As 42 CFR Part 2 faces possible demise, methadone patients panic, taper

Last month, the U.S. House of Representatives passed H.R. 6082, which would abolish key protections of 42 CFR Part 2, the regulation requiring most substance use disorder (SUD) treatment providers to obtain patient consent before releasing their records or any information about them. As a result, methadone patients are terrified.

“I am speeding up my taper in light of the House vote,” said one long-term methadone patient, who started a taper for clinical reasons two years ago. If he’s not done with the taper when the Senate bill passes (that bill still doesn’t have a name or number), he will go to outpatient detoxification “that very day,” he told ADAW last week. He doesn’t trust the commercial insurance company that covers his treatment to keep his information safe without 42 CFR Part 2, and he doesn’t think his clinic would protect him either, in absence of the regulation. “To think any physician or pharmacist might be able to see I’m in treatment and what dose I’m on — potentially even my urinalysis drug screen history….” he trailed off. “There’s too much stigma out there to risk that.”

The additional protections of

Controversial label of gaming disorder fuels speculation around facility marketing

The World Health Organization’s (WHO’s) inclusion of “gaming disorder” in the 11th revision of the International Classification of Diseases (ICD-11) has generated both renewed criticism of the WHO and some anxiety over whether video gaming tracks will begin emerging as the newest marketing tactic in the addiction treatment space.

Much of the research community believes the WHO has acted hastily in embracing a diagnosis with a limited evidence base, saying that the decision appears to be grounded more in a generation gap in understanding the behaviors of adolescents and young adults.

“Excessive gaming is more perhaps a coping mechanism for people with underlying issues such as depression and anxiety,” Christopher J. Ferguson, Ph.D., a professor of psychology at Stetson University who has researched video game participation and has criticized the WHO’s direction on the issue, told ADAW.

Conversely, some practitioners say they see clear parallels between problematic online or video gaming behavior and substance or process

Bottom Line…
OTP patients are terrified Congress will take away consent and confidentiality provisions of 42 CFR Part 2: the House already has; it now falls to the Senate in the coming weeks to decide.

Bottom Line…
Much of the research community remains convinced that the World Health Organization’s embrace of a gaming disorder classification amounts to a hasty move with a limited evidence base.
METHADONE from page 1
42 CFR Part 2 are why I was comfortable going to treatment years ago,” he said. “I wonder if I would have sought treatment if this bill was law back then.”

What opponents of CFR Part 2 really want — and have wanted for the past nine years — is to put SUD treatment records, including methadone treatment, in the electronic health record (EHR). It’s a convenience to the health care system. But it’s exactly this that patients don’t want—they want the right to determine who gets their information. Most would gladly share it with their trusted physicians. But if it’s “in the computer,” everyone gets it.

And this is why OTP patients want to taper. As another long-term patient, who also requested anonymity, told us, “I already started my own taper at home. I will not have my name put in a computer with the stigma I have already endured.” She added that her clinic has added more and more rules, and she doesn’t trust it without the protection of 42 CFR Part 2. She is an older person, and the stigma she would face in the medical field if they had access to her information would be unbearable, she said. “I will be needing health care more and more as I age. I can’t see coming into contact with the stigma I will have in the medical field here. I don’t want to leave the clinic but feel I have no choice,” she said. “I can’t trust the decisions of our country.”

OTP director concerned
Zac Talbott, program director of Counseling Solutions Treatment Centers, based in Chatsworth, Georgia, sympathizes with such views, which are being reported anecdotally around the country. He built up his programs from the ground starting more than three years ago, and at the age of 35, is widely considered one of the top leaders in the field. He credits his own recovery to methadone, and questions the wisdom in the midst of an opioid epidemic of making a change that will drive patients away from treatment. “People will die because of this,” said Talbott. “Patients will leave treatment. Prospective patients won’t seek treatment.”

Talbott is particularly galled by the fact that the American Society of Addiction Medicine (ASAM) supports abolishing 42 CFR Part 2. Over the last five years, he has become concerned that ASAM has begun to lose some of its “moral and ethical leadership” in the field. “But I never thought I’d see an assault on 42 CFR Part 2.”

