42 CFR Part 2 now up for SAMHSA rulemaking change

After complaining about 42 CFR Part 2, the regulation requiring patients to consent to release of their substance use disorder (SUD) treatment records, for years, but saying that Congress had to fix it, the Substance Abuse and Mental Health Services Administration (SAMHSA) is on the brink of changing the regulation.

“We don’t know what the change will say, so we can’t comment on it,” was a common reaction from sources we called. But since Elinore McCance-Katz, M.D., Ph.D., who heads SAMHSA, has been publicly in favor of getting rid of the regulation, as have a growing number of organizations (most recently the American Medical Association; see “AMA delegates vote to align 42 CFR Part 2 with HIPAA,” ADAW, June 17), the change is expected to be toward weakening it.

The consent provision, which is basically all that is left after SAMHSA repeatedly used subregulatory tactics (see “SAMHSA stops short of aligning 42 CFR Part 2 with HIPAA, but questions remain,” ADAW, Jan. 8, 2018), is required by statute, so that indeed would need to be changed by Congress, according to Paul Samuels, director and president of the Legal Action Center.

DEA data offer glimpse at origins of crisis as communities look forward

A first-ever public examination of Drug Enforcement Administration (DEA) data on where opioid manufacturers and distributors send the medications has caused ripples of reaction across the country, even as many treatment administrators are now focused on addressing the more recent iterations of the opioid crisis.

In some cases, a read of The Washington Post’s exhaustive and region-specific analysis of data from the DEA’s Automation of Reports and Consolidated Orders System (ARCOS) could detour into misinterpretation. For example, the region around Charleston, South Carolina, showed staggering numbers in the 2006–12 analysis, but one must account for the contextual point that Charleston houses one of the Department of Veterans Affairs’ handful of mail-order pharmacy operations, Christine Martin, who heads the South Carolina Association for the

Bottom Line…

The latest attack on 42 CFR Part 2 comes from the agency that promulgates it: SAMHSA, which wants to make information-sharing easier, based on the preview of a proposed rule.

Bottom Line…

As a media analysis exposes the insidious nature of prescription opioid distribution that fueled a national crisis, treatment providers continue to look for creative ways to meet service needs in hard-hit areas.
SAMHSA from page 1

According to the SAMHSA proposal, titled “Coordinating Care and Information Sharing in the Treatment of Substance Use Disorders,” the agency “is proposing broad changes to Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations (CFR) 2, also known as 42 CFR part 2 to remove barriers to coordinated care and permit additional sharing of information among providers and part 2 programs assisting patients with substance use disorders (SUDs).”

That’s all it says, but it’s clearly toward making it easier for all providers to see who is in treatment. Since the last bastion of patients covered under 42 CFR Part 2 is those in opioid treatment programs (OTPs), which use methadone, this change would likely enable those patients’ medical information to be viewed by all medical providers, and subject to the same confidentiality requirements. These requirements, currently covered under the Health Insurance Portability and Accountability Act (HIPAA), are very loose, and do not give the patient the right to consent to their release to anyone. Most patients have to sign a blanket disclosure form just for a routine checkup.

For the proposal, go to https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201904&RIN=0930-AA32.

The law authorizing the statute, 42 USC 290dd–2, has “some specificity,” said H. Westley Clark, M.D., J.D., Dean’s Executive Professor at Santa Clara University, and former director of the Center for Substance Abuse Treatment at SAMHSA. The regulation is more flexible. “But the tradition the government has given itself is protecting the vulnerable,” he said.

This administration, it appears, is moving in a different direction. In the name of care integration and coordination, SAMHSA is retreating from the support of the vulnerable.

Will there be lawsuits against treatment providers who disclose information that results in adverse consequences to their patients? Most likely, but the government will wait for that to happen.

When proponents of making 42 CFR Part 2 like HIPAA talk about their own interpretation, it’s important to remember that HIPAA is not mandatory. “It allows the holder of the information to disclose or not disclose,” noted Clark.

Ask the patient

As always, Clark said that if providers really want to know a patient’s SUD history, they should just ask. If the patients trust you, they will tell you.

