirements for Mental Health Review Agents § 6(A)(10)[8]; *see also* N.Y.S. Dep't of Fin. Servs. Utilization Review Agent Report Application and Attestation (requiring utilization review agents to submit every two years a "[c]omplete set of UR policies and procedures … demonstrating Agent's ability to carry out the relevant requirements" of state and federal insurance law).[9]

B. Industry accreditation requirements.

In addition to legal requirements, many plans are accredited by independent entities that impose their own particular requirements for formulating guidelines as a condition of accreditation. For instance, the National Committee for Quality Assurance (NCQA), an independent nonprofit, accredits many health plans. NCQA accreditation "is a rigorous assessment of health plans' structure and process, clinical quality and patient satisfaction." https://www.ncqa.org/about-ncqa/. NCQA issues specific standards and guidelines for accrediting managed care organizations setting forth requirements for accredited plans' UM processes and systems.

[8] https://dfr.vermont.gov/reg-bul-ord/licensing-requirements-mental-health-review-agents

[9] https://www.dfs.ny.gov/system/files/documents/2020/01/ul_application_instruction.pdf

https://www.ncqa.org/programs/health-plans/utilization-management/benefits-support/standards/.

NCQA-accredited plans must "use[] written criteria based on sound clinical evidence" to make utilization decisions and "specif[y] procedures for appropriately applying the criteria." (Trial Ex. 1011 p. 7.) This includes having "written UM decision-making criteria that are objective and based on clinical evidence," which means "clearly written criteria to evaluate the necessity of medical and clinical services." (*Id.* pp. 7-8.) The plan must have "written policies for applying the criteria based on individual needs." (*Id.*) The plan must have "written policies for applying the criteria based on an assessment of the local delivery system," including the ability of local services to meet the member's particular healthcare needs. (*Id.*) And plans must "[i]nvolve[] appropriate practitioners in developing, adopting and reviewing criteria." (*Id.* p. 7.) "Appropriate practitioners are behavioral healthcare practitioners with professional knowledge or clinical expertise in the area being reviewed [who] have an opportunity to give advice or comment on development or adoption of UM criteria and on instructions for applying the criteria." (*Id.* p. 9.) The plan may "solicit opinions [about the UM criteria] through practitioner participation on a committee or by considering comments from practitioners to whom it has circulated the criteria." (*Id.*) The plan

must "[a]nnually review[] the UM criteria and the procedures for applying them, and update[] the criteria when appropriate." (*Id.* p. 7.)

Another independent, nonprofit accreditation entity, URAC, requires that accredited plans, among other things, "utilize[] explicit clinical review criteria or scripts" that are "[d]eveloped with involvement from appropriate providers with current knowledge relevant to the criteria or scripts under review," "[b]ased on current clinical principles and processes," and "[e]valuated at least annually and updated if necessary by ... [t]he organization itself; and [] [a]ppropriate, actively practicing physicians and other providers with current knowledge relevant to the criteria or scripts under review." (Trial Ex. 1012 p. 154 (emphases omitted).)

C. How plans develop clinical guidelines.

Consistent with various sources guiding plans' development and use of UM criteria, plans do not formulate guidelines in a vacuum, but rather through processes that accord with specific legal and industry requirements. Plans typically establish multidisciplinary committees composed of practitioners from within and outside the company in various clinical specialties, internal and external medical directors, legal counsel, and others. Committees develop medical policy and guidelines that are evidence-based and reflect current scientific data and clinical thinking, and they regularly review current research and materials published by professional associations.

Some plans, rather than creating guidelines, purchase or license guidelines from external, independent sources of guidelines geared toward plans' use. Those guidelines, such as those developed by InterQual or MCG (formerly known as Milliman Care Guidelines), "are widely used by payers for most routine and even complex benefits decisions ...." Peter R. Kongstvedt, ESSENTIALS OF MANAGED HEALTH CARE pp. 187-88 (Jones & Bartlett Learning 6th ed. 2013) (ESSENTIALS). "Many payers modify these guidelines to some degree to conform to particular local conditions or to align with the focus of their UM priorities or business requirements. Payers may also supplement the guidelines with ones developed by their own clinical advisors or with other externally available guidelines for particular types of specialized care." *Id.* In all cases, the payers' goal is to apply reasonable guidelines. Plans derive no benefit from relying on arbitrary, unfounded, or overly stringent guidelines. *Id.* "Unsupportable decisions do not result in good service or good coverage decisions, and are ultimately harmful in the market and in court." *Id.*

IV. CLINICAL GUIDELINES ARE AN ESSENTIAL TOOL OF UM

A. Plans conduct UM as a key part of managed care.

The backdrop against which a plan's development and application of clinical guidelines occur is the managed healthcare system. Managed care developed as an alternative to standard fee-for-service compensation of providers and is the

dominant form of healthcare coverage in the United States. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 369 (2002); *Aoki*, 163 Cal. App. 4th at 1510-11.

