ALCOHOLISM & DRUG ABUSE WEEKLY
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In This Issue...

Our lead stories this week look at the latest round of 42 CFR Part 2 arguments, with patient advocates on one side and almost everyone else on the other, and at the recent NAADAC conference.

. . . *See stories, beginning on this page*

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Patient confidentiality campaign launched in 42 CFR Part 2 battle

Bottom Line...
The ongoing battle over 42 CFR Part 2 now goes to Congress, with advocates and lawyers taking sides.

Headed by the Legal Action Center, more than 100 treatment and recovery organizations have joined a "Campaign to Protect Patient Privacy Rights," focused on maintaining the confidentiality of substance use disorder (SUD) patients.

The campaign, launched last week, comes on the heels of legislative attacks on confidentiality. The first attack came in the Overdose Prevention and Patient Safety Act (H.R. 3545), which would place all SUD patient records under the much looser protections of the Health Insurance Portability and Accountability Act (HIPAA) and was proposed by Rep. Tim Murphy (R-Pennsylvania) (see *ADAW*, Aug. 7). The second attack came last week in a "bill to amend the Public Health Service Act to protect the confidentiality of substance use disorder patient records" (S. 1850) proposed by Sen. Joe Manchin (D-West Virginia). Also this summer, a group that includes the Hazelden Betty Ford Foundation and the American Society of Addiction Medicine emerged to repeal 42 CFR Part 2 (see *ADAW*, Aug. 7).

(While the legislative and advocacy initiatives are taking place, lawyers are making arguments as well.

See **Campaign** page 2

NAADAC members seek broader skill set, wider recognition via credentialing

Bottom Line...
An expanded vision of co-occurring disorders and a greater appreciation for gender factors in treating men were among the training messages delivered at the annual conference of NAADAC, The Association for Addiction Professionals.

The opioid crisis might be fueling the thirst for information reflected in an attendance of more than 1,000 at last month's annual conference of NAADAC, The Association for Addiction Professionals, but conference attendees' preferences suggested that they are seeing a much broader range of problems in their patient populations. Sessions on gender-sensitive services for men and co-occurring disorders beyond mental health received enthusiastic feedback from counselors ready to capitalize on heightened public awareness about addiction and related issues.

"There's concern about there not being enough money out there, and salaries [in the profession] are definitely an issue, but now I'm hearing more instead about the need for more money for programs and for training," NAADAC President Gerard Schmidt told *ADAW* in assessing the collective mood at the Denver conference.

"The feeling I got from the group

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Campaign from page 1

See below for an analysis of H.R. 3545 by Netsmart and a response by H. Westley Clark, M.D.)

Last week's announcement by the Legal Action Center clearly sets the stage for a battle between the mental health community and others. In addition to the Legal Action Center, the campaign includes the American Association for the Treatment of Opioid Dependence (AATOD), AIDS United, Faces & Voices of Recovery, the Harm Reduction Coalition, Facing Addiction and National Advocates for Pregnant Women, and others.

The goal of the campaign is to advocate for maintaining the confidentiality of SUD patients, by preserving the federal confidentiality rules known as 42 CFR Part 2. This regulation, established more than 40 years ago, prevents treatment providers from disclosing information about a patient without the patient's consent.

For the principles of the campaign, including the list of supporters as of Sept. 27, go to https://lac.org/wp-content/uploads/2017/09/CPPart2-Principles-.pdf.

Supporters, opponents and bystanders

AATOD, a membership organization of opioid treatment programs that provide treatment with methadone and other medications, strongly supports keeping 42 CFR Part 2, and always has. But conspicuously absent from the list of campaign supporters are three treatment provider organizations: the American Society of Addiction Medicine (ASAM), the National Association of Addiction Treatment Providers (NAATP), and the National Association of State Alcohol and Drug Abuse Directors (NASADAD), whose members receive Substance Abuse Prevention and Treatment block grant funds. ASAM came out against 42 CFR Part 2 this summer, as mentioned earlier (see *ADAW*, Aug. 7). NAATP, while it has not taken a stand one way or another, has prominent members who also oppose 42 CFR Part 2, notably Hazelden Betty Ford (see *ADAW*, Aug. 7). NASADAD did not have consensus on the issue, but several NASADAD members — including New Jersey and Tennessee — did sign on to the campaign to protect privacy and 42 CFR Part 2.