But what the industry — as opposed to individual clinicians, who do care about their patients — wants to see is a registry, said Clark. “They want methadone reported. They want a registry of anybody who’s had an SUD problem,” he said. This would be available to law enforcement, insurance and others. All this while 94% of patients who need treatment aren’t getting it, said Clark. This would just erect another barrier to treatment. But it would also mean doctors don’t even need to ask. Just look it up on the computer. And this is what many patients — and, we hear, physicians themselves — are rebelling against.

Liability

It’s also important to remember that the National Association of Addiction Treatment Providers and the American Society of Addiction Medicine, who want to weaken 42 CFR Part 2, have members who “don’t like to be sued, especially when personal liability may be an issue,” said Clark.

“We believe most treatment providers were covered by HIPAA, 42 CFR Part 2 and were opposed to this kind of a registry. But what has happened is that the industry is increasingly rebelling against HIPAA, 42 CFR Part 2, have members who want a registry. This would be available to law enforcement agencies, insurance and others. All this while 94% of patients who need treatment aren’t getting it, said Clark. This would just erect another barrier to treatment. But it would also mean doctors don’t even need to ask. Just look it up on the computer. And this is what many patients — and, we hear, physicians themselves — are rebelling against.

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CFR Part 2 offered them additional protection against inappropriate disclosure,” he said. “With alignment, providers will have to think more seriously about HIPAA. Thus, they should be aware of the federal fines and the growing issue of state liability issues derived from HIPAA violations.”

He noted that this is not “scaremongering or fearmongering,” but rather, it is reality. And both patients and providers have the same thing at stake: loss of enthusiasm for getting treatment. “I think you can ethically balance the interests of the providers against the interests of the patients. At many places, they converge,” Clark told ADAW.

“For instance, third-party liability for harms that an overmedicated patient causes is a reality,” he said. “Many of the providers patients are undercapitalized as a result of their substance use and cannot offer the deep pockets that a plaintiff’s attorney seeks; so the provider becomes the target.”

And there are civil matters with which many treatment providers have had little experience. These were previously avoided because they required patient consent under 42 CFR Part 2, but would not under HIPAA. “Yet, the patient can find a plaintiff’s attorney who litigates on contingency,” said Clark. “This is of concern to the provider, because the cost of doing business goes up with increased risk.” As he noted, “Liability insurance is not free.”

If a patient is told that their treatment will be confidential, it better be true. “As soon as you lie, then you have your own liability issues,” said Clark.

On the other side (favoring changing 42 CFR Part 2) is a slew of providers and organizations, including Richard Saitz, M.D., Professor at Boston University School of Public Health, who told ADAW last week: “I fully understand that patients with addiction are stigmatized and discriminated against, and that can lead to poor care and harm. But separate health records and rules, and separate uncoordinated care, perpetuate poor unsafe care, the idea that addiction is not a health condition like others and stigma. To address that, CFR 42 Part 2 should change such that the records for people with addiction are treated similarly to those with other health conditions, in which patients consent to record releases. Changes should allow for clinicians caring for patients who consent to receive that care to access their full health record while doing so.” •

NAATP to court: AAC doesn’t have a case

Citing “actions that it had every right to take, statements of opinion it had every right to make, and the actions and the conduct of third parties” for which it had no control or responsibility, the National Association of Addiction Treatment Providers (NAATP) filed a motion to dismiss the complaint against it by American Addiction Centers (AAC) filed in May (see ADAW, May 13, May 20).

In other words, NAATP says AAC doesn’t have a case.

AAC, based in Nashville, Tennessee, sued NAATP on the first day of the organization’s annual conference, at which AAC was prominently absent. AAC claimed it had been defamed by NAATP, which it used to belong to. AAC has been struggling financially.

AAC CEO Michael Cartwright and NAATP Executive Director Marvin Ventrell had a very public disagreement during a congressional hearing on fraud in substance use disorder (SUD) treatment last year (see ADAW, July 30, 2018). At the time, Cartwright seemed to portray some regret, but AAC did not change enough to be made a member. And the lawsuit, with its highly symbolic timing, ensured AAC was a topic of discussion at last May’s meeting even though it wasn’t there.

