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# Clark comments to HHS on Part 2 NPRM: Suspend, retract, withdraw the rulemaking

ADAW has obtained some of the comments on the 42 CFR Part 2 Notice of Preliminary Rulemaking (NPRM) submitted to the Office of Civil Rights (OCR) of the Department of Health and Human Services (HHS) last month (see https://onlinelibrary. wiley.com/doi/10.1002/adaw.33678, https://onlinelibrary.wiley.com/doi/ 10.1002/adaw.33684, https://online library.wiley.com/doi/10.1002/adaw. 33628, https://onlinelibrary.wiley.com/ doi/10.1002/adaw.33661). The comments are in response to the HHS proposal to change the federal rules regarding confidentiality of substance use disorder (SUD) patient records. Since 2010, the rules, known now as Part 2, have been under threat due to electronic health records, which make obtaining written, individualized consent from

# **Bottom Line...**

Veteran confidentiality expert Westley Clark comments on Part 2 NPRM, calls for suspension and withdrawal.

patients for release of the records inconvenient (*ADAW* has written more than 100 articles on this topic, go to the website for more).

ADAW will be covering the submitted comments on these pages; the last time the federal government "summarized" the comments on a Part 2 rulemaking, the comments protesting the changes on behalf of patients were mainly edited out (see https://onlinelibrary.wiley.com/doi/10.1002/adaw.32640). So we are making sure they become part of the public record here, for those

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# Appellate court overturns judgment for health plan members in *Wit* case

The news continues to be deeply disappointing for advocates who had believed the original decision in the *Wit v. United Behavioral Health* case represented a landmark moment for the rights of insured individuals. Following an appellate panel's 2022 reversal of the ruling for plan members in 2019, the full Ninth Circuit Court of Appeals

## **Bottom Line...**

The latest ruling in the much-watched Wit v. United Behavioral Health case suggests that insurers have wide discretion in establishing the criteria used to make coverage determinations.

last month reversed the U.S. District Court's original judgment that the managed behavioral health care company had wrongfully denied benefits to plan members.

At the heart of the decisions at each stage of this long-standing law-suit has been the question of whether UBH's internally derived guidelines for determining substance use and mental health coverage were reasonable and consistent with generally accepted standards of care (GASC) — and, if not, if this placed the company in violation of the Employee Retirement Income Security Act (ERISA). U.S. District Judge

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who can't navigate the complicated system to find and read them all.

This comment, which ADAW has edited for length, is from H. Westley Clark, M.D., J.D., M.P.H., who has, with colleagues, spearheaded the move to protect patient confidentiality. These advocates have said that if patients are afraid their records will be exposed — thus threatening their jobs, custody of their children, or even their freedom — they will be less likely to seek treatment. The new NPRM, as the Legal Action Center has clearly laid out, is particularly ominous for the loss of freedom, as it gives law enforcement the go-ahead to use SUD treatment records to prosecute and incarcerate people.

"As a former director of Center for Substance Abuse Treatment, psychiatrist, lawyer, addiction medicine specialist and public health advocate with over 45 years of experience in patient treatment and advocacy, I am submitting my comments in the hope that the Department will suspend this rulemaking process until it is truly ready to move forward with moving 42 CFR Part 2 forward, as required by the CARES Act," Clark writes in his comments.

"Below I outline seven areas of grave concern that militate against the utility of this NPRM and that indicate that it should be withdrawn because it is premature and fatally incomplete."

# Missing CARES Act anti-discrimination protections

The CARES Act requires new anti-discrimination protections for individuals in a variety of settings, including employment, housing and health care. However, the current NPRM does not include those antidiscrimination provisions, preferring to defer those protections until some undetermined later date. Because the anti-discrimination protections were an offset for weakening the confidentiality provisions of in 42 USC 290dd-2 and its implementing regulations in 42 CFR Part 2, promulgating this new NPRM without those anti-discrimination provisions essentially leaves those with substance use disorders extremely vulnerable to the capriciousness of discrimination, reinforcing the stigma that attends being diagnosed or treated with an SUD.

# 2. Missing HITECH Act requirement for accounting of disclosures

Not only have the anti-discrimination provisions of the CARES Act not been codified in regulations, a final HIPAA rule on the accounting of disclosures that would apply to TPO disclosures by covered entities has not been issued. Although the Department published in the Spring 2021 Regulatory Unified Agenda, an intent to publish a RFI seeking comment on the HITECH Act requirement for accounting of disclosures,

insufficient progress has been made on this essential activity. This weakens the NPRM and militates against its utility; as a result, the NPRM should be suspended until the critical work associated with the HITECH Act requirement for accounting disclosures has been completed.

# 3. Failure to address the Issue of Redisclosure of non-member treating prescribers in §2.34(d) in 42 CFR Part 2

The NPRM proposes to modify §2.34(b) to align it with the language of the Privacy Rule. However, the NPRM fails to address the issue of redisclosure by a treating prescriber of information about a patient in an Opioid Treatment Program [OTP, otherwise known as a methadone clinic] received by a central registry.

Section 2.34 permits a treating prescriber to get unconsented information about a patient from a central registry. Furthermore, the treating prescriber may communicate with the central registry "as necessary" to verify that no error has been made and to prevent "improper prescribing." If the central registry and the non-member treating prescriber can communicate "as necessary," this then means that the central registry must have an ongoing process in place to communicate with the OTP.

As originally conceptualized, the central registry simply facilitated communication between OTPs within a



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200-mile radius. This meant, for example, that the six OTPs in Washington, D.C., the 21 OTPs in Delaware, the 22 OTPs in Rhode Island or the 65 OTPs in New Jersey could communicate with each of their respective OTP networks regarding clients to avoid multiple enrollments.

However, changes to 42 CFR Part 2 made in 2020 permit disclosure to non-member treating providers. Those changes meant that instead of six OTPs in Washington, D.C., the central registry for D.C. would have to have the capacity to exchange information with an estimated 6,000 physicians, plus a number of advance practice nurses and/ or physician assistants; for Delaware, this means communication between the central registry for Delaware and over 1,700 prescribers; for Rhode Island, communication between the central registry and an estimated 3,000 prescribers; for New Jersey, communication between the central registry and over 16,000 prescribers.

The numbers described in the above paragraph result, because new modes of health care delivery involve large networks of providers with dynamic and changing participating providers. The recipient of information from the central registry may be a provider who represents a cluster of providers within an extended network practice, any of whom may see the OTP patient or none of whom may actually see the OTP patient.

Unfortunately, the Department has not promulgated standards or specifications for central registries, nor have central registries been classified as qualified service organizations or business associates. Hence there are no standards or information safeguards protecting the nature of information exchanged between central registries and non-member providers. The patient consents to patient identifying information conveyed by a Part 2 to the central registry, but not to patient identifying information conveyed to a nonmember treating prescriber.

The information that the central registry may disclose to the non-member treating prescriber includes the name, address, and telephone number of the member program in which the patient is enrolled. In addition, the central registry can disclose the type and dosage of any medication for SUD being administered or prescribed to the patient by the member program(s).

However, section 2.43(d)(3) does NOT state that non-member treating prescriber who receives patient specific information from the central registry cannot re-disclose that information to other than the central registry or to the OTP from which the patient receives medications to manage their withdrawal or maintenance.

Given that § 2.34 applies to more than 300,000 patients receiving care from OTPs, the failure to address the re-disclosure issue implicit in §2.34(d) is a glaring omission. This omission warrants the suspension of this NPRM process by withdrawal pending resolution of this issue.

4. Expanding the reach of §3221(i) (1) to create safe harbors for the criminal justice communities for violations of 42 CFR Part 2 is beyond the intent of Congress

The CARES Act does not require the creation of a limitation on civil or criminal liability for persons acting on behalf of investigative agencies if they unknowingly receive Part 2 records. The NPRM proposed safe harbor operates on a standard of knowledge about Part 2 records in an active investigation of a program or other person holding Part 2 records.

Without first obtaining the requisite court order, the proposed safe harbor is simply an evasion of Part 2 protections. This proposed safe harbor provision has the potential of having a negative impact on patient privacy and access to SUD treatment, discouraging patients from pursuing treatment.

While it is important to protect patients and society from

dysfunctional or criminal treatment programs, the purpose of 42 USC 290dd-2 and HIPAA in this context should be to protect patients. There is no need for a safe harbor that can be used based on a "judgement call."

If an investigative agency is scrutinizing a Part 2 program, it should be obvious that some of [the] records received will undoubtedly involve Part 2 records. The list of infractions or crimes committed by a Part 2 program will fall within a defined spectrum of possibilities:

- (1) Medicare, Medicaid or other government funding fraud not involving patients;
- Medicare, Medicaid or other government funding involving patients;
- (3) Medication mismanagement or diversion;
- (4) HIPAA or 42 CFR Part 2 violations involving patients;
- (5) HIPAA or 42 CFR Part 2 violations not involving patients;
- (6) Anti-kick statute violations;
- (7) Beneficiary Inducements Civil Monetary Penalties violations;
- (8) Self-Referral Statute violations;
- (9) False Claims Act; and
- (10) Tax violations.

In short, if an investigative agency is investigating a Part 2 program, Part 2 program director (or staff), or a person holding Part 2 records, the presumption should be that Part 2 records would be involved.

Creating a limitation on civil or criminal liability under §2.3 of 42 CFR Part 2 or a "good faith" exception under the proposed new paragraph under §2.66(a)(3) of 42 CFR Part 2 will actually encourage lax investigative actions on the part of an investigative agency. Investigative agencies should continue to seek an authorization from a court to use and/or disclose any records implicated by Part 2 protections.

Admonishing an investigative agency to cease using or disclosing Part 2 records after the fact is essentially giving the investigative agency license to screen and review Part 2

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records. The "good faith" standard of \$2.66(a)(3) offers investigative agencies an "excuse" to receive and review Part 2 records.

In addition, the proposed option in §2.66(b) for a substitute notice by publication when it is deemed "impracticable" under the circumstances to provide individual notification of the opportunity to seek revocation or amendment of a court order issued under §2.66 should be removed, because the whole purpose of 42 USC 290dd-2 is to protect patients. That a patient cannot be found "under the circumstances" should not diminish their right to confidentiality in order to investigate or prosecute the Part 2 Program or a person holding Part 2 protected records.

In summary, §2.3, §2.66(a)(3) and the proposed notice by publication to be lodged in §2.66(b) should be eliminated from the final rule as not required by the CARES Act, and it is deleterious to the confidentiality of a patient relying on Part 2 protections of their records in seeking or receiving SUD treatment.

5. The current NPRM fails to adequately address the concerns and interests of people suffering from SUDs, in general, and opioid use disorders (OUDs) in particular.

The discussion in this NPRM about the need for the proposed rule substantially ignores the wishes of those who suffer from SUDs, in general, and OUDs, in particular. In addition, the epidemiology of SUDs is overshadowed by interest(s) of the health care business community and the convenience interest of law enforcement.

It is often asserted that 42 CFR Part 2 stigmatizes those with SUDs and discourages them from seeking treatment. However, those who make such an assertion continue to ignore the criminal sanctions imposed not by 42 CFR Part 2, but by state and federal laws which prohibit possession, manufacturing,

[and] distribution of controlled substance(s) not otherwise permitted. In addition, the Americans with Disabilities Act (ADA) does not protect a current and active user of illicit drugs; thus, such a person may be denied a job based on current illegal drug use, not because of 42 CFR Part 2. If a woman uses marijuana, misses her period, discovers that she is pregnant, lives in Tennessee and goes to a prenatal visit, admits to marijuana use and has a positive toxicology, she may have committed a crime; that same woman living in 16 other states can be charged with child endangerment or child abuse. A person may be denied housing if it is determined that they are currently illegally using a controlled substance. This is where stigma lies, not in privacy and confidentiality.

However, societal stigma and discrimination do not end with the end of active drug use. The following examples appeared in a Health Affairs article:

- A father in recovery who was being denied visitation with his children because he was in methadone treatment, despite the fact that he was not using any illegal substances;
- (2) A mother who was being threatened with eviction from a shelter because she was being treated with prescribed methadone for her opioid addiction; and,
- (3) A young man whose employer refused to allow him to return to work after he successfully completed treatment for alcoholism, alleging that he was a safety threat even though his physician had cleared him to return to work with no restrictions.

The ability to choose to whom to disclose personal health information is inextricably tied to the respect for the autonomy of a patient. Furthermore, it is the patient who chooses to engage the substance use disorder treatment system; therefore, it is incumbent upon on public policy to make the SUD treatment system as welcoming as possible. The NPRM, as currently constructed, should be retracted, as it fails to consider the role of primary care in the delivery of SUD services and curtails, unnecessarily, the protections of 42 CFR Part 2 as currently constructed.

 The NPRM mischaracterizes the existing substance use disorder treatment system and in so doing diminishes the utility of 42 CFR Part 2 and HIPAA.

With the removal of the X-waiver in the FY2023 Consolidated Appropriations Act in December 2022, it is expected that a larger number of primary care providers will be prescribing buprenorphine. Unless these new prescribers hold themselves out to be an SUD treatment program, they will not fall under the aegis of 42 CFR Part 2. In fact, prior to the removal of the X-waiver, 71% of the 138,052 practitioners who held an X-waiver asked to treat only 30 patients or less. Despite this, there were an estimated 1.7 million people who reported using buprenorphine as prescribed in the past year. Given that there are over 1 million practitioners now eligible to prescribe buprenorphine for the treatment of OUD, the majority of these practitioners will not fall under 42 CFR Part 2, but under HIPAA, as they are private practitioners who do not hold themselves out as providing SUD diagnosis, treatment or referral for treatment.

Thus, patients requesting assistance from the majority of these new buprenorphine practitioners should be informed that 42 CFR Part 2 does not apply to them or protect their SUD-related information, but there is no mechanism in the NPRM to apply to this situation. In addition, primary care clinicians have long been able to treat alcohol withdrawal with sedative hypnotics, such as benzodiazepine or to treat alcohol use disorders with acamprosate or naltrexone; these providers are not Part 2 programs, more often than not.

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7. Although the NPRM addresses the issue of lack of capacity to sign an informed consent, it fails to address the issue of diminished capacity associated with intoxication, withdrawal, medication induction, and early phases of treatment, as a result the NPRM should be withdrawn until the issue of diminished capacity, rather than lack of capacity, has been adequately addressed.

Although §2.15 (a)(2) of the NPRM and the proposed rule addresses the issue of non-adjudicated lack of capacity to provide consent to make health care decision(s), it does not address the issue of diminished capacity associated with intoxication, withdrawal, medication induction and early phases of treatment. The issue of temporary diminished capacity is critical to the proposed perpetual consent for TPO purposes promoted by the NPRM. In short, a single consent [that is] signed when a patient is intoxicated, in withdrawal, experiencing medication induction or in the early phase of treatment [and] endures until such time as the patient cancels the consent may be unethical and legally problematic.

At the time of presentation to an SUD program, or even to a primary care clinician, patients may have the limited capacity to agree to treatment because they are in clinically significant distress or in urgent need of care; in addition, the treatments to which they would be agreeing are evidence-based with low risk of longer-term adverse effects. However, the substances upon which they are dependent and the medications with which they are being treated cause short-term neurocognitive effects, especially medication like benzodiazepines for alcohol withdrawal. Keep in mind that alcohol is the number one substance for which a person presents to treatment.

In short, it is highly unlikely that a person intoxicated or in withdrawal can appreciate the significance of an ongoing consent or comprehend

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# **Movies: A recovery resource**

By John de Miranda

In my teaching preparing counselors to work in addiction treatment, I have often used clips from feature films to provide some realism and, of course, entertainment. For example, scenes from *Reefer Madness*, Sinatra in *The Man with the Golden Arm* and *The Lost Weekend* can assist in understanding concepts such as diagnostic criteria, withdrawal and patient placement protocols. Equally important, at least in my courses, film can capture the social construction of drug problems as it shifts over time and in different political and cultural contexts. For example, it's possible to see the roots of our recent drug war policies embedded in the craziness of *Doped Youth: Victims of Marihuana*, another title for *Reefer Madness*.

It has been 78 years since America was educated about alcoholism by *The Lost Weekend* which won four Oscars, including best picture and best actor. In my current courses at the University of California, San Diego, we dissect *Traffic*, Steven Soderberg's multitrack cautionary tale of which *The New York Times* wrote,

'Traffic is a sprawling multicultural jazz symphony of clashing voices sounding variations of the same nagging discontent. The movie, which jumps around from Tijuana to Cincinnati to Washington to San Diego, from a posh Ohio suburb to the inner city to the Mexican desert to the White House itself, offers a coolly scathing overview of the multibillion-dollar drug trade and the largely futile war being waged against it.'

I also require viewing of *The Anonymous People* and *Lost in Woonsocket*, both of which have been screened by treatment and recovery centers for fundraising and community education purposes. An internet search will yield long lists of American and foreign films dealing with addiction.

Ted Perkins, a recovery advocate with deep roots in the film world, initiated his personal path back to health by viewing a large number of films dealing with addiction and decided to share his observations. The result, *Addicted in Film: Movies We Love About the Habits We Hate*, was published in 2022. Twenty-eight films are described and discussed.

His knowledge of the film industry provides interesting footnotes and behind-the-scenes details. For example, Billy Wilder, director of *The Lost Weekend*, stated that the liquor industry was so threatened, its executives tried to kill the release by offering \$5 million to "shelve the film forever."

When he learned that some recovery programs were using his book to frame therapeutic group discussions, Perkins decided to create a workbook for use by participants in treatment/recovery programs, as well as those struggling with addictions on their own.

In one of my courses I use Michael Keaton's *Clean and Sober* to help students understand the dynamics of the treatment process. In describing the film's usefulness in an actual treatment environment, the workbook states,

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No Hollywood film of this magnitude and with this budget made about the inpatient rehab experience had ever been attempted before *Clean and Sober*. It was arguably the first time that mainstream audiences, unfamiliar with how addiction recovery works, went inside an actual facility and saw the struggles people face as they try to get sober and complete their inpatient stay. More importantly, the film is also an honest look at all the challenges people face after they get out of rehab.

In posing issues to think about while viewing the film the workbook suggests pondering,

- How many people who enter rehab are there to satisfy a court mandate or family obligation, but do not truly believe they have a problem;
- What role does lying and self-deception play in the initial stages of a person's recovery process; and
- Why romantic relationships that begin inside of rehab may have little chance of success outside of rehab.

Viewers are asked to literally write their reactions in the workbook to prompts such as, 'Rate each of Daryl's problems on a scale of 1-10 (1 = easiest to solve); Daryl is Michael Keaton:

- Cocaine withdrawal;
- Paying back the money he stole from his employers;
- Not relapsing;

- Admitting to himself and others that he has a problem; and
- Getting a new job

Participants are also asked to relate scenes and issues in the film to their own situation. For example, 'Share with others in your Meet-Up group how your personal addiction and recovery journey is similar to that experienced by Daryl Poynter in Clean and Sober.' Said Perkins about the workbook, "My hope is that treatment programs and recovery centers will use it to spice up their basic services. Good films have educated, surprised, and inspired us for decades. With this tool they can also help us heal and recover."

www.addictedinfilm.com is the website where one can sign up for a monthly newsletter, join the *Addicted in Film* movie club and participate in online watch parties. Proceeds from sales of the books (available on Amazon.com) are used to support a non-profit, Recovery TV, which hosts these and other recovery advocacy activities.

John de Miranda, Ed.M., is an independent consultant specializing in substance use disorder, recovery and disability issues. He has no financial issues to disclose and can be reached at 650-218-6181; solanda@sbcglobal.net. Ted Perkins can be reached at 310-508-3902 and smartrecoverytv@gmail.com.

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the significance of agreeing to release their PHI to a cascade of entities associated with the modern health care delivery system, law enforcement or other parties interested in the patient's SUD status, history or behavior.

Therefore, a single enduring consent made at a time when a person is most vulnerable and cognitively compromised is unethical, if not exploitative, even if there is an option to revoke such consent in writing at some future time; to exercise such an option, the patient would need to recall what was signed during the fog of early engagement with SUD treatment, whether with a Part 2 program or a primary care setting.

Consequently, given the need for treatment and the exigencies that may arise causing a person to seek treatment, a signed consent around the time of treatment entry should be valid for no more than six months. This would give the person time to

be stabilized neuropsychologically so that they could appreciate the significance of signing a consent that endures well after their treatment is over and be made aware that they have the option to terminate in writing any prior consent.

Even if a Part 2 program simply gave a patient a copy of the consent that they signed upon entry into treatment, given the high dropout rate from SUD treatment prior to six months, this would not significantly ameliorate the neurocognitive impairment associated with substance use.

The NPRM does not address the issue of diminished capacity at all; it assumes that a presenting patient has full capacity and the cognitive ability to appreciate the longitudinal impact of being induced to provide a single consent or lacks such capacity. This assumption is made by the NPRM despite the well-established, scientifically validated observations

that most substances of misuse cause significant executive function decrements.

As a result of the failure of the NPRM to address the issue diminished capacity associated with intoxication, withdrawal, and early abstinence, the NPRM should be withdrawn until such time as this issue has been adequately addressed. By using the construct of "lack of capacity", the NPRM dodges the larger issue of diminished capacity and misleads patients, Part 2 programs and those interested in respecting the autonomy of the patient. A proposed rule that is reformulated and consistent with the science is required.

Clark is Board Certified in General Psychiatry, Board Certified in Addiction Medicine, and a member of the Washington, D.C. bar. •

See next week's issue for more comments on the Part 2 NPRM.

# IC&RC on SOTU message: Support SUD professionals

On Feb. 7, President Biden in his State of the Union (SOTU) address cited the importance of substance use disorder (SUD) professionals. "We also need more first responders and other professionals to address growing mental health and substance abuse challenges," the President declared.

The International Certification & Reciprocity Consortium (IC&RC), whose member certification and licensing organizations represent more than 50,000 SUD professionals, stressed that the gaps in the treatment field won't be filled without a focus on substance use.

There are shortages among professionals who are credentialed to work in the single diagnoses of substance use disorders, according to the IC&RC. According to a report by the Senate Finance Committee, the Health Resources and Services Administration

(HRSA) "projects a shortage of 24,060 providers in 2030. HRSA projects this shortage to reflect insufficient adult psychiatrists and addiction counselors in 2030 if there are no changes in behavioral health care utilization." HRSA anticipates an adequate supply of remaining behavioral health practitioners to meet the needs of Americans. As a result, the focus of policymakers must be on SUD professionals, according to IC&RC.

"We are extremely pleased that President Biden saw fit to include SUD professionals in his State of the Union," said Mark Attanasi, executive director of the IC&RC. "We face dire shortages in our profession, and our efforts to increase our ranks must not only focus on recruitment, but retention as well. Countless studies have shown that while other health professions may face moderate shortfalls, there is

a chasm between the number of professionals we have and the number of professionals we need if we are to provide competent care to every American who will benefit from it."

While Congress and the White House have been welcome partners in the creation and growth of loan repayment programs for SUD professionals, more is required, according to the IC&RC, which is calling upon policymakers to invest not only in recruitment, but retention as well.

Poor reimbursement rates, as well as high stress and burdensome administrative duties are all factors in SUD professionals leaving the profession.

IC&RC promotes public protection by setting standards and developing examinations for the credentialing and licensing of prevention, substance use treatment, and recovery professionals.

## WIT from page 1

Joseph Spero in 2019 had ruled that the UnitedHealthcare group subsidiary had breached its fiduciary duty under ERISA, but the appellate court in its ruling last month disagreed.

Citing UBH plan provisions that exclude coverage for treatment that is inconsistent with GASC, the Ninth Circuit opinion written by U.S. District Judge Michael M. Anello states, "While the GASC precondition mandates that a treatment be consistent with GASC as a starting point, it does not compel UBH to cover all treatment that is consistent with GASC. Nor does the exclusion — or any other provision in the plans — require UBH to develop guidelines that mirror GASC."

The latest ruling calls into question whether insurers managing substance use treatment benefits in plans governed by ERISA can be required to adhere to level-of-care standards that the treatment provider community widely accepts — most notably, the American Society of Addiction Medicine's (ASAM's) level-of-care criteria for substance use treatment.

"We need to work shoulder-to-shoulder with the insurance industry, but we also need to hold their feet to the fire to enforce their obligations," Marvin Ventrell, J.D., president and CEO of the National Association of Addiction Treatment Providers (NAATP), told *ADAW*. "This decision does not help with that piece."

Ellen Weber, senior vice president of health initiatives at the Legal Action Center, told *ADAW* about the latest ruling, "It is basically saying that the UBH guidelines, even if they don't mirror accepted standards of care, are permissible." She said that suggests, "Health plans don't have to follow medical necessity criteria. One would be shocked to see that in the context of any health condition."

## **Reactions somewhat muted**

For a case that attracted so much attention when the original ruling was issued in 2019, there has been surprisingly little public comment on the appellate court's Jan. 26 ruling. Nearly a full two weeks after the decision was issued, the websites of

prominent groups such as the Legal Action Center and the Kennedy Forum still included no mention of it.

Also, *ADAW* was unable to reach an attorney for plaintiffs who had prominently spoken out about the case in its earlier stages. The executive director of the professional association representing managed behavioral health care companies, the Association for Behavioral Health and Wellness, also confirmed to *ADAW* that the association is not commenting on the latest decision.

Some of this might reflect that not all of the legal issues in the case have been completely resolved, as the Ninth Circuit Court of Appeals has remanded the case in part to the District Court for further action. But clearly the two latest rulings in *Wit v. United Behavioral Health* represent a major turnaround in favor of the managed care entity.

The U.S. District Court in its 2019 ruling had ordered reprocessing of all denied claims by plan members designated as part of the classes in

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the class action, mandating that The ASAM Criteria be used in the reprocessing. It also appointed a special master to oversee the insurer's compliance over a 10-year period. But last March, a short-written decision from a three-judge appellate panel stated that the District Court had misapplied a standard of review of UBH's authority to interpret the terms of the health plans it manages (see https://onlinelibrary.wiley.com/doi/10.1002/adaw.33392).