The primary feature distinguishing managed care from the indemnity insurance model is "management" of healthcare through UM (or utilization review (UR)) to protect against unwarranted utilization of healthcare services, which harms patients and drives up healthcare costs for all members. *Pegram v. Herdrich*, 530 U.S. 211, 219 (2000) (managed care organizations "commonly require utilization review (in which specific treatment decisions are reviewed by a decisionmaker other than the treating physician) and approval in advance (precertification) for many types of care, keyed to standards of medical necessity or the reasonableness of the proposed treatment"); Cal. Health & Saf. Code § 1342.6 ("It is the intent of the Legislature [in enacting California's Knox-Keene Act] to ensure that the citizens of this state receive high-quality health care coverage in the most efficient and cost-effective manner possible.").

In conducting UM, plans make coverage decisions by reviewing benefit requests to determine whether services are medically necessary, protecting members from unnecessary utilization of services and preventing inefficient and inappropriate use of resources. *Aoki*, 163 Cal. App. 4th at 1510-11 (describing UM); ESSENTIALS, *supra*, at 176-95.

B. The role of clinical guidelines in UM.

Clinical guidelines are an essential tool of UM. They provide structure for analyzing benefits requests to determine the clinically appropriate level of treatment for the members' conditions, while leaving room for reviewing plan clinicians to exercise judgment and respond flexibly to particular circumstances. Through UM, plan members receive the care that is most appropriate for the particular member at the particular time. "Part of the UM process is to ensure, as much as possible, that appropriate medical necessity criteria are met, that the benefits are being applied as they should be, and that they are being applied consistently to all members. A major portion of this is determining whether or not a service is 'medically necessary' or meets the definition of 'medical necessity.'" ESSENTIALS, *supra*, at 186.

The process of UM demonstrates how clinical guidelines are applied in practice:

> For most managed care companies, utilization management is conducted telephonically by licensed mental health professionals, referred to as care managers, who review cases with the provider, facility, or program personnel…. The care managers use evidence-based medical necessity criteria addressing intensity of services and severity of need to determine the most appropriate level of care. The care managers have access to licensed clinical supervisors, board-certified psychiatrists, and addictionologists to assist in clinical decision making. Utilization review occurs when treatment is requested and is reviewed at intervals thereafter to assess treatment

> issues, screen for potential quality of care issues, and arrange for discharge and aftercare planning.

Id. at 291.

C. Plans need not make decisions in the same way as providers.

That a provider may recommend a particular level of care as medically necessary does not and should not deprive the plan of a say in whether that level is most appropriate for the member for purposes of determining coverage. If it did, plans would do little more than rubber-stamp providers' recommendations. But that is not how managed care works. A managed care plan has a quality oversight role in addition to its role as payer and is concerned with, among other things, arranging care with high-quality outcomes for its members in the most efficient and cost-effective way. These are not necessarily concerns for providers.

Thus, when a plan concludes a provider's recommended treatment is not medically necessary under the plan terms because it is not the most appropriate care, that does not mean the provider is wrong; it does not mean the plan is unduly parsimonious; and it does not mean the plan's benefits determination conflicts with generally accepted medical standards. Again, medical standards vary. A provider may believe one standard is best, but that does not mean a plan must make the same determination as long as the patient obtains appropriate treatment.

Contracts between plans and their members typically reflect these basic managed care principles, providing that care is covered if medically necessary as

determined by the plan, and that a provider's recommendation does not make a treatment medically necessary. The California Supreme Court emphasized:

> [A] function, basic to the insurer, is the right "... to determine whether ... [a] claim should be allowed or rejected." The function of reviewing claims is obviously reserved by the insurer and implied by the mandatory process of submitting a proof of claim. Without such a right, an orderly establishment, administration and dispensation of insurance benefits would be virtually impossible.

Sarchett v. Blue Shield of Cal., 43 Cal. 3d 1, 9-10 (1987) (citation omitted).

This does not mean plans make benefit decisions divorced from medical decision-making. Federal and state laws require that licensed medical professionals be involved in plans' denial of benefits for lack of medical necessity. Under ERISA, group plans must provide that, "in deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment …, the appropriate named fiduciary shall consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment[.]" 29 C.F.R. § 2560.503-1(h)(3)(iii). Under California law, a plan must employ a licensed medical director to oversee the process by which it reviews medical necessity, Cal. Health & Saf. Code § 1367.01(c); Cal. Ins. Code § 10123.135(c), and any medical necessity determination must be made by a licensed physician or health care professional. Cal. Health & Saf. Code § 1367.01(e); Cal. Ins. Code § 10123.135(e).