DATA 2000 — the law that allows doctors to get a waiver to prescribe buprenorphine, an opioid, to treat opioid use disorder — created the dynamic of “big pharma,” in the addiction field, said Talbott. “Methadone was never a big pharma big patented moneymaker from day 1 of its FDA approval for SUDs in 1972,” he said.

In fact, ASAM is far more supportive of office-based opioid treatment, which uses buprenorphine, than it is of opioid treatment programs (OTPs). “This is ultimately an assault on OTPs and methadone,” he said. “We need a mass call to ASAM from patients,” he said.

One of the bills that passed the House last month as part of H.R. 6 would allow Medicare to pay for treatment in an OTP. This was a huge win for OTPs (see story, p. 5). But in the process, H.R. 6082, the bill to replace 42 CFR Part 2 with HIPAA, slipped through. “The Medicare bill was a perfect distraction,” said Talbott. “Smart move for those who want to obliterate 42 CFR Part 2,” he added, noting that if people are scared to go to treatment because they will lose their confidentiality, it’s doesn’t matter who is paying.
AATOD not hopeful

“...I have always been concerned about the patient’s response, which is why we have advocated against this for such a long time,” said Mark W. Parrino, president of the American Association for the Treatment of Opioid Dependence (AATOD). “As you know, this has to go to the Senate and this will be our last bastion of defense,” said Parrino. “Given the majority vote in the House, I cannot claim to be hopeful."

However, Parrino was skeptical about the number of patients who are tapering. “It is too soon to get any sense of patients wanting to taper,” he said. And he urged that before any changes are implemented, a lot of work will need to be done. “This will require a labor-intensive effort on the part of OTP staff explaining how to approach [tapering] decisions,” he said.

Parrino also questions that patients only enter treatment because they know their information will be confidential, but does agree that their reasons for staying in treatment include confidentiality. “Please keep in mind that when new admissions cross the threshold of an OTP, they are desperate for care,” he said. “On the other hand, I believe that decisions to remain in care will be affected if they know that their treatment is no longer confidential.”

Patients who have not disclosed their treatment to family or employers, and pregnant patients, would be particularly impacted by the loss of confidentiality, said Parrino. “The bottom line is that this is a major policy mistake,” he said.

“We don’t have any idea either how many patients are feeling the stress, but also are hearing stories that people are scared, and understandably so,” said Paul Samuels, president of the Legal Action Center, which has been advocating to save 42 CFR Part 2. Asked whether OTPs would be required to divulge patient information if the regulation changes, Samuels said, “We haven’t thought down the road here about what might happen in terms of the mechanics of this, in part because this is still in process.” The best-case scenario would be for the Senate version not to pass, said Samuels. “This is a moving target which we’re still hoping we’ll be able to stop,” he said. “And if something does pass, we don’t know what that will be. We are focused totally on advocacy with the Senate right now to hopefully prevent anything from passing in the Senate, and to keep any changes to Part 2 out of any legislation. We are continuing to inform Congress of the problems with this legislation.”

The main message, Samuels said, is this: “In the middle of the nation’s worst opioid epidemic we should be encouraging everyone to stay in treatment.” Samuels urges everyone who is concerned about patient privacy to contact their senators. And Samuels urges patients not to taper. “Don’t get scared, don’t stop your lifesaving treatment; use your constitutional rights,” he said. “Members of Congress pay attention to the phone calls and mail.”

The medical record

Meanwhile, the American Psychiatric Association (APA) selected H.R. 6082 for commendation. “This law will allow our doctors to better treat patients with substance use disorders by giving them access to much-needed information, while still protecting the patient,” said APA CEO and Medical Director Saul Levin, M.D., M.P.A. “This will ensure that patients are not harmed due to a provider not receiving some medical information. We applaud the House for taking this action and we urge the Senate to pass this legislation.”