There are proposals to replace 42 CFR Part 2 with HIPAA, but those standards are too relaxed to sufficiently protect SUD patients. SUD patients face severe penalties from disclosure — or disclosure by a third party — of their treatment records. For example, they face criminal investigation, arrest and/or prosecution by law enforcement; denials of disability, life and other types of insurance; loss of child custody; and redisclosures of SUD information that can cause loss of employment and other harm.

"The confidentiality law is often the only shield between an individual in recovery and the many forms of discrimination that could irreparably damage their lives and future," said Paul Samuels, president/director of the Legal Action Center. "Unfortunately, there is a very real danger of serious negative consequences for people whose history of substance use disorder is disclosed without their explicit consent."

"Many of us would not have gone to treatment or accepted services if we thought that our information would have been shared with other entities without our permission," said Patty McCarthy Metcalf, executive director of Faces & Voices of Recovery. "We would not have put our careers, reputation or families at risk of stigma and discrimination if we were not assured that information about our substance use disorder was safe and would only be shared with our consent."

"In the midst of the worst opioid epidemic in our nation's history, we cannot afford to have patients fearful of seeking treatment because they do not have faith that their con-

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fidentiality will be protected," said Mark Parrino, AATOD president.

Legal arguments on H.R. 3545

Gerald DeLoss of the Greensfelder law firm and Kevin Scalia of Netsmart wrote an analysis of the Murphy bill (H.R. 3545) on Aug. 17. H. Westley Clark, M.D., former director of the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration (SAMHSA), which promulgates 42 CFR Part 2, responded to that critique in an email to *ADAW* last month. Greensfelder represents Netsmart. The analysis was circulated by groups who want to see 42 CFR Part 2 amended, including the National Council for Behavioral Health, whose president and CEO, Linda Rosenberg, is on the board of Netsmart. We asked Netsmart and DeLoss (via email) for a link to their document, but they were not able to provide one.

Below are excerpts from Clark's responses to the Greensfelder/Netsmart critique of criticisms of 42 CFR Part 2:

- "Greensfelder/Netsmart contend that modifications under H.R. 3545 would be only for treatment, payment, and health care operations purposes," said Clark. However, under HIPAA, health care operations are defined broadly, and many more entities would have access to information currently protected by 42 CFR Part 2, he said.
- The Greensfelder/Netsmart argument also says H.R. 3545 "actually strengthens the existing prohibitions on the use or disclosure of substance use disorder (SUD) treatment records in criminal proceedings, and would not allow for a 'war on drugs.'" Clark rebutted that current law clearly states that except as authorized by a court order, no SUD record can be used to initiate or substantiate or investigate a patient. H.R. 3545, on the other hand, restricts additional protections only to treatment, payment and health care operations — after exempting those operations from 42 CFR Part 2. "In short, the 'additional protections' and the exclusionary effect would not be necessary if it weren't for H.R. 3545 in the first place," said Clark. "Finally, the 'war on drugs' is not just a criminal justice oriented phrase; it involves civilian activities such as employment, housing, health care, and social concerns as well."
- The Greensfelder/Netsmart paper contends that H.R. 3545 mandates the exclusion of the SUD treatment record and imposes an automatic dismissal of the criminal action. But what the paper doesn't mention, said Clark, is the "escape clause" in the bill, which states that "absent good cause shown" shall result in the automatic dismissal of any proceedings for which the record was offered, said Clark. "In other words, all the authorities have to do is present a 'good cause' showing in order to prevent an automatic dismissal," he said. There are "severe limitations" to this "automatic dismissal."
- According to Greensfelder/Netsmart, H.R. 3545 doesn't change the existing 42 CFR Part 2 protections for disclosure of SUD treatment records in civil proceedings. Clark responds that first, the bill excludes health care operations from the existing CFR Part 2 protections, which is indeed a major exclusion. Second, said Clark, HIPAA allows disclosure of protected health information "in response to a lawful process such as a subpoena, discovery request or other lawful process if those who want the substance use disorder information about a patient state in writing that reasonable efforts have been made to give notice to the patient or that reasonable efforts have been made to secure a qualified protective order." All the seeking party needs to do, said Clark, is to provide a statement that a notice was sent to the individual's last known address. "In other words, there doesn't have to be any actual notice given, just an attempt to give the notice; that attempt turns on the efforts of the seeking party who may have a vested interest not to pursue notice too aggressively."
- The Greensfelder/Netsmart argument is that any disclosure for payment or collection purposes would be limited to the minimum necessary under HIPAA, and diagnosis and other detailed clinical information could not be shared with collection agencies. But Clark notes that HIPAA gives covered entities flexibility, and unlike with 42 CFR Part 2, the patient has no say in this prior to disclosure. The Department of Health and Human Services contends that this is a "reasonableness standard," said Clark, adding that "this is a loose standard that may deprive patients of adequate protections against disclosure." Unlike HIPAA, 42 CFR Part 2 "requires the specific purpose or need for the disclosure, how much and the type of information to be disclosed, the patient's right to revoke the consent in writing and exceptions to the right to revoke."
- The current final revised 42 CFR Part 2 regulations prohibit the direct sharing of data by one provider in an HIE, ACO or IHH to another provider in the same integrated setting, something Greensfelder/Net-