But the law is well established that a plan need not defer to a treating physician's opinion when asked to approve a particular treatment for a particular patient. *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 834 (2003) ("courts have no warrant to require administrators automatically to accord special weight to the opinions of a claimant's physician; nor may courts impose on plan administrators a discrete burden of explanation when they credit reliable evidence that conflicts with a treating physician's evaluation"). Requiring unquestioning deference to a treating physician would make UM a nullity. *Sarchett*, 43 Cal. 3d at 11-12 ("If the treating physician makes the final decision whether the treatment he prescribes is covered by the policy, inevitably a few will abuse that power by overutilization of medical procedures, imposing excessive costs on the insurer."); *Cowan v. Myers*, 187 Cal. App. 3d 968, 983 (1986) ("we are convinced [that] leaving the determination of medical necessity solely in the hands of the providers ... is unreasonable. In such circumstances it is the physician who would determine whether he or she should be reimbursed for providing health care.").[10]

The same principle logically establishes that plans conducting UM are not necessarily required to use the same tools applied by providers to make treatment

[10] Plans' utilization controls as a check on physicians' medical necessity determinations also are explicitly permitted in the government payer sector. *Sarchett*, 43 Cal. 3d at 12; Cal. Welf. & Inst. Code §§ 14133, 14133.3(b).

decisions, as long as the criteria the plans apply are supported by clinical evidence and consistent with the requirements of the plan and applicable law.

A plan's decision that treatment at a lower level of intensity would be more or equally effective as a higher level recommended by a treating provider (for example, intensive outpatient therapy rather than residential treatment) may reduce costs. But controlling costs goes hand-in-hand with preventing unnecessary utilization of healthcare services, which means better healthcare treatment and outcomes for plan members, and is therefore a valid consideration. The Supreme Court has explained: "[Managed care organizations] take steps to control costs[,]" which frequently include "utilization review (in which specific treatment decisions are reviewed by a decisionmaker other than the treating physician) and approval in advance (precertification) for many types of care, keyed to standards of medical necessity or the reasonableness of the proposed treatment." *Pegram*, 530 U.S. at 219. The MHPAEA regulation and the DOL's Self-Compliance Tool expressly identify factors such as cost of treatment, high cost growth, and variability in cost and quality as among the factors an ERISA plan "may consider ... in designing medical management techniques" for mental health and substance use disorder benefits. (Tool at 20; 29 C.F.R. § 2590.712(c)(4)(iii) (Example 8).)

D. Guidelines focused on provider treatment and placement decisions may not be a good fit with a plan's UM process.

1. Provider-focused guidelines may be insufficient for UM.

Guidelines developed not for the purpose of evaluating coverage and benefits requests, but rather for making *treatment* or *placement* decisions in the first instance (*e.g.*, LOCUS/CALOCUS, which the district court imposed on UBH, 1-ER-8-9, 13-14), evaluate matters through a different prism and may not be a good fit for purposes of UM.[11]

Provider-focused guidelines assist providers in determining how to treat a particular patient. Managed care plans, however, are not merely payers; they also provide a critical quality oversight function that is sacrificed if a plan must perform only the same analysis a provider performs. Guidelines developed to guide treatment or placement decisions are not benefit management tools and may lack features that are important in determining coverage. For instance, they may not be subject to regular review or may not have medical/surgical equivalents as required under parity laws.

In addition, placement tools such as LOCUS/CALOCUS do not incorporate or consider detailed, condition-specific medical criteria based on externally validated research, such as those developed by professional associations or

[11] Nothing prevents a plan from voluntarily adopting provider-focused guidelines, as some plans do. But it should not be compelled to do so.

independent third-party entities such as InterQual and MCG. Applying LOCUS/CALOCUS answers only part of the question about the appropriateness of the treatment. It may be sufficient for purposes of providers but not for plans.

2. Plans strive to achieve administrative efficiency.

One important objective of UM is to achieve administrative efficiency to facilitate prompt, accurate, and uniform review and administration of benefits requests and claims. Plans must approve or deny claims or requests to preauthorize benefits subject to statutory deadlines. *See, e.g.*, 29 C.F.R. § 2560.503-1(f)(2)(iii)(A) (group health plan must notify claimant of benefit determination on preservice claim within 15 days); *id.* § 2560.503-1(f)(2)(iii)(B) (30 days for post-service claim); Cal. Health & Saf. Code § 1371(a)(1) (California health plans must approve or deny claims within 30 or 45 working days).