Attorneys representing the two classes of plaintiffs (one having sought treatment for inpatient care and the other for outpatient services) requested an "en banc" review of the case by the full Ninth Circuit following the three-judge panel's decision. That led to the ruling issued last month, again in favor of UBH regarding its interpretation of health plan terms.

While the appellate court acknowledged there could be some validity to the District Court's contention that UBH has conflicts of interest based on dual roles as plan administrator and insurer, and on financial incentives to keep expenses down, it wrote that the District Court's "substitution of its interpretation of the plans for UBH's interpretation that is consistent with the language of the plans was erroneous."

Advocates remain concerned that the appellate court's ruling gives insurers maximum flexibility to apply any standards they choose for coverage determinations. Based on what the District Court had found regarding UBH's practices, Weber said, this would allow for treating addiction and mental illness as acute conditions rather than chronic illnesses, and routinely denying more intensive levels of care. "It does defy logic," she said of the latest court decision.

The appellate court also ruled that the District Court erroneously excused some class members from not having exhausted all of the administrative remedies available to them after a coverage denial from their health plan.

# Coming up...

The 2023 **Rx and Illicit Drug Summit** will be held **April 10-13** in Atlanta, Georgia. For more information, go to **https://www.rx-summit.com/** 

The 2023 **ASAM conference** will be held **April 13-16** in Washington, DC. For more information, go to **https://annualconference.asam.org/** 

The 2023 American Psychiatric Association conference will be held May 20-24 in San Francisco, California. For more information, go to https://www.psychiatry.org/psychiatrists/meetings/annual-meeting

The National Association of Addiction Treatment Providers (NAATP) **Annual Leadership Conference** will be held **May 21-23** in Washington, DC. For more information, go to <a href="https://www.naatp.org/">https://www.naatp.org/</a>

## Possible next steps

Outside of any remaining court proceedings in this case, there are several potential avenues that could be taken to strengthen protections for substance use and mental health coverage, advocates believe.

"Clearly what states should be doing is adopting legislation that sets out what the appropriate criteria are for utilization review," Weber said. Some states have done that, but that of course only applies to health plans that fall under state regulation.

Whether anything could be done to shore up legal protections under ERISA remains unclear. Advocates also have looked to the U.S. Department of Labor to get more involved in enforcing insurance protections for consumers.

Weber also emphasized that other court jurisdictions could end up issuing more favorable opinions regarding health plans' obligations. But that hasn't lessened concern over what occurred at the Ninth Circuit.

"NAATP is disappointed in the outcome and somewhat surprised by it," Ventrell said.

Beyond the question of whether managed behavioral health care companies should be held to accepted standards of care, there remains the question of whether the addiction treatment field is united enough on what those guidelines should be. Ventrell suggested the field still needs to move toward the same level of standardization that other sectors of health care enjoy. •

# In case you haven't heard...

Drugs were a topic, of course, in President Biden's State of the Union (SOTU) speech on Feb. 7. Not only did he refer to past efforts of his administration, but to hopeful changes for the future, noting correctly that indeed, treating substance use issues is not political. Rahul Gupta, M.D., director of the Office of National Drug Control Policy, issued a statement that night. Gupta touted removal of the X-waiver for buprenorphine (see ADAW https://onlinelibrary. wiley.com/doi/10.1002/adaw.33651) as the main factor in making treatment more accessible. "The overdose epidemic is not a red state problem or a blue state problem — it's America's problem and the President has reaffirmed his commitment to continuing our work together to beat this crisis," he said. Gupta added that, "the President called for removing barriers to treatment, and we have delivered on that, working with Republicans and Democrats in Congress to remove the X-waiver." Gupta also cited a reduction in opioid overdose deaths. For a fact sheet from the White House on the SOTU, go to https://www.whitehouse.gov/briefing-room/statements-releases/2023/02/07/ fact-sheet-in-state-of-the-union-president-biden-to-outline-vision-to-advanceprogress-on-unity-agenda-in-year-ahead/.