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smart object to. But Clark points out that the organizations could follow the revised 42 CFR Part 2, and obtain consent, or, if they wanted to, they could use SAMHSA's Consent-2Share open source software. "The reality is that SAMHSA developed a data segmentation for privacy initiative with the Veterans Administration and industry participants," wrote Clark, who oversaw this ex periment while at SAMHSA. "Additionally, it appears that one of the limitations to sharing of data is a lack of understanding of the standards, technology and regulations," he said. "SAMHSA's Consent-2Share open source software integrates EHRs and HIEs and allows the patient to provide electronic consent; this reduces any burden."

- In an oft-stated complaint about 42 CFR Part 2, the Greensfelder/Netsmart paper notes that the regulation segments SUD treatment information from the rest of the health care record, "providing an incomplete picture." This complaint "captures the essence of the problem with HR 3545," said Clark. "It assumes that most of the substance use treatment record is medication and physical health based. It ignores the prevalence of psychological and social information that constitute the majority of a substance use disorder treatment record. This item also ignores the fact that in the absence of capability of the software highly personal and potentially prejudicial information that would appear in what is basically psychotherapy notes." Clark noted that in revising 42 CFR Part 2 in 2017, "SAMHSA anticipated there will be more individuals with substance use disorders participating in organizations that facilitate the exchange of health information (e.g., health information exchanges (HIEs)) and organizations that coordinate care (e.g., ACOs) and coordinated care organizations (CCOs)), leading to increased efficiency and quality in the provision of health care for this population." He added that "the revised 42 CFR Part 2 allows for a consent category called 'general designation,' which should accommodate the variety of entities seeking access to substance use disorder records."
- Greensfelder/Netsmart state that 42 CFR Part 2 prohibits disclosure by a Part 2 covered program directly to a Prescription Drug Monitoring Program (PDMP), so checking a state's PDMP may not provide full and accurate data. "This statement is a distortion of the reality of the situation," said Clark. "42 CFR Part 2 does not prohibit the sharing of prescription controlled medications in the outpatient context. Since the majority of patients receiving buprenorphine will do so in the outpatient context, any physician checking the PDMP will have access to the list of the controlled medications that a patient is receiving."
- In another frequent criticism of 42 CFR Part 2, Greensfelder/Netsmart contend that under the current regulations, if an emergency room physician was provided SUD treatment information from a covered program — either by way of consent or as a medical emergency — for treating an overdose, he or she would not be allowed to redisclose that information to family members. But this is another distortion, said Clark. "42 CFR Part 2 states that patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained. After the bona fide medical emergency has been met, such as treating an overdose, the question is if medical personnel want to disclose that information to the family why shouldn't the medical personnel get permission from the patient," Clark said. "Disclosing substance use disorder information about an adult patient even to family members without the patient's consent can create substantial problems for the patient. Within HIPAA, if a patient objects, information cannot be shared with family members. So, with patient consent, the information about substance use can be shared with family members under 42 CFR Part 2 and under HIPAA."
- Speaking on behalf of SUD treatment providers, the Greensfelder/Netsmart paper states that it is a "hassle" for a provider to ensure "that each and every potential recipient" of patient information is identified at the outset and named in a consent form that the patient must sign upon intake. Insurance companies who are paying may not even be known at the time. But again, this is a distortion, said Clark. "Quite naturally, an SUD provider would want an individual consent for an insurer in order to assure payment," he said. "With regard to MCOs, care coordinators and others, because the composition of these entities varies widely and because the risk of misuse of what should be confidential information, the SUD provider should want to know just to whom it would be releasing information. Thus, the 'hassle' mentioned in this item becomes assurance that the

patients served by the SUD provider are not being harmed by the any of the many entities to whom it would be releasing information entrusted to the SUD provider. Keeping in mind that the SUD provider possesses among other things psychotherapy notes and other sensitive information that often exceed the necessary information that insurers, MCOs, care coordinators and others would need to conduct effective, efficient, and responsible interactions with the patient. The 'hassle' is simply the price of doing business, of assuming responsibility to the patient, of building a trust relationship with a patient, and of operating within the umbrella of state laws."