Plans also strive to apply a consistent process in making individual coverage decisions for large numbers of claims and members. Plans must be able to apply streamlined and efficient guidelines developed for UM that factor in relevant clinical considerations but that are not unduly cumbersome in application and allow for independent clinical judgment.

Provider-focused guidelines can be complex and inefficient, and therefore poorly suited for plans conducting UM. For instance, LOCUS/CALOCUS guidelines require that each patient be analyzed by a practitioner across multiple

separate dimensions to determine a combined score, which is then used to guide recommendations regarding placement into a particular level of care. *See Wit*, 2019 WL 1033730, at *14-*15. Evaluating patients for placement under these guidelines requires a complicated analysis and may not address all relevant levels of care, conditions, or ages. In short, applying provider-focused guidelines may run counter to the administrative streamlining purposes and needs of UM.

3. Plans must be able to approve efficacious alternative treatments that are more cost-effective.

Another consideration in UM is the recognition that there may be multiple, alternative approaches to treating a particular condition and applying the varying levels of care on the continuum in the behavioral health context. Different treatments may be equally efficacious under generally accepted standards yet be less restrictive and have different costs. In addition, plans exercising their UM function serve as a check on self-interested providers who may recommend excessive care beyond what is medically appropriate for the patient. Where alternative approaches to clinical treatment exist and are consistent with generally accepted standards, a member may be treated just as (if not more) efficaciously with a less intensive level of care. *See* Cal. Health & Saf. Code § 1342.6 ("It is the intent of the Legislature [in enacting California's Knox-Keene Act] to ensure that the citizens of this state receive high-quality health care coverage in the most efficient and cost-effective manner possible."). In the ERISA context, plans must

not use plan assets—which are for the benefit of all members—to pay claims for unnecessary services for a member when an alternative is equally efficacious but more cost-effective.

To conduct effective UM and protect against unnecessary utilization of services, plans must be able to develop and apply guidelines that will approve benefits at the most cost-effective level. Employer groups rely on plans to achieve this purpose and carry out this function.

V. PLANS, NOT COURTS, SHOULD DETERMINE CLINICAL GUIDELINES

A. Plans are entitled to deference in clinical guidelines.

As shown, a basic assumption of managed care—and of applicable legal requirements—is that plans develop coverage guidelines and will do so in accordance with a process that requires the guidelines to be medically appropriate but also achieves the plan's UM function. When a plan chooses to apply a particular guideline to make a coverage determination, its decision is entitled to deference under principles of managed care and as matters of law and contract.

It is not a court's role to condemn evidence-based clinical guidelines that a plan has chosen to apply under its own contracts—even if the court or a party's paid experts believe different standards are better or conclude the plan should have weighed the relevant considerations differently. A court's role in reviewing a legal challenge to guidelines developed or applied by a plan is and should be limited.

At most, if a plan requires guidelines to be consistent with generally accepted standards, and if the other elements of an ERISA claim are established, a court can decide whether particular guidelines appear to violate the plan. A court should not simply dictate to a plan what the generally accepted standards are and which criteria it must adopt and apply. If a court finds that a plan guideline is problematic, and the plaintiff shows that the denial of a benefit was caused by the problematic guideline, then the proper remedy is a remand to the plan to reconsider the guideline by evaluating the various sources of generally accepted standards—not imposition of a different set of guidelines selected by the court. *See, e.g.*, *Saffle v. Sierra Pacific Power Co. Bargaining Unit Long Term Disability Income Plan*, 85 F.3d 455, 460 (9th Cir. 1996) (where a plan administrator vested with discretion has misconstrued plan terms and has not had an opportunity to apply the plan as properly construed, "[i]t should be up to the administrator, not the courts, to make that call in the first instance"). "It is not the court's function *ab initio* to apply the correct standard to [the participant's] claim. That function, under the Plan, is reserved to the Plan administrator." *Id.* at 461 (citation omitted).

B. The district court's non-deferential analysis overstepped the court's limited role.

The district court did not accord proper deference and effectively usurped the plan's role. The decision demonstrates the intrusive and overreaching effect of

courts imposing their views of appropriate medical standards and mandating a single set of criteria that the court prefers.