We asked the APA for more information on why they support legislation that would deter patients from seeking treatment. “As we address this crisis, physicians need to be able to better coordinate care for patients seeking treatment for opioid use disorder and other substance use disorder, including those with co-occurring conditions,” the APA responded. “As it currently stands, health care providers may not have access to a patient’s full health record, limiting their ability to provide the best care and outcomes for their patients. For example, this can be an especially dangerous problem if a patient arrives unresponsive to an emergency room and is not able to provide the details of their condition to the treating provider.”

Like many organizations, the APA appeared to be unaware of the emergency exception to 42 CFR Part 2. Asked about this, however, the APA conceded that it just wants all patient information, including about SUD treatment, to be in the patient’s medical record. “The emergency exception to Part 2 does not cover all potential scenarios where the patient is unresponsive or unable to provide their consent. Segmenting Part 2 information from general medical data in the electronic record results in incomplete records being shared across health care providers. During an emergency, the responding clinician has no way of knowing if a patient has an SUD with corresponding health data located in any particular EHR system that has previously been kept separated from...
Continued from page 3
the rest of the record or that the
owners of these data (e.g., a treat-
ment facility where the patient has
received care) would be available to
share it during said emergency.
Adopting a uniform standard for
storing, retrieving and sharing infor-
mation around HIPAA helps to miti-
gate segmentation of the record in
the first place and improve access so
that medical decisions can be made
with a complete patient record.”

Commercial harms to
providers

The problems are not limited to
OTPs. Patients with severe SUD issues
“may have little to lose and therefore
not complain about the possible
breaches,” agreed H. Westley Clark,
M.D., J.D., Dean’s Professor at Santa
Clara University and former director
of the Center for Substance Abuse
Treatment at the Substance Abuse and
Mental Health Services Administra-
tion, which oversees SAMHSA. These
patients are not candidates for em-
ployment, most insurance and even
most legal arrangements, like mar-
rriage, he said. “But those with mild
to moderate SUD issues will be the most
vulnerable,” he said.

Basically, only those patients
who have lost all or nearly every-
ting for one thing. For another, there is
no mention of supervised work ex-
perience with individuals who have
coccurring disorders.

Originally proposed by the Con-
necticut Nonprofit Alliance, the plan
was rejected by the CCB because it
does not adhere to the CCB’s mis-
sion of public protection and client
safety. While allowing LADCs to pro-
vide services to patients with co-
curring disorders, “in reality it cre-
ates potential dangers for clients and

LADCs shouldn’t treat co-occurring without training: CCB

Standards for certification as an
addiction counselor, clinical super-
visor or prevention professional in
Connecticut are set by the Connecti-
cut Certification Board (CCB), which
certifies counselors. Now the state
wants to change the scope of prac-
tice for the Licensed Alcohol and
Drug Counselor (LADC) credential
to include the treatment of those
with co-occurring mental health and
substance use disorders. This change
was put into place as part of a larger
bill in the state legislature. The CCB
is opposed to this change because
the requirements for the LADC do
not require sufficient training to treat
coccurring disorders.

Originally proposed by the Con-
necticut Nonprofit Alliance, the plan
was rejected by the CCB because it
does not adhere to the CCB’s mis-
sion of public protection and client
safety. While allowing LADCs to pro-
vide services to patients with co-
curring disorders, “in reality it cre-
ates potential dangers for clients and
Opioid bills pass House of Representatives

Last month, the House of Representatives passed H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, which includes many bills that had been passed by committees this spring. Included are some of the following measures:

• Require state Medicaid programs to not terminate a juvenile’s medical assistance eligibility because the juvenile is incarcerated. A state may suspend coverage while the juvenile is an inmate but must restore coverage upon release without requiring a new application unless the individual no longer meets the eligibility requirements for medical assistance (H.R. 1925).
• Require the Centers for Medicare and Medicaid Services (CMS) to carry out a demonstration project to provide an enhanced federal matching rate for state Medicaid expenditures related to the expansion of substance use treatment and recovery services targeting provider capacity (H.R. 5477).
• Require all state Medicaid programs to have a beneficiary assignment program that identifies Medicaid beneficiaries at risk for substance use disorder (SUD) and assigns them to a pharmaceutical home program, which must set reasonable limits on the number of prescribers and dispensers beneficiaries may utilize (H.R. 5808).
• Require the CMS to issue guidance on neonatal abstinence syndrome treatment options under Medicaid and require a study by the nonpartisan Government Accountability Office on coverage gaps for pregnant women with SUD (H.R. 5789).

Continues on page 6
Continued from page 5
• Provide additional incentives for Medicaid health homes for patients with SUD (H.R. 5810).
• Provide access to medication-assisted treatment (MAT) in Medicare through bundled payments made to opioid treatment programs (methadone clinics) for holistic service (Section 2 of H.R. 5776).
• Makes the buprenorphine prescribing authority for physician assistants and nurse practitioners permanent. Temporarily allows advanced practice registered nurses to prescribe buprenorphine. In addition, H.R. 6 will permit a waived practitioner to immediately start treating 100 patients at a time with buprenorphine (skipping the initial 30-patient cap) if the practitioner has board certification in addiction medicine or addiction psychiatry, or if the practitioner provides MAT in a qualified practice setting. Medications, such as buprenorphine, in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of opioid use disorder (H.R. 3692).


Also passed last month, separately from H.R. 6: The Overdose Prevention and Patient Safety Act (H.R. 6082), which amends 42 CFR Part 2 to be more like HIPAA (see story, page 1).

Bupe ingestion up 30% among children: Poison center study

Poison control centers received 11,275 reports of children and adolescents, mostly children under age 6, ingesting buprenorphine during the 2007–16 time period, according to a study published in the current issue of Pediatrics. Most (97.3 percent) of the exposures were to a single substance; 86.1 percent of all of the exposures were in children under age 6, and 89.2 percent of all exposures were unintentional. Among the 11.1 percent of exposures among adolescents, 77.1 percent were intentional (including 12.0 percent suspected suicide), and 27.7 percent involved multiple substances. The multiple-substance exposures increased the odds of hospital admission and a serious medical outcome.

The study, “Buprenorphine Exposures Among Children and Adolescents Reported to US Poison Control Centers,” recommended that manufacturers use unit-dose packaging for all buprenorphine products, and that adolescents should receive information on the risks of substance use and misuse. The data came from calls to U.S. poison control centers, from the National Poison Data System. Among children 6 or older, 48.1 percent of buprenorphine exposures resulted in hospital admission and 21.4 percent in a serious medical outcome. Among adolescents 13 to 19 years old, 21.5 percent of exposures resulted in hospital admission and 22.0 percent in a serious medical outcome.

From 2007 to 2010, exposure rates increased more than 200 percent, which the authors attributed to the increasing number of buprenorphine prescriptions dispensed. Despite the number of prescriptions almost tripling from 2008 to 2016, there was a transient decrease in buprenorphine exposures during 2010–13, which may have been influenced by a shift in buprenorphine prescriptions to an older population (ages 40 to 59), and a decrease in office visits for buprenorphine among 20–39-year-olds. Another reason for the decline in exposures during that time period were changes in packaging. From 2007 to 2010, tablets accounted for almost all exposures in this study from 2007 to 2010—which is to be expected, because virtually all of the prescriptions from 2008 to 2010 were tablets. The decline in the exposure rate coincided with the approval of a buprenorphine film that was sold only in unit-dose child-resistant packaging.

(Reckitt Benckiser, now Indivior, the manufacturer, pulled the tablets from the market at the same time that it received approval for the film of its product—Suboxone—which at the time enjoyed patent

“[R]egardless of formulation, buprenorphine is dangerous to young children, and primary prevention of access is key.”

Sara Post et. al.
protection on buprenorphine. Individual is still under investigation by the federal government for the switch from tablets to film, which enabled it to prolong its patent just as generic competition was emerging.)

**Overdose risk in children**

From 2013 to 2016, there was a 30 percent increase in the frequency of exposures among children and adolescents to buprenorphine film, which the researchers attributed to the continued increase in prescriptions.

“In this study, the type of formulation (tablet versus film) did not affect the odds of a serious medical outcome among young children,” the researchers wrote. “Therefore, regardless of formulation, buprenorphine is dangerous to young children, and primary prevention of access is key.”

The oft-repeated statement that it’s impossible to overdose on buprenorphine is not true for children, the researchers suggested. Therapeutic doses of buprenorphine-naloxone for pediatric patients are 2 to 6 micrograms/kilogram, so ingestion of a single 2-mg sublingual tablet in a 10-kilogram child can result in more than a 30-fold overdose, the researchers noted. “This is particularly dangerous, because children exposed to buprenorphine do not display the ‘ceiling effect’ reported in adults, in which escalating doses do not lead to additional increases in respiratory depression,” they wrote.

“Young children also often experience a delay in the onset of symptoms after buprenorphine exposure; the median time from exposure to respiratory depression was 4.4 hours in 1 study. This known delay in symptom onset likely contributes to the higher admission rate for young children.”

**Euphoria**

Although buprenorphine is a treatment medication for opioid use disorders and does not result in euphoria in opioid-dependent individuals, abuse and diversion of the medication does occur, either for self-medication of withdrawal or for euphoria. Respiratory depression is increased when multiple CNS depressants are taken: combining benzodiazepines and buprenorphine was responsible for three of the four deaths of adolescents in this study.

The researchers noted that the American Academy of Pediatrics in 2016 advocated that adolescents with opioid use disorders have access to buprenorphine. “This recommendation is warranted because of the high and increasing prevalence of opioid dependence among adolescents,” they wrote. “However, caution should be used, because increased prescriptions among adolescents could lead to increased diversion and abuse and increased access to younger children in the home. Therefore, patient education for adolescents should include information about the dangers of misusing and/or abusing prescription drugs and the proper storage of medications.”

For the article, by Sara Post and colleagues, go to http://peditiatrics.aappublications.org/content/early/2018/06/21/peds.2017-3652.

---

**Gaming from page 1**

addictions. Cali Estes, Ph.D., a nationally prominent counselor and recovery coach who works a great deal with young people categorized under the “failure to launch” label, told **ADAW** that she has seen some patients whose gaming pursuits have interfered greatly with key domains of their life.

“I think they should have come out with this [classification] years ago,” Estes said.

**Implications of move**

The ICD is the global health information standard for morbidity and mortality data, and determines resource allocation and reimbursement for more than two-thirds of the world’s health expenditures. It customarily takes years, however, for the presence of a new diagnostic classification in an ICD revision to translate to providers’ widespread use of billing codes for reimbursement for treatment services associated with that disorder.

The ICD-11 includes gaming disorder in a section on “disorders due to addictive behaviors.” The disorder is defined as a pattern of video or digital gaming behavior (it is important to point out that this is distinct from gambling behavior) that is characterized by impaired control over gaming, increasing priority given to gaming such that it takes precedence over other interests, and continuation of gaming despite the occurrence of negative consequences in the individual’s life.

A 2017 debate paper published in the *Journal of Behavioral Addictions*, co-authored by Ferguson and a group of researchers, questioned the evidence base for a gaming disorder, stating that there is a lack of research evidence of physiological withdrawal associated with the behavior. Ferguson and others see the interest in advancing a gaming disorder as reflecting a “moral panic” in which advances in technology often breed exaggerated fears. Ferguson said this concern has been particularly prominent in Asian countries that have significantly influenced the WHO’s thinking on this issue.

“Most of this fear comes from parents whose kids are sitting at home for four to six hours when they really want them to go outside and look at trees,” Ferguson said.

To extend the WHO’s argument, he believes, there would also need to be diagnostic categories for excessive exercise, or dance, or just about any other pursuit that activates neurotransmitters. “Why don’t these other people matter?” Ferguson said.

Continues on page 8
Continued from page 7

He believes that for those who seek to advance the gaming disorder concept in the United States, the “bigger prize” would be its potential inclusion in the Diagnostic and Statistical Manual of Mental Disorders (DSM). The DSM-5 designates “Internet gaming disorder” as a condition for further study, meaning that it could be listed as a disorder in the future, depending on emerging research evidence. The American Psychiatric Association’s (APAs) diagnostic manual states that the issue is most commonly seen in young males ages 12 to 20.

Ferguson thinks the APA will wait to observe any fallout from the ICD’s move before taking any definitive action on this potential diagnosis.

Sign of the times

Estes believes the emergence of problems she has seen with some young people around gaming reflects a cultural phenomenon that seems to value instant gratification over genuine human interaction. Even participation in seemingly innocent online games can begin to affect other areas in a young person’s life, she said.

From a socioeconomic standpoint, she sees young people who have been given a great deal materially by their parents as being particularly susceptible to problematic gaming behavior.

She suggests to adults, “Don’t park your child in front of the TV as a babysitter,” saying, “This can quickly morph into gaming.”

Although Estes believes a gaming disorder diagnosis is overdue, and even thinks it’s only a matter of time before a social media addiction diagnosis makes it into the DSM, she admits to some concern over the possibility that treatment centers will rush into opening and promoting gaming tracks in their programs.

“The training of staff doesn’t support this yet,” she said. Online gaming has components that should make its treatment different from that of pathological gambling, she said. These features specific to gaming behavior include the lack of direct monetary loss in most gaming pursuits, and the feeling of invincibility among the young people who are most prone to gaming behavior, she said.

Ferguson believes the WHO acted hastily in its decision on gaming disorder, suggesting that it did not sufficiently consider the views of those without a vested interest in seeing an expansion of the diagnostic map. He doesn’t think the WHO’s decision will open the floodgates to widespread insurance reimbursement in the short term, but believes treatment providers certainly will see opportunity in this development.

For families concerned about a young person’s behavior around gaming, Ferguson suggests that while he doesn’t see the games themselves as the source of a disorder, certain behaviors could raise a red flag. His main advice in these cases: “Bring the person to a professional who specializes in working with adolescents,” rather than one who advertises as specializing in gaming. The adolescent treatment specialist “will look at any underlying issues,” Ferguson said.

Coming up...

The National Recovery Schools Conference will be held July 10–12 in Houston. For more information, go to https://collegiaterecovery.org/event/9th-national-collegiate-recovery-conference/.

The 29th annual National Prevention Network Prevention Research Conference will be held Aug. 28–30 in Boston. For more information, go to http://www.npnconference.org/.

In case you haven’t heard...

Last month, the federal Food and Drug Administration (FDA) approved a purified form of the drug cannabidiol (CBD), one of the more than 80 active chemicals in marijuana, which is illegal. The new product, Epidiolex, was approved June 25 to treat epilepsy in patients two years of age and older. This is not the same as “medical marijuana,” the FDA noted, adding that marijuana is a Schedule I compound (as is CBD). Schedule I of the Controlled Substances Act (CSA) is reserved for drugs that have no accepted medical use in the United States and high abuse potential. The FDA assists drug developers who want to investigate marijuana or its components through clinical trials, the agency states. The approval of CBD was based on clinical trials. In addition, the drug is delivered in reliable dosage form and through a reproducible route of delivery, the agency said. Smoking is neither reliable in terms of dosage nor reproducible. Under the CSA, CBD itself is currently a Schedule I substance based on its derivation from the plant cannabis sativa (also known as marijuana), an FDA spokesman told ADAW last week. “Therefore, for Epidiolex to be lawfully marketed under the CSA, a change in scheduling will be necessary,” said the spokesman. “When a change in scheduling is needed, the FDA (in consultation with the National Institute on Drug Abuse) prepares and transmits, through the Department of Health and Human Services, a medical and scientific analysis of the substance, and provides recommendations to the Drug Enforcement Administration (DEA) regarding controls under the CSA. The DEA then makes a final scheduling determination. These activities for CBD remain ongoing.” Proponents of marijuana legalization hailed the ruling as opening the doors to legalization of marijuana. Opponents of marijuana legalization hailed the ruling as science-based.