- Greensfelder/Netsmart also asserts that patients must execute either an opt-in or not execute an opt-out order to include protected health information in an HIE. This is objectionable because it gives the patient too much control over his or her data, they suggest. "This item captures the entire tension inherent in HR 3545 and in the objections that Greensfelder/Netsmart and their allies have to the revised 42 CFR Part 2," said Clark. "Netsmart as a Electronic Health Record (EHR) vendor appears to believe that the protected health information inherent in substance use disorder treatment carries no sensitivity in American society, despite the plethora of evidence to the contrary. Greensfelder/Netsmart appear to want to ignore the consequences of harmful disclosure of sensitive information. This treats the patient as a means to the ends of commercial endeavors and mere profit, diminishing the autonomy and dignity of the patient."
- Another issue for Greensfelder/Netsmart is HIEs and data networks, which, they "have still been told," are prevented from inclusion by 42 CFR Part 2. Again, Clark cites the open source Consent-2Share software that was developed by SAMHSA and could be used to foster inclusion and diminish barriers to patient care, "while respecting the autonomy and dignity of the patient."

Clark added, "Keep in mind that many SUD treatment providers do not have the EHR capacity to participate in HIEs and data networks. Keep in mind that many SUD treatment providers do not have EHR systems that are interoperable with HIEs and data networks. Keep in mind that without the protections that the revised Part 2 attempt to promote, many patients of sufficient means will opt for the self-pay exception to HIPAA. As a result, SUD treatment providers will still need EHR systems which would allow them to determine which patients are self-pay and entitled to an opt-out of HIPAA and disclosures. The revised 42 CFR Part 2 continues to recognize that privacy and confidentiality are essential elements of care for many people with SUDs. Removing or diminishing privacy and confidentiality will only drive SUD patients away from medically oriented SUD care into non-medically oriented care. This, in fact, may compromise not only the patient's health, but the public health."

Clark said the Greensfelder/Netsmart analysis not only "ignores the impact of HR 3545 on patients, patient decisions, and ultimately on SUD providers," but is "simply a self-serving assessment of the situation operating in the service of promoting the convenience of software vendors and their commercial customers." •

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wasn't gloom and doom," Schmidt said. "It was 'I can't wait to get back to my program and see how we might integrate some of these ideas.'"

A best-practices emphasis in this year's conference curriculum (this year's theme was "Elevate Your Practice") largely involved "anything around co-occurring disorders," said Schmidt, who is halfway through his two-year term as NAADAC president and serves as chief operations officer at Valley HealthCare System in West Virginia. The reach of co-occurring disorders is much broader than co-morbid depression or anxiety, suggested Schmidt, who said presentations such as a plenary address from Stefanie Carnes on sex addiction drew a great deal of attention.

While some attendees of such sessions might decide that these are new populations that they want to serve more directly, Schmidt said it is important for all attendees at least to broaden their awareness that problematic sexual behavior could be a component of what some of their patients are facing.

"The goal is to get as much training as possible in the toolkit, so they don't overlook the potential impact of these issues," he said.

Shortcomings of men's treatment

Observers say that a conference audience that was predominantly female seemed to appreciate that for the first time, the topic of gender dynamics affecting men's treatment was receiving focused attention at a NAADAC conference.

It wasn't long ago that men were seen as having significant advantages in accessing appropriate treatment services, Schmidt said. But

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as more attention has been paid to providing gender-sensitive care to women, the field's shortcomings in working with men have received renewed exposure.

"There are groups that are run as men's groups, but it's just putting men together," Mark Woodford, Ph.D., a conference presenter this year and director of counselor education at the College of New Jersey, told *ADAW*. "Women's groups, on the other hand, are addressing gender-specific stuff."

Woodford conducted one of three NAADAC conference sessions on men's treatment, and said he tried to elevate attendees' "consciousness to seeing men as a gender. It is the focal organizing principle on everything males do." Around 100 chairs had been set up for Woodford's session, and more had to be brought in during the presentation, he said.

He starts his discussion about men by addressing how men think about themselves, based largely on societal expectations that are communicated clearly by the time of adolescence. Any work with men must then proceed to building emotional awareness. If the discussion of emotