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.

(caption continued on inside cover)

On Appeal from the United States District Court
for the Northern District of California
Nos. 3:14-cv-2346-JCS, 3:14-cv-5337-JCS | Hon. Joseph C. Spero

BRIEF OF AMERICAN PSYCHIATRIC ASSOCIATION, AMERICAN MEDICAL ASSOCIATION, CALIFORNIA MEDICAL ASSOCIATION, SOUTHERN CALIFORNIA PSYCHIATRIC SOCIETY, NORTHERN CALIFORNIA PSYCHIATRIC SOCIETY, ORANGE COUNTY PSYCHIATRIC SOCIETY, CENTRAL CALIFORNIA PSYCHIATRIC SOCIETY AND SAN DIEGO PSYCHIATRIC SOCIETY AS *AMICI CURIAE* IN SUPPORT OF APPELLEES AND SUPPORTING AFFIRMANCE

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May 19, 2021

(caption continued)

GARY ALEXANDER, et al.,

Plaintiffs-Appellees,

v.

UNITED BEHAVIORAL HEALTH,

Defendant-Appellant.

CORPORATE DISCLOSURE STATEMENT

American Psychiatric Association, American Medical Association, California Medical Association, Southern California Psychiatric Society, Northern California Psychiatric Society, Orange County Psychiatric Society, Central California Psychiatric Society, and San Diego Psychiatric Society are nonprofit organizations. No *amici* has a parent corporation, and no publicly held corporation has 10% or greater ownership in any *amici*.

/s/ *Aaron M. Panner*
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May 19, 2021

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INTEREST OF *AMICI CURIAE*[1]

Amicus American Psychiatric Association ("APA"), with more than 37,400 members, is the nation's leading organization of physicians specializing in psychiatry. APA has participated as *amicus curiae* in numerous cases in this Court, other federal courts of appeal, and the Supreme Court. APA members engage in research into and education about diagnosis and treatment of mental health and substance use disorders. For decades, APA and its members have developed evidence-based recommendations and standards for assessment and treatment of psychiatric disorders, including substance use disorders. As front-line physicians treating patients with mental health and/or substance use disorders, APA's members have a strong interest in ensuring their patients can access quality, evidence-based treatment consistent with generally accepted standards of care.

Amicus American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all U.S. physicians, residents, and medical students are represented in the AMA's policy-making process. The

[1] Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), *amici curiae* state that no party's counsel authored this brief in whole or in part, and that no party, party's counsel, or other person, other than *amici* or its counsel, contributed money that was intended to fund preparing or submitting this brief. All parties consented to this brief's filing.

objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in every specialty, including psychiatry, and in every state.

Amicus California Medical Association ("CMA") is a nonprofit incorporated professional association of more than 44,000 physicians practicing in California in all specialties. CMA's membership includes most of the physicians who are engaged in the private practice of medicine in California.

The AMA and CMA each join this brief on their own behalf and as representatives of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state, and the District of Columbia, whose purpose is to represent the viewpoint of organized medicine in the courts.

Amici Southern California Psychiatric Society, Northern California Psychiatric Society, Orange County Psychiatric Society, Central California Psychiatric Society and San Diego Psychiatric Society, are nonprofit organizations that represent approximately 3,000 psychiatric physicians who work in every county in California. Their members support use of level of care guidelines developed by nonprofit professional organizations, reflecting generally accepted standards of care, to supplement clinicians' experience-based professional judgments in making treatment decisions.

INTRODUCTION

In 2019, nearly one in four American adults had either a mental illness or a substance use disorder, and nearly ten million had both.[2] But most went untreated. Only 44.8% of adults who had a mental illness in 2019 received mental health services, while just 10.3% of individuals who had a substance use disorder received treatment.[3] As for adults suffering with mental illness and a substance use disorder that year, only 7.8% received treatment for both.[4]

The COVID-19 pandemic has brought new urgency to this longstanding undertreatment crisis. One study found that the share of adults reporting symptoms of anxiety or depressive disorder in January 2021 had increased nearly 400% from a similar period in 2019.[5] The pandemic has also raised the already substantial barriers to care.[6] In the last two weeks of February, 2021, over a quarter of adults

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[2] Substance Abuse & Mental Health Servs. Admin., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health* 46 (2020) ("*SAMHSA Report*"), https://bit.ly/3yafkzv.

[3] *Id*. at 50, 59.

[4] *Id*. at 63.

[5] Nirmita Panchal et al., *The Implications of COVID-19 for Mental Health and Substance Use*, KFF (2021), https://bit.ly/2Qot2h7.

[6] *Id*.

experiencing symptoms of anxiety or depressive disorder said their treatment needs went unmet.[7]

Millions of untreated individuals cannot afford needed care. Of the 5.8 million adults with a mental illness who went without needed mental health services in 2019, 43.9% blamed the cost.[8] That share is even higher among those with severe mental illness—51.8%.[9] And while costs are doubtless a concern for the uninsured, even those with health insurance are often denied coverage for needed care and forced to either pay out of pocket or forgo treatment.[10]

The undertreatment crisis inflicts an immediate toll on those who cannot access care, but its impact is far broader. One study determined that the prevalence of Major Depressive Disorder alone was associated with $210.5 billion of costs to the U.S. economy in 2010.[11] Only 45-47% of that amount were direct costs, *i.e.*,

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[7] *Unmet Need for Counseling or Therapy Among Adults Reporting Symptoms of Anxiety and/or Depressive Disorder During the COVID-19 Pandemic*, KFF, https://bit.ly/3bw3DJy (last visited May 18, 2021).

[8] *SAMHSA Report* at 62.

[9] *Id*.

[10] *See* APA, *Position Statement on Level of Care Criteria for Acute Psychiatric Treatment* 1 (2020) ("APA Position Statement"), https://bit.ly/3hwkEaC.

[11] Paul E. Greenberg et al., *The Economic Burden of Adults with Major Depressive Disorder in the United States (2005 and 2010)*, 76 J. Clinical Psychiatry 155, 158 (2015).

costs of diagnosis and treatment; 48-50% were workplace costs, *i.e.*, absenteeism and reduced productivity.[12] Proper treatment of mental health and substance use disorders could drastically reduce such costs; 80% of employees who receive mental health treatment report improved productivity and work satisfaction.[13]

This case highlights one significant barrier to effective treatment for mental health and substance use disorders. By applying stringent utilization review practices like those described in the district court's detailed findings, managed care organizations frequently deny benefits even when the requested treatment is consistent with generally accepted standards of care.[14] As the district court explained, the Defendant "created a set of clinical policies and guidelines" including "Level of Care Guidelines" and "Coverage Determination Guidelines" that it used to make coverage determinations for health benefit plans.[15] These guidelines "are supposed to reflect generally accepted standards of care,"[16] but the district court found that Defendant's guidelines departed from those standards in significant ways. In *amici*'s experience, such departures—and the resulting

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[12] *Id.*

[13] APA, *Making the Business Case: Investing in a Mentally Healthy Workforce is Good for Business*, https://bit.ly/3okFxH7 (last visited May 18, 2021).

[14] APA Position Statement at 1.

[15] 2-ER-246-51.

[16] 2-ER-250.

obstacles to appropriate treatment—are a pervasive problem affecting the quality and availability of care nationwide.

SUMMARY OF ARGUMENT

Managed care organizations tightly control access to psychiatric care by applying "medical necessity" criteria that are inconsistent with generally accepted standards of care. Despite the availability of professionally-developed, evidence-based guidelines embodying generally accepted standards of care for mental health and substance use disorders, managed care organizations commonly base coverage decisions on internally-developed "level of care guidelines" that are inappropriately restrictive. Such guidelines may lead to denial of coverage for treatment that is recommended by a patient's physician and even cut off coverage when treatment is already being delivered.

I. Managed care organizations subject mental health and substance use disorders to greater scrutiny than physical health disorders when making coverage decisions. Although progress has been made toward parity in "quantitative treatment limitations," *e.g.*, annual limits on the number of covered inpatient days, managed care organizations continue to apply "non-quantitative treatment limitations" to mental health and substance use disorder treatment in a discriminatory manner. As the district court's findings illustrate, managed care organizations commonly develop their own criteria to determine whether requested

treatment is medically necessary. Those criteria often focus on stabilizing acute symptoms of mental health and substance use disorders, rather than treating underlying conditions and providing support to prevent relapse.

II. Managed care organizations' criteria reflect an outdated view of available treatment for mental health and substance use disorders. Half a century ago, professionally developed standards for treatment of mental health and substance use disorders were yet to gain wide acceptance. That time has passed. The mental health profession has coalesced around generally accepted standards to assess appropriate levels of care, including the eight principles articulated by the district court. Professional associations with clinical expertise, including mental health clinicians, have developed unbiased, evidence-based guidelines embodying these generally accepted standards. These guidelines undergo multiple levels of review before publication, and they are regularly updated to reflect the latest developments in treatment of mental health and substance use disorders. The guidelines are crafted without reference to the short-term financial impacts of treatment decisions, but rather the long-term health of patients. Managed care organizations may resist adherence to these guidelines because in-house utilization review based on stringent criteria designed to limit coverage may help control financial risks.

III. Guidelines like those developed by the Defendant are out of step with generally accepted standards of care. Consistent with the district court's findings, many managed care organizations employ internally-developed level of care guidelines that are overly focused on stabilizing acute symptoms of mental health and substance use disorders. They insufficiently provide for continuing and comprehensive care and ignore the often complex nature of those disorders. Insurers also place a thumb on the scale in favor of offering less intensive care when a higher level may be safer and more effective. Guidelines like Defendant's also do not adequately provide integrated treatment for co-occurring conditions.

IV. Managed care organizations' failure to align their coverage determinations with generally accepted standards of care harms patients. Withholding appropriately intensive treatment from patients transitioning from inpatient to outpatient environments results in high rates of rehospitalization, crime, violence, and suicide. Similarly, failure to provide multiple levels of care for treatment of substance use disorders leads to relapse, overdose, transmission of infectious diseases, and death. And when insurers prevent coordinated care for individuals with both mental health and substance use disorders, patients more frequently experience medical complications and hospitalization.

ARGUMENT

I. Stricter Standards Are Applied to Mental Health and Substance Use Disorder Benefit Requests Than Physical Health Benefit Requests

Managed care organizations have long subjected mental health and substance use disorders ("MH/SUD") to stricter coverage limits than physical health disorders.[17] In 1999, the Surgeon General's first-ever report on mental health identified this disparity as a primary barrier to MH/SUD treatment.[18] In a striking example, the report found that a family with $60,000 in mental health expenses in a year faced an average out-of-pocket bill of $27,000.[19] For those with similar physical health expenses, the out-of-pocket burden was $1,800.[20] These disparities persist, and are a key driver of MH/SUD undertreatment.

Managed care organizations have applied discriminatory treatment to MH/SUDs along three dimensions: financial requirements, quantitative treatment

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[17] Colleen L. Barry et al., *A Political History of Federal Mental Health and Addiction Insurance Parity*, 88 Milbank Q. 404, 406 (2010) ("Limits on insurance benefits date back to the inception of third-party payment for mental health services.").

[18] U.S. Dep't of Health & Human Servs. ("DHHS"), *Mental Health: A Report of the Surgeon General* 426-27 (1999) ("[M]ental health benefits are often restricted through greater limits on their use or by imposing greater cost-sharing than for other health services.").

[19] *Id.* at 427.

[20] *Id.*

limitations, and non-quantitative treatment limitations.[21] Financial requirements include deductibles, copayments, and coinsurance.[22] Quantitative treatment limitations include, for example, annual limits on the number of inpatient days or office visits covered.[23]

Most relevant to this case, non-quantitative treatment limitations comprise a more varied and less straightforward set of practices. Non-quantitative treatment limitations can be any "non-numerical limitations on the scope or duration of" treatment.[24] Common non-quantitative treatment limitations include "prior authorization" requirements. Before a patient can embark on a particular course of treatment, a managed care organization may require the patient obtain its authorization. Other examples are so-called "fail-first" requirements—more intensive levels of care are withheld until a less intensive treatment fails to improve a patient's condition.

Yet another non-quantitative treatment limitation is utilization review. Before, or even during, a particular course of treatment, a managed care

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[21] U.S. Gov't Accountability Office, *Mental Health and Substance Use: State and Federal Oversight Compliance with Parity Requirements Varies* 9 (2019) ("*GAO Report*"), https://bit.ly/3uYnLfa.

[22] *Id.*

[23] *Id.*

[24] *Id.*

organization or a third-party panel reviews the treatment plan and independently determines whether it is medically necessary and thus covered.[25] Utilization review of MH/SUD treatment is most often conducted using medical necessity criteria developed by the managed care organizations themselves. These criteria frequently deviate from generally accepted standards of care. For instance, medical necessity criteria applied by managed care organizations persist in a short-sighted focus on "crisis stabilization," despite the widespread understanding that effective MH/SUD treatment demands addressing more than a patient's most acute symptoms.[26] Once an individual's acute symptoms are controlled, managed care organizations often deny access to levels of care necessary to prevent future crises.[27]

Federal law now mandates parity with respect to financial requirements and quantitative and non-quantitative treatment limitations alike. In 2008, Congress enacted the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction

[25] *Id.*; *see also* Exec. Office of the President of the United States, *The Mental Health & Substance Use Disorder Parity Task Force: Final Report* 18 (2016).

[26] *See, e.g.*, A. Thomas McLellan et al., *Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance, and Outcomes Evaluation*, 284 JAMA 1689, 1693 (2000) ("[D]rug dependence is similar to other chronic illnesses.").

[27] Eric M. Plakun, *Clinical and Insurance Perspectives on Intermediate Levels of Care in Psychiatry*, 24 J. Psychiatric Prac. 111, 115 (2018).

Equity Act ("MHPAEA"),[28] which provides that limitations applied to MH/SUD treatment in group health insurance plans must be no more restrictive than those applied to physical health treatment.[29] In 2010, the Patient Protection and Affordable Care Act expanded MHPAEA's reach to individual plans.[30]

Yet more than a decade after MHPAEA's enactment, disparities remain, and they are most stark with respect to non-quantitative treatment limits. While differences in quantitative treatment limits are readily identified—annual 30 inpatient-day limits for MH/SUD treatment that are absent for physical health treatment are easily spotted—discriminatory non-quantitative treatment limits have proved more difficult to identify and address.[31] Non-quantitative treatment limits thus remain a principal tool used by managed care organizations to control

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[28] Pub. L. No. 110-343, Div. C, Tit. V., Subtit. B, §§ 511-12, 122 Stat. 3765, 3881-93.

[29] 29 U.S.C. § 1185a. By regulation, MHPAEA applies to quantitative and non-quantitative treatment limitations alike. 29 C.F.R. § 2590.712(a). *See also GAO Report* at 8-9.

[30] Pub. L. No. 111-148, §§ 1201, 1302, 1311(j), 124 Stat. 119, 161, 163-64, 181.

[31] *GAO Report* at 36 (noting that, due to "complexities in assessing" non-quantitative treatment limits, "regulators may fail to identify noncompliance"), 37 (noting that "determin[ing] how [a non-quantitative treatment limit] described in plan documents is actually being implemented and experienced by consumers in practice" can be difficult).

MH/SUD costs to the detriment of plan beneficiaries.[32] "[U]tilization review is used more restrictively for mental health treatment than for other medical care."[33]

II. Managed Care Organizations Persist in Applying an Outdated Approach to MH/SUDs Despite Significant Advancement in Standards of Care

The enhanced scrutiny described above is rooted in an outdated understanding of MH/SUD treatment. Several decades ago, MH/SUD treatment was characterized by a patchwork of often-conflicting standards.[34] Concern was widespread that patients were receiving expensive, inpatient services unnecessarily.[35] Some expressed skepticism about the efficacy of mental health

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[32] *See, e.g.*, Meiram Bendat, *In Name Only? Mental Health Parity or Illusory Reform*, 42 Psychodynamic Psychiatry 353, 359 (2014) (noting that "plans frequently employ [non-quantitative treatment limitations] for behavioral health conditions that are more restrictive than those used for other medical/surgical conditions").

[33] Susan G. Lazar et al., *Clinical Necessity Guidelines for Psychotherapy, Insurance Medical Necessity and Utilization Review Protocols, and Mental Health Parity*, 24 J. Psychiatric Prac. 179, 182 (2018).

[34] David Mee-Lee & David R. Gastfriend, *Patient Placement Criteria, in The American Psychiatric Publishing Textbook of Substance Abuse Treatment*, Ch. 6, at 3 (2008) (explaining that providers were once faced with "40-50 sets of treatment-matching protocols for addictions, many of which were . . . conflicting").

[35] David Mechanic et al., *Management of Mental Health and Substance Abuse Services: State of the Art and Early Results*, 73 Milbank Q. 19, 20 (1995) (describing 1991 study finding that "as much as 40 percent of all psychiatric hospitalization [was] inappropriate"); *see also* Wesley Sowers et al., *Level of Care Utilization System for Psychiatric and Addiction Services (LOCUS): A Preliminary Assessment of Reliability and Validity*, 35 Community Mental Health J. 545, 546 (1999) ("*LOCUS Assessment*").

treatment.[36] But the very conditions that led managed care organizations to be wary of MH/SUD benefit claims also spurred medical professionals to coalesce around generally accepted standards of care and to develop rigorous and standardized criteria for determining appropriate levels of care. Today, there is far less variation in standards clinicians apply to MH/SUD treatment. Managed care organizations nonetheless continue to apply overly stringent utilization review and, in doing so, harm both patients and the mental healthcare system.

A. The Development of Evidence-Based Standards of Care

In the 1980s, MH/SUD treatment costs were "ris[ing] at an alarming rate."[37] The lack of standardized guidelines for "resource utilization or 'level of care'" decisions was partially to blame.[38] Because clinicians lacked clear guidance on how to select the appropriate treatment setting and intensity, costs could not be

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[36] Richard G. Frank, *The Creation of Medicare and Medicaid: The Emergence of Insurance and Markets for Mental Health Services*, 51 Psychiatric Servs. 465, 468 (2000) (describing "the difficulty in defining mental illness, [and] the lack of evidence on effective treatments").

[37] *LOCUS Assessment* at 546.

[38] *Id.*; *see also* Wesley Sowers et al., *Level-of-Care Decision Making in Behavioral Health Services: The LOCUS and the CALOCUS*, 54 Psychiatric Servs. 1461, 1461 (2003) (describing the "somewhat elusive goal" of "developing behavioral health service practices that are of high quality"); Mee-Lee & Gastfriend, *supra* note 34, at 2 ("Beginning in the latter half of the 1980s, cost containment and managed care brought pressure on providers to justify treatment referrals.").

predicted or controlled. With no resource management tools developed by mental health professionals, private insurers took charge of developing placement guidelines.[39] But these insurers often lacked the experience and expertise needed to develop proper placement criteria.[40] And because insurer "profits were derived from limiting the quantity of intensive services provided," patients and physicians began to worry that insurer-designed placement guidelines were withholding necessary care.[41]

Against this backdrop, associations of MH/SUD experts began efforts to identify generally accepted standards of care and to design easily-understood level of care placement criteria that reflected those standards of care.[42] For example, the American Association of Community Psychiatrists ("AACP") developed what would become the *Level of Care Utilization System for Psychiatric and Addiction Services* ("LOCUS") and partnered with the American Academy of Child & Adolescent Psychiatry ("AACAP") to develop its child/adolescent counterpart, CALOCUS.[43] Separately, the American Society of Addiction Medicine

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[39] *LOCUS Assessment* at 546.

[40] *Id.*

[41] *Id.*

[42] *Id.* at 547-48; Mee-Lee & Gastfriend, *supra* note 34, at 5.

[43] *LOCUS Assessment* at 547. The AACAP later refined CALOCUS and created a separate, similar tool, known as the Child and Adolescent Service

("ASAM") established task forces to develop its *Patient Placement Criteria for the Treatment of Psychoactive Substance Use Disorders* ("ASAM Criteria").[44] The development of these guidelines illustrates the rigorous, evidence-based process employed by professional associations when creating access to care guidelines.

1. LOCUS and CALOCUS

The development of LOCUS and CALOCUS began in 1995. Experts in the field undertook a "thorough review of existing patient placement practices and clinical experience with th[o]se practices" to identify core principles the planned guidelines should reflect.[45] Those experts aimed to create a simple and concise system capable of accounting for all relevant variables.[46] The developers hoped to produce guidelines that consistently recommend "decisions that result in good outcomes," *i.e.* were "reliable and valid."[47]

Intensity Instrument ("CASII"). The tools have now been unified. *See* AACAP, *AACAP & AACP Partner to Unify CALOCUS and CASII Assessment Instruments* (2020), https://bit.ly/3ojKPCy. For ease, this brief refers to each iteration as "CALOCUS."

[44] Leslie C. Morey, *Patient Placement Criteria: Linking Typologies to Managed Care*, 20 Alcohol Health & Res. World 36, 37 (1996).

[45] Sowers, *supra* note 38, at 1461-62.

[46] *Id.*

[47] *Id.*

Before final publication, LOCUS "was subjected to extensive field testing."[48] LOCUS also underwent rigorous reliability testing that found it could "facilitate the consistent placement of patients in psychiatric or addiction services."[49] LOCUS has been periodically revised to reflect developments in the field and to make it simpler to use.[50] CALOCUS underwent similarly rigorous review. It was subjected to a "multisite national study of its reliability and validity," and produced strong results.[51] Both tools have been "well received by clinicians" and are used by numerous "state and local behavioral health agencies" nationwide.[52]

2. ASAM Criteria

ASAM published its placement criteria in 1991.[53] The criteria resulted from a "[m]ultidisciplinary" process that drew on the knowledge of "addiction treatment

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[48] *LOCUS Assessment* at 553.

[49] *Id*. at 558.

[50] AACP, *Level of Care Utilization System for Psychiatric and Addiction Services: Adult Version 2010*, at 2 (2009) ("*LOCUS*").

[51] Sowers, *supra* note 38, at 1462.

[52] *Id*.

[53] David Mee-Lee & Gerald D. Shulman, *The ASAM Criteria and Matching Patients to Treatment, in The ASAM Principles of Addiction Medicine*, Ch. 30, at 433 (2019).

specialists" including "counselors, psychologists, social workers, and physicians."[54]

The ASAM Criteria have been rigorously tested. Studies of the criteria demonstrate that individuals who receive an intensity of treatment below what the criteria recommended do "consistently worse."[55] In one study, patients being treated for alcohol dependence who "received a lower level of care than that recommended by" the ASAM Criteria "had significantly and substantially poorer alcohol-use outcomes 90 days later" than those who received the recommended level of care.[56] Yet another study analyzed patient placement at the Department of Veterans Affairs and found that undertreated patients, according to the ASAM Criteria, "utilized significantly and substantially *more* hospital bed days" over the next year than those who received the proper level of care.[57] An initial failure to provide sufficient care meant a patient would ultimately need more care than if the patient had received appropriate treatment from the start.

Numerous studies have analyzed the efficacy of the ASAM Criteria in various clinical settings, and results have shown the instrument to be "valid[ ],"

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[54] *Id*.

[55] Mee-Lee & Gastfriend, *supra* note 34, at 9-10.

[56] *Id.*

[57] *Id*. (emphasis added).

"cost-effective[ ]," and useful to both individual patients and to the substance use treatment system.[58] As a result, the ASAM Criteria have garnered wide acceptance—of the 43 states requiring use of patient placement criteria for MH/SUDs, two thirds require the ASAM Criteria.[59]

B. Generally Accepted Standards of Care Emerge

These and other efforts of professional associations, including APA, have brought standardization to level of care decision-making. The district court found that the various professionally developed guidelines it reviewed, the academic literature, and the credible testimony of experts in the field evinced widespread agreement on the proper principles to guide MH/SUD level of care determinations.[60]

First, the district court accurately described MH/SUD care as a continuum of treatment intensity comprising several levels of care. Practitioners agree that access to a continuum of care helps to "ensure consistency throughout treatment

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[58] *Id.*; *see also* Mee-Lee & Shulman, *supra* note 53, at 443 ("The ASAM Criteria are the most intensively studied set of addiction placement criteria.").

[59] Mee-Lee & Gastfriend, *supra* note 34, at 11.

[60] Other sources of evidence-based generally accepted standards of care include, as the district court noted, the Centers for Medicare & Medicaid Services Benefit Manual and the APA's practice guidelines. 2-ER-255-56. As with the treatment of physical health conditions, all of these professionally-developed guidelines supplement clinicians' "experientially based professional judgments." *See, e.g.*, Mee-Lee & Shulman, *supra* note 53, at 436.

and to ease" a patient "through treatment."[61] Reflecting this consensus, LOCUS "defines six levels of care," each level "describ[ing] a flexible array of services" and overlapping somewhat with adjacent levels.[62] CALOCUS is similar but is "modified to incorporate principles of child and adolescent development."[63] "The ASAM Criteria," too, "conceptualize treatment as a continuum marked by five basic levels of care."[64] The continuum reflected in these instruments ranges from minimally intensive services to 24-hour a day monitoring and treatment in a secure residential facility.[65] These nuanced levels of care allow for "flexible use of a wide continuum of services" and aid in "maintain[ing] the patient in ongoing treatment, . . . improv[ing] outcome[s] and prevent[ing] dropout[s] and relapse[s]."[66]

The district court also correctly identified eight principles to guide assessment of the appropriate level of care:

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[61] DHHS, *Substance Abuse: Clinical Issues in Intensive Outpatient Treatment* 17 (2006), https://bit.ly/3eSj017; *see also* APA Position Statement at 2.

[62] Sowers, *supra* note 38, at 1462.

[63] *Id.*

[64] Mee-Lee & Shulman, *supra* note 53, at 439 (noting that the five levels of care are further divided to allow the instrument to "express[ ] gradations of intensity" and "improve[ ] precision").

[65] *LOCUS Assessment* at 551-52.

[66] Mee-Lee & Gastfriend, *supra* note 34, at 3.

1. Practitioners must undertake a multidimensional assessment prior to designing a treatment plan. Physicians must assess "not only a patient's needs, obstacles, and liabilities but also . . . strengths, skills, resources, and supports to promote recovery."[67] LOCUS provides six "evaluation parameters": 1) Risk of harm; 2) Functional status; 3) Medical, addictive, and psychiatric co-morbidity; 4) Recovery environment; 5) Treatment and recovery history; and 6) Engagement and recovery status.[68] APA recommends consideration of similar criteria and encourages physicians also to account for "[s]ocial determinants of health."[69] The ASAM criteria similarly instruct providers to consider a patient's immediate condition along with potential complications from co-occurring conditions, readiness to change, previous experiences with relapse and periods of sobriety, and recovery environment.[70]

2. Effective MH/SUD treatment requires addressing underlying conditions, not merely presenting symptoms. Addressing a patient's acute symptoms when presenting for treatment is a consideration, but care should not be limited to "crisis stabilization." The goal of effective treatment is not suppression

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[67] Mee-Lee & Shulman, *supra* note 53, at 438.

[68] *LOCUS Assessment* at 549-50; *see also LOCUS* at 6-16.

[69] APA Position Statement at 2.

[70] Mee-Lee & Shulman, *supra* note 53, at 438.

of symptoms, but recovery: a process through which patients "improve their health and wellness" and are placed in a position to "live a self-directed life."[71]

3. Proper treatment of MH/SUDs requires coordinated treatment of co-occurring conditions. In 2019, nearly ten million people had both a substance use disorder and a mental illness;[72] co-occurring physical illnesses are also common. Indeed, "[c]omorbidity between medical and mental conditions is the rule rather than the exception."[73] Co-occurring illnesses may "prolong the course of illness" or may call for "more intensive or more closely monitored services."[74] Care for co-occurring conditions thus must be coordinated with MH/SUD treatment.[75]

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[71] SAMHSA, *SAMHSA's Working Definition of Recovery: 10 Guiding Principles of Recovery* 3 (2012), https://bit.ly/3uWZAhk.

[72] *SAMHSA Report* at 46.

[73] Sarah Goodell et al., *Mental Disorders and Medical Comorbidity*, Research Synthesis Report No. 21, at 4 (2011).

[74] *LOCUS* at 9; *see also* Michael Dennis & Christy K. Scott, *Managing Addiction as a Chronic Condition*, 4 Addiction Sci. & Clinical Prac. 45, 48 (2007) ("[I]ndividuals with SUDs have high rates of additional health and social burdens that increase the difficulty of treatment.").

[75] Goodell, *supra* note 73, at 12 (explaining that "'[c]ollaborative care' approaches" are "the most effective" method for treating comorbid disorders).

4. Patients should be placed in the least restrictive level of care that is both safe *and* effective.[76] Although undertreatment is associated with poorer health outcomes, overtreatment carries its own risks.[77] Moreover, physicians must be sensitive to a patient's right to "participate in society" to the fullest extent possible.[78]

5. When the proper level of care is ambiguous, physicians should exercise caution and place the patient in the higher level of care. Because the risks of overtreatment are lower than the risks of undertreatment, when there is uncertainty as to which of two care levels is appropriate, physicians should

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[76] Sowers, *supra* note 38, at 1463 (noting that LOCUS and CALOCUS "can . . . help to ensure the use of least restrictive service alternatives"); Mee-Lee & Shulman, *supra* note 53, at 436 ("[T]he preferred level of care is the least intensive level that meets treatment objectives while providing safety and security for the patient.").

[77] Mee-Lee & Gastfriend, *supra* note 34, at 9 (describing study in which patients placed in a level of care higher than recommended had "significantly higher no-show rates").

[78] DHHS, *Detoxification and Substance Abuse Treatment* 12 (2006), https://bit.ly/33P9eXi.

In its brief (at 20), *amicus* Association for Behavioral Health and Wellness ("ABHW"), sounds a false alarm that "[r]equiring unquestioning deference to a treating physician" would make the provision of MH/SUD treatment ripe for "abuse." *See* Dkt. No. 41. But the district court's decision does not eliminate managed care organizations' role in approving treatment, it simply requires that level of care determinations be made in line with generally accepted standards of care, consistent with plan requirements.

typically exercise caution by placing their patient into the higher level of care. LOCUS, for instance, advises that when the choice between two levels of care is uncertain, "[i]n most cases, the higher level of care should be selected" absent a "compelling rationale to do otherwise."[79]

6. Effective MH/SUD treatment often requires providing continuing services to support recovery and prevent relapse or deterioration. Continuing services, especially during the initial months after discharge from more intensive treatment, are vital to maintaining any progress that was achieved.[80] Moreover, a patient's underlying condition may be—and often is—chronic, and should be treated accordingly.[81]

7. Duration of care should be individualized and not subject to arbitrary limits. Appropriate treatment duration is the length of time needed for

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[79] *LOCUS* at 5.

[80] *See, e.g.*, Bryan R. Garner et al., *The Impact of Continuing Care Adherence on Environmental Risks, Substance Use, and Substance-Related Problems Following Adolescent Residential Treatment*, 21 Psychol. of Addictive Behavs. 488, 495 (2007).

[81] McLellan, *supra* note 26, at 1689; *see also* A. Thomas McLellan et al., *Can Substance Use Disorders Be Managed Using the Chronic Care Model? Review and Recommendations from a NIDA Consensus Group*, 35 Pub. Health Revs. 1 (2013); Dennis & Scott, *supra* note 74, at 46 ("Epidemiological data affirm that SUDs typically follow a chronic course.").

the "patient to achieve identified treatment goals and safely transition" through the continuum of care.[82]

8. Treatment plans for children and adolescents must account for their unique needs. In designing a course of care, special attention must be paid to the developmental stage of a child or adolescent.[83] Each developmental stage presents unique treatment considerations, and failure to account for them risks poorer patient outcomes.[84]

III. Managed Care Organizations' In-House Placement Guidelines Diverge from Generally Accepted Standards of Care

Despite the availability of professionally-developed patient placement instruments, managed care organizations persist in applying in-house guidelines that ostensibly reduce the cost of care for MH/SUDs. Although those guidelines purport to be "derived from generally accepted standards of behavioral health practice,"[85] in *amici*'s experience, they often restrict necessary care and result in harm to patients and the mental healthcare profession generally.

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[82] APA Position Statement at 2.

[83] Helmut Remschmidt & Myron Belfer, *Mental Health Care for Children and Adolescents Worldwide: A Review*, 4 World Psychiatry 147, 150 (2005).

[84] *See generally, e.g.*, Dana A. Weiner et al., *Clinical Characteristics of Youths with Substance Use Problems and Implications for Residential Treatment*, 52 Psychiatric Servs. 793 (2001).

[85] 12-ER-2499.

The use of a managed care organization's own "Level of Care Guidelines" to determine what treatment is "medically necessary"[86] is a common practice. "[M]any insurance companies create [MH/SUD] utilization review guidelines" that are out of step with "generally accepted standard[s]."[87] The Defendant's practices detailed in the district court's findings illustrate the types of divergence often observed between coverage decision-making and generally accepted standards of care.

First, managed care organizations continue to focus on "crisis stabilization" and symptom suppression rather than treating patients' underlying conditions.[88] The district court detailed several practices that revealed this acute-focused perspective, including a requirement that treatment will improve a patient's "presenting problem," the use of so-called "why now" factors, and the cessation of coverage once acute symptoms have been managed.[89] These and similar practices employed by managed care organizations make it difficult for physicians to guide their patients through the continuum of care. Clinicians understand that gradual movement through the continuum is necessary to preserve gains made in more

[86] 12-ER-2501.

[87] Plakun, *supra* note 27, at 111.

[88] *Id*. at 114-15.

[89] 2-ER-270-82.

intensive levels of care.[90] As the district court described, a patient's acute symptoms may justify a relatively intensive level of care. Once those acute symptoms are controlled, however, managed care organizations may decline to approve coverage for a course of treatment that gradually transitions the patient through increasingly less intensive levels of care. Instead, because each level of care decision is made with a primary focus on acute symptoms, in the absence of such symptoms, a managed care organization may next approve only minimal care.[91] As a result, the patient's course of treatment will fail to achieve the gradual transition envisioned by generally accepted standards of care.

Related problems arise from the failure to provide continuing care.[92] As is true of the guidelines at issue in this case, managed care organizations often demand that treatment be associated with tangible "improvement" in a patient's

[90] Plakun, *supra* note 27, at 112 (explaining that intermediate levels of care "help patients achieve enough mastery of . . . underlying issues to return to outpatient treatment better able to use it and better able to function between sessions").

[91] 2-ER-278; Plakun, *supra* note 27, at 114.

[92] 2-ER-289 (district court finding that UBH Level of Care Guidelines fail to provide "treatment to maintain level of function").

condition.[93] Supports for *maintenance* of patient progress, however, are vital in treating MH/SUDs.[94]

Managed care organizations' practices also fail to support coordinated care of co-occurring conditions. Coverage decisions that do not properly account for co-occurring conditions hamper the accurate multidimensional assessments that form the basis of any level of care decision. And by focusing on a patient's "current condition,"[95] managed care organizations risk denying patients more effective integrated care for all co-occurring conditions.[96] Similarly, guidelines that "push patients to lower levels of care"[97] risk ultimately requiring more care for a particular patient than if the patient received the right level of care from the start.[98]

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[93] 2-ER-289-90.

[94] Plakun, *supra* note 27, at 112-13 (explaining that treatment addressing more than intermittent acute crises "may be the best hope for interrupting cycles of recurrent crisis admissions to inpatient units").

[95] 12-ER-2504.

[96] Dennis & Scott, *supra* note 74, at 48 ("Clinical trials have demonstrated that when patients have an SUD combined with one or more non-substance-related disorders, it can be more effective—in terms of both clinical outcome and cost—to provide integrated care.").

[97] 2-ER-286-87.

[98] Mee-Lee & Gastfriend, *supra* note 34, at 9 (describing study showing that accurate use of the ASAM "was associated with reductions in subsequent hospital utilization").

The district court considered (and found not credible) testimony to the effect that, to the extent there was a mismatch between generally accepted standards of care and the internal guidelines, the standards of care guided benefit decisions.[99] *Amici*'s experience and the academic literature suggest that managed care organizations' internal guidelines have significant impact on access to care.[100] For example, guidelines that primarily address acute symptoms and push patients to lower levels of care "represent a short sighted clinical focus intended to reduce costs."[101] Managed care organizations have a financial incentive to enforce those guidelines as written. Such guidelines thus have a real effect on coverage determinations and a real effect on the treatment patients can afford and ultimately receive.[102]

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[99] For example, one witness explained that "[a]ny practitioner worth their salt" would not rely on level of care guidelines or similar documents "to conduct the art of the practice of medicine" and that he would not follow the level of care guidelines' more specific commands, but would instead "adhere to generally accepted standards of care." 8-ER-1696-97.

[100] Plakun, *supra* note 27, at 114 ("Clinicians who interface with utilization managers have the experience from frequent denials of care that a different perspective is being used by insurance or managed care entities.").

[101] *Id*. at 115.

[102] Indeed, despite the managed care industry's call to "control[ ] costs" and "prevent[ ] unnecessary utilization of healthcare services," ABHW Br. at 21, spending on behavioral health care pales in comparison to spending on physical health, *see generally* Stoddard Davenport et al., *How Do Individuals with Behavioral Health Conditions Contribute to Physical and Total Healthcare Spending?* (2020).

IV. Managed Care Organizations' Use of Self-Interested Internal Guidelines Harms Patients

Managed care organizations' use of internal guidelines harms their plan members. For instance, denying coverage for treatment that allows patients to progress through the various levels of care may put them at serious risk of harm or even death. By failing to adequately account for the chronic nature of substance use disorders, managed care organizations withhold necessary continuing care. And by focusing narrowly on a patient's "presenting problem" rather than all co-occurring conditions, managed care organizations deny necessary integrated care.