In a “memorandum of law” supporting the motion to dismiss, NAATP noted that the 79-page complaint by AAC “contains no claims for relief against NAATP that are (1) plausible, (2) not time-barred by a statute of limitations, and (3) not protected by an absolute or qualified privilege.”

NAATP would not provide any comment beyond the legal

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documentation, and has not commented on the lawsuit except for briefly up until this month's court filings. It still has no comment, Ventrell told ADAW last week.

At issue is marketing, not clinical quality of treatment. LegitScript and Google worked with NAATP to come up with a fair marketing system that did not take advantage of vulnerable people seeking treatment on the internet. AAC felt frozen out of this and, because of its marketing, was not readmitted to NAATP membership. The complaint against NAATP was like a “press release,” NAATP said, which spun “an implausible tale of NAATP as part of a cabal out to get” AAC and Recovery Brands (under which AAC did its marketing).

**NAATP bigger than Google?**

The “story” AAC wants the court to believe, according to NAATP, “quickly descends from a narrative of untimely raised grievances to a ridiculous tale of the implausible.”

For example, under the heading “NAATP pressures Google to suspend paid online advertising,” AAC includes 20 paragraphs that “attempt to paint NAATP as somehow being capable of dictating decision-making to one of the world’s largest and most influential companies — Google.” The complaint goes on to paint NAATP as a “puppet master” for LegitScript, an online certification company.

In 2017, Google suspended its AdWords program at all SUD treatment centers due to unscrupulous and deceptive marketing (see *ADAW*, Sept. 27, 2017). Google had only done this for payday loans and locksmiths, both groups that have reputable and disreputable players, just like rehabs. All three groups serve consumers who are desperate — for money, to get into their houses or cars, or for addiction treatment. LegitScript worked with Google to develop a system under which addiction treatment could again advertise (see *ADAW*, April 23, 2018).

NAATP, a not-for-profit trade association whose members are voluntary, noted that AAC, in its complaint, did not seek membership. However, NAATP “suspects that is the true goal of this abusive litigation against NAATP.” Otherwise, why not sue Google, LegitScript or “any of the other third parties whose conduct is described in the complaint in hopes that NAATP’s lack of resources would result in it being bullied into simply agreeing to convey membership”?

**Ethics**

NAATP has been working hard at revising its ethics code and monitoring the marketing tactics of its members in order to improve the reputation of the SUD treatment industry.

Competition is stiff, and some of the top treatment organizations in the country are not only NAATP members, but their CEOs are officials. AAC then viewed anything these CEOs said as NAATP’s responsibility, but this is meritless, said NAATP.

The story involves a treatment organization that was once a growing behemoth and a small membership organization that has had its own problems. Again, the conflict is not over clinical quality, but over marketing tactics — something NAATP views as key to good ethics.

As NAATP Executive Director Ventrell said at the 2018 annual meeting, when the storm over SUD treatment center marketing was well under way and there were many press reports criticizing the “bad apples”: “It’s by speaking our truth that we get through this time.”

AAC gave us this response to NAATP’s motion to dismiss: “NAATP appears to think that simply because it is a not-for-profit trade organization, it is entitled to smear high quality for-profit providers that compete with NAATP member organizations...AAC wants to help foster an honest conversation about addiction treatment where all voices are heard and respected.”

American Addiction Centers
FDA cracks down on CBD claims

Last week, the Food and Drug Administration (FDA) issued a warning letter to Curaleaf Inc. of Wakefield, Massachusetts, for illegally selling cannabidiol (CBD) with claims that their products treat cancer, Alzheimer's disease, opioid withdrawal, pain and “pet anxiety,” among other conditions and diseases.

“As we examine potential regulatory pathways for the lawful marketing of products containing cannabis and cannabis-derived compounds like CBD, protecting and promoting public health remains our top priority,” said Acting FDA Commissioner Ned Sharpless, M.D., in announcing the warning July 23. “Selling unapproved products with unsubstantiated therapeutic claims — such as claims that CBD products can treat serious diseases and conditions — can put patients and consumers at risk by leading them to put off important medical care.”

In the search for nonopioid treatments for opioid use disorder, many new products and devices have been touted. None have been proven effective, compared to methadone, buprenorphine and naltrexone. While tetrahydrocannabinol (THC), the active ingredient of cannabis, may be useful in treating withdrawal symptoms, there is no evidence that it is useful as a replacement for opioids (see “Marijuana as treatment for OUDs? Most medical experts say no,” ADAW, Feb. 11).

But like THC, CBD is marketable. If products make unsubstantiated health claims, and are not approved by the FDA, they will be stopped — at least, that’s what Sharpless’ action suggests.

People in withdrawal from opioids, including people who were taking them from pain, are among those vulnerable to claims such as those made by Curaleaf. So are people with cancer or Alzheimer’s disease.

But that doesn’t mean the FDA is ignoring CBD. The agency has a working group to explore various types of CBD products, which is evaluating information related to the safety of CBD products. The FDA held a public hearing in May and opened a docket for written comments.

“We will continue to work to protect the health and safety of American consumers from products that are being marketed in violation of the law through actions like those the FDA is taking today,” said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., on July 23. “At the same time, we also recognize the potential opportunities and significant interest in drug and other consumer products containing CBD,” she added. “We understand this is an important national issue with public health impact and of interest to American hemp farmers and many other stakeholders.”

As described in the warning letter issued to Curaleaf, the company used product webpages, its online store and social media websites to make unfounded claims about more than a dozen different CBD products. Examples of the claims made by the company include:

• “CBD has been demonstrated to have properties that counteract the growth of [and/or] spread of cancer.”
• “CBD was effective in killing human breast cancer cells.”
• “CBD has also been shown to be effective in treating Parkinson’s disease.”
• “CBD has been linked to the effective treatment of Alzheimer’s disease.…”
• “CBD is being adopted more and more as a natural alternative to pharmaceutical-grade treatments for depression and anxiety.”
• “CBD can also be used in conjunction with opioid medications, and a number of studies have demonstrated that CBD can in fact reduce the severity of opioid-related withdrawal and lessen the buildup of tolerance.”
• “CBD oil is becoming a popular, all-natural source of relief used to address the symptoms of many common conditions, such as chronic pain, anxiety … ADHD.”
• “What are the benefits of CBD oil?… Some of the most researched and well-supported hemp oil uses include … Anxiety, depression, post-traumatic stress disorders, and even schizophrenia … Chronic pain from fibromyalgia, slipped spinal discs … Eating disorders and addiction.…”
• “[V]ets will prescribe puppy Xanax to pet owners which can help in certain instances but is not necessarily a desirable medication to give your dog continually. Whereas….”

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CBD oil is natural and offers similar results without the use of chemicals. 

- “For dogs experiencing pain, spasms, anxiety, nausea or inflammation often associated with cancer treatments, CBD (aka cannabidiol) may be a source of much-needed relief.”

For more information, go to: 
- “What You Need to Know (And What We’re Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD” (https://www.fda.gov/consumers/ consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis)

**ASAM supports eliminating the x-waiver for buprenorphine**

The American Society of Addiction Medicine (ASAM) has for months not taken any position on the “x the x-waiver” movement, which would deregulate the prescription of buprenorphine, eliminating the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000), which require prescribers to have training and to have a special registration with the Drug Enforcement Administration (DEA). Last week, however, ASAM came out with this: It agrees with making buprenorphine more accessible by getting rid of the x-waiver.

ASAM played a crucial role in the development of the buprenorphine approval process, including the x-waiver.

(The x-waiver is a provision allowing prescription of an opioid to treat opioid use disorder [OUD], something that has been banned since the 1914 Harrison Narcotics Act. Under DATA 2000, physicians, once they have earned the x-waiver, can prescribe buprenorphine, a Schedule III opioid, for this purpose, waiving them from the law. Methadone cannot be prescribed or dispensed for opioid use disorder except by an opioid treatment program, a highly regulated form of treatment.)

 Asked whether ASAM is concerned about losing members if the x-waiver is eliminated, Kelly M. Corredor, senior director of advocacy and government relations, responded, “No.”

The ASAM position on the buprenorphine waiver underwent scrutiny by the board, which voted on it earlier this month, ADAW has learned. The position was first made clear in the testimony of Margaret A.E. Jarvis, M.D., ASAM board member, in her testimony before the Congressional Bipartisan Opioid Task Force. On July 23, she focused on the need for more treatment, and on the need for policy changes.

She emphasized the need to strengthen the substance use disorder (SUD) workforce, praising the House of Representatives for including full funding in the House Labor–Health and Human Services (HHS) bill for two key workforce programs: the SUPPORT Act’s SUD loan repayment program and the CURES Act’s training demonstration program.

She also urged Congress to pass the Opioid Workforce Act, which would increase the number of resident physician positions available in hospitals that either have or are developing residency programs in addiction psychiatry or addiction medicine or pain medicine.

Jarvis also asked the House Committee on Energy and Commerce to hold a hearing on the Comprehensive Addiction Resources Emergency Act of 2019, which would authorize $100 billion over the next 10 years for addiction treatment. This legislation could benefit ASAM, which would consult with the federal HHS to develop model licensure standards for the regulation of addiction treatment programs based on nationally recognized levels of care.

But the big news was ASAM’s endorsement of the Mainstreaming Addiction Treatment Act, introduced by Rep. Paul Tonko (D-New York), which would eliminate the separate DEA waiver for prescribing buprenorphine for treatment of
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Treatment of Opioid Dependence, told ADAW.

But the numbers, made public as a result of a court order in a legal battle that the Post and the Charleston (W.Va.) Gazette-Mail waged with the government and the pharmaceutical industry on the opposing side, do illustrate the presence of what the Post called a “virtual opioid belt” across parts of West Virginia, Virginia and Kentucky. This area includes 12 of the top 20 counties in the number of opioid pills distributed per capita, and 18 of the top 20 in deaths caused by prescription opioids.

Many of these communities still lack sufficient supply of opioid dependence treatment, such as in West Virginia, where providers and families have experienced, among other barriers, the effects of a moratorium on establishment of new opioid treatment program (OTP) sites. The State Opioid Treatment Authority for West Virginia did not respond to questions from ADAW about current access to opioid addiction treatment services in the state.

Around 1,100 drug manufacturers and distributors report data to ARCOS each year, with more than 30 million transactions reported annually. These entities are required to report inventories, acquisitions and dispositions of all Schedule I and II substances, as well as Schedule III narcotics.

The newspapers’ analysis tracked shipments of oxycodone and hydrocodone pills in the late 2000s and early 2010s, finding that three companies (Mallinckrodt subsidiary SpecGX, Actavis Pharma and Endo Pharmaceuticals subsidiary Par Pharmaceutical) manufactured 88% of all of the opioids in the period studied.

OTPs’ view
ADAW spoke last week with Martin and her fellow OTP leader Kenny House. They offered similar views of a shifting opioid crisis but a lingering problem of treatment access in some communities in their states.

House, who chairs the North Carolina Association for the Treatment of Opioid Dependence and serves as clinical director of Coastal Horizons in Wilmington, said it is difficult for OTPs to establish viable operations in some of the hardest-hit rural communities of the state. The combination of multilevel government regulation, accessibility challenges for rural residents and an often uninsured or underinsured target population makes for significant challenges for providers looking to make the investment.

The insurance issues are particularly troubling to House, who says he too often sees that private insurance plans don’t cover opioid dependence treatment. “With parity laws, that shouldn’t happen,” he said.

He said some OTPs in the state have sought to expand access by offering buprenorphine in addition to methadone, but cost factors have caused many to step away from that plan.

Providers and the State Opioid Treatment Authority are working to come up with ways to overcome some of the access challenges without compromising treatment quality (i.e., to ensure that patients continue to have access to behavioral support in addition to medication treatment). Ideas include establishing some form of a hub-and-spoke system in which providers of comprehensive treatment would partner with physicians as the outposts.

Also, there has been talk of establishing mobile treatment units that would broaden access for some patients. “This has to be done well,” House said. “You have

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to make sure behavioral interventions are available so that these don’t become just a drug-dispensing organization.” In addition, state regulations that are about two decades old would have to be revised to accommodate some of these innovative options, he said.

House sees the ARCONS data as a reminder of the origins of a crisis with effects still being felt strongly across the state. “The pain industry really drove this,” he said.

Martin, director of clinical services at the Center for Behavioral Health, said South Carolina has 22 OTPs, a number considerably smaller than the supply in neighboring North Carolina and Georgia. The programs are largely clustered in urban areas, while other communities in need lack options. Myrtle Beach has high overdose rates and only one OTP, for example.

Some regulatory barriers to expanding treatment have been lifted in the state, such as a prior effort to limit each county to one OTP. However, “We have some state issues that make operational costs higher,” Martin said. What she termed “over-involvement” from the state board of pharmacy is at the heart of this, as she said South Carolina is the only state that mandates that a pharmacist be present at all times of an OTP’s operating hours.

Martin said the state is trying to encourage more physicians to become waivered to prescribe buprenorphine, and is also looking at the concept of satellite treatment units that would offer drug screens and medication (with patients then having to travel farther only for support services). Yet she wonders whether, given the state’s history, these sites would be ushered in with a requirement that they be permitted and regulated as pharmacies, which would add to the costs necessary to make that concept a reality. •

In case you haven’t heard…

Last week, a report came out in which The New York Times noted that ODs are falling in many states (https://www.nytimes.com/interactive/2019/07/17/upshot/drug-overdose-deaths-fall.html). We wondered how to trace the cause of a decline in ODs. Increased use of naloxone? Decrease in prescription of opioid analgesics? Increase in treatment for opioid use disorders? We decided to ask expert Keith Humphreys, Ph.D., the Esther Ting Memorial Professor of Psychiatry and Behavioral Sciences at Stanford University. “It does appear that naloxone really took off in 2016, which could have mattered,” he said (https://www.healthaffairs.org/do/10.1377/hblog20180316.599095/full/). “The decline in prescriptions should also have helped. I assumed it would be about five years from when prescriptions declined to when prescription deaths declined, because it takes time for not initiating people to translate into less addiction and death,” Humphreys told ADAW last week. “The data suggest that was the right guess.” Also, he would not underemphasize the impact of publicity about illicit fentanyl. Years ago, only a few people (including Humphreys and ADAW) knew what it was. “Now it has high visibility, and this may be affecting the willingness of many people to try heroin either as their first opioid or as a transition from pill misuse,” said Humphreys.

Journal Watch

Long-term use of methylphenidate continues to confer benefits

Patients continue to receive benefits from treatment for attention-deficit/hyperactivity disorder (ADHD) with methylphenidate after long-term use, researchers have found. Some patients may be withdrawn from the medication, however. Therefore, all patients should be assessed periodically to determine whether they continue to need the medication. The study, published in the *American Journal of Psychiatry*, was conducted because, while long-term use of methylphenidate for children with ADHD is frequent clinical practice, its benefits are unclear. They looked at whether the medication remains beneficial after 2 years. Methylphenidate, a stimulant, has been controversial in some quarters because it is a controlled substance, however, the first-line treatment for ADHD is psychostimulant medication, such as methylphenidate. How long children should take is is a question, but 60% of children receive stimulant treatment for ADHD for more than 2 years, and this is increasingly common, extending even into adolescence and adulthood. This is partly due to the awareness that ADHD is not a pediatric-only condition. The study, “Continued benefits of methylphenidate in ADHD after 2 years in clinical practice: A randomized placebo-controlled discontinuation study,” was published online May 21 by the *American Journal of Psychiatry*. •