First, the court applied "significant skepticism" to UBH's formulation of guidelines, noting UBH's interest in managing benefit expenses and its inclusion of finance personnel in the guideline adoption process. *Wit*, 2019 WL 1033730, at *53. The court ultimately rejected UBH's guidelines, finding its Finance Department's role in the decision not to adopt other guidelines showed a financial "conflict of interest ... had a significant impact on decision-making as to the development of the Guidelines." *Id.* The district court also sharply limited UBH's ability to factor financial considerations into its guidelines, concluding UBH's coverage of behavioral health services at levels more restrictive than what the court deemed to be the generally accepted standards of care gave rise to a strong inference that UBH's financial interests interfered with the development process. *Id.* at *48. The court observed UBH's process *complied* with NCQA's accreditation requirements, but nonetheless deemed it "fundamentally flawed because it is tainted by UBH's financial interests." *Id.* at *46.

Under the proper deferential analysis, a financial conflict of interest is not dispositive, as the court found it was here; rather, the conflict "must be *weighed as a 'factor* in determining whether there is an abuse of discretion.'" *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105, 111 (2008) (quoting *Firestone Tire & Rubber*

Co. v. Bruch, 489 U.S. 101, 115 (1989); emphasis in *Glenn*); *see also Glenn*, 554 U.S. at 117 ("We believe that *Firestone* means what the word 'factor' implies, namely, that when judges review the lawfulness of benefit denials, they will often take account of several different considerations of which a conflict of interest is one[,] ... reaching a result by weighing all together."). The district court gave undue weight to this single factor.

Second, the court made findings as to what *the court* deemed to be the *universally applicable* generally accepted standards of care for behavioral health. The court found UBH's guidelines did not comply with these standards. It then made its own selection of the appropriate sources of guidelines and mandated that UBH use those or similar guidelines—even though the court specifically found "[t]here is no single source of generally accepted standards of care." *Wit*, 2019 WL 1033730, at *14. But judicially mandating particular guidelines is inconsistent with MHPAEA, the DOL Self-Compliance Tool, and the state laws discussed *supra* Part III.A, which permit plans to formulate guidelines and subject the process to regulatory review but do not mandate particular criteria. The court should have remanded to allow UBH to select alternative guidelines that fit its UM purpose—not mandated the single set of guidelines UBH must apply, prospectively as well as retrospectively.

Third, the district court mandated that plans making decisions about benefits and coverage must use the same clinical criteria that providers use when making treatment decisions about level of care for particular patients. The two discrete purposes (coverage and treatment) are not the same and, as discussed *supra* Part IV, guidelines intended for one purpose may not work well for the other.

Lastly, the court disregarded how guidelines are applied in practice, rejecting the testimony of UBH witnesses that guidelines are applied flexibly. *Wit*, 2019 WL 1033730, at *8. A "guideline," however, is not a hard and fast rule, but "a piece of information that *suggests* how something should be done."[12] Guidelines "are not intended to be absolute. Guidelines are used to inform the process and to facilitate consistency based on evidence-based practices." ESSENTIALS, *supra*, at 187-88. Typically, plan clinicians who review claims for benefits to determine medical necessity and coverage retain discretion to exercise their independent clinical judgment depending on the circumstances of a particular case. *See* 29 C.F.R. § 2590.712(c)(4)(i) (MHPAEA regulation noting a plan achieves parity when its medical/surgical and behavioral health standards are comparable "as written and in operation").

[12] https://dictionary.cambridge.org/us/dictionary/english/guideline (emphasis added).

C. Substituting a court's judgment for a plan's in developing guidelines creates additional problems.

Permitting individual district courts to impose their preferred clinical standards on plans could lead to inconsistent and conflicting judicial mandates. The court required UBH to apply particular criteria, but another court in another case could reach a different conclusion regarding the most appropriate guidelines for another plan, requiring similarly situated plans to apply conflicting and disparate guidelines or else violate the law.

There is another potential adverse consequence when a court mandates its preferred behavioral health criteria: the mandate could create disparity between a plan's treatment of physical and mental conditions. To comply with federal and state mandates requiring parity of coverage between physical and mental health conditions, many plans adopted behavioral health guidelines from the same vendor (InterQual or MCG) already used on the medical/surgical side. Here, for example, the court acknowledged UBH had developed certain of its behavioral health guidelines in response to parity laws to match the process it used on medical side. *See Wit v. United Behavioral Health*, 317 F.R.D. 106, 113 (N.D. Cal. 2016). A court's decision imposing particular behavioral health criteria may disrupt that attempt to establish and maintain parity.

VI. CONCLUSION

The court's imposition of its preferred clinical criteria, without appropriate deference to the plan, improperly exerted control over the plan and failed to respect the purposes and functioning of managed care. ABHW urges reversal.

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FOR THE NINTH CIRCUIT

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Signature /s/ Joanna S. McCallum **Date** 4/14/2021