Transitions from one level of care to another are vulnerable periods for individuals with MH/SUDs. That is especially true of the transition from inpatient to outpatient care.[103] Patients who do not receive timely care after being discharged are far more likely to be rehospitalized.[104] In one study, however, only 49% of adults received outpatient care within 30 days of being discharged from

[103] Nat'l Action All. for Suicide Prevention, *Best Practices in Care Transitions for Individuals with Suicide Risk: Inpatient Care to Outpatient Care* 2 (2019), https://bit.ly/3yjx6Ab; Daniel Thomas Chung et al., *Suicide Rates After Discharge from Psychiatric Facilities*, 74 JAMA Psychiatry 694 (2017) ("The immediate postdischarge period is a time of marked risk.").

[104] *See* Paul Kurdyak et al., *Impact of Physician Follow-Up Care on Psychiatric Readmission Rates in a Population-Based Sample of Patients with Schizophrenia*, 69 Psychiatric Servs. 61, 65 (2018).

inpatient mental health treatment.[105] Many children likewise fail to successfully navigate the transition—in one study, 30% did not appear for outpatient treatment within 30 days of discharge, meaning they did not receive prescribed care.[106] Patients who cannot successfully transition are at increased risk for homelessness,[107] violent behavior,[108] and more likely to come into contact with the criminal justice system.[109] Those who do not receive sufficient care upon discharge are also far more likely to die by suicide. Individuals discharged from inpatient psychiatric care are, according to one study, 100 times more likely to die by suicide than the general population.[110] Such grim statistics underscore the importance of treatment that gradually moves patients through the continuum of

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[105] Bradley D. Stein et al., *Predictors of Timely Follow-Up Care Among Medicaid-Enrolled Adults After Psychiatric Hospitalization*, 58 Psychiatric Servs. 1563, 1565 (2007).

[106] Cynthia A. Fontanella et al., *Factors Associated with Timely Follow-Up Care After Psychiatric Hospitalization for Youths with Mood Disorders*, 67 Psychiatric Servs. 324, 326 (2016).

[107] Mark Olfson et al., *Prediction of Homelessness Within Three Months of Discharge Among Inpatients with Schizophrenia*, 50 Psychiatric Servs. 667, 671 (1999).

[108] Eric B. Elbogen et al., *Treatment Engagement and Violence Risk in Mental Disorders*, 189 British J. of Psychiatry 354, 354 (2006).

[109] Richard A. Van Dorn et al., *Effects of Outpatient Treatment on Risk of Arrest of Adults with Serious Mental Illness and Associated Costs*, 64 Psychiatric Servs. 856, 860 (2013).

[110] Chung, *supra* note 103.

care. Level of care guidelines that focus on treating acute symptoms and fail to provide adequate coverage for the smooth progression through levels of care put patients at serious risk.[111]

Similarly, managed care organizations' focus on crisis stabilization leads to poor outcomes for individuals with substance use disorders. Patients with such disorders often find themselves in a cycle of "treatment, abstinence, [and] relapse."[112] This cycle owes in large part to the failure to gradually move patients through the continuum of care. Patients who are admitted for intensive inpatient treatment following an acute substance use crisis, for instance, are often left with no or minimal care once that crisis subsides. But such patients are far more likely to remain abstinent if provided with a course of continuing care. Continuing care can take many forms: placement in a less intensive residential level of care, participation in varying intensities of outpatient care, or participation in non-professional 12-step programs.[113] Providing these continuing care services for substance use disorders "significantly reduce[s] substance use" and also "reduce[s]

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[111] APA Position Statement at 1.

[112] Brandon G. Bergman et al., *The Effects of Continuing Care on Emerging Adult Outcomes Following Residential Addiction Treatment*, 153 J. Drug Alcohol Depend. 207 (2015).

[113] *Id.*; *see also* Dennis McCarty et al., *Substance Abuse Intensive Outpatient Programs: Assessing the Evidence*, 65 Psychiatric Servs. 718, 724 (2014).

healthcare costs."[114] Indeed, in one study of young adults discharged from inpatient treatment for a substance use disorder, patients were twice as likely to remain abstinent if they attended three outpatient sessions per week following discharge.[115] And they were over six times more likely to abstain from substance use if they spent 100 days in a sober living environment following discharge.[116] These intermediate forms of treatment are an essential tool to ensure that individuals make meaningful progress toward lasting control of their substance use disorders rather than fall into a cycle of acute treatment, temporary abstinence, and relapse. Failure to provide such continuing care services leads to increased rates of relapse, overdose, infectious diseases, and death.[117]

Finally, failure to adequately account for co-occurring conditions is similarly dangerous. Patients with both an MH/SUD and a co-occurring disorder are more likely to face medical complications.[118] Those with mental health disorders may find it more difficult to adhere to treatment for co-occurring disorders and will

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[114] McLellan, *supra* note 81, at 10.

[115] Bergman, *supra* note 112, at 8.

[116] *Id.*

[117] DHHS, *Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health* 4-22 (2016), https://bit.ly/3tNy9ox.

[118] Goodell, *supra* note 73, at 9.

likely face increased health care costs.[119] They are also two-to-four times more likely to suffer premature death.[120] Because of the complex interaction between MH/SUDs and other disorders, the generally accepted standard of care is to treat them in an integrated fashion. An atomistic approach to coverage determinations, however, makes such integrated care unavailable to many patients.

CONCLUSION

This Court should affirm the district court's orders.

Respectfully submitted,

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[119] *Id.* at 11.

[120] *Id.* at 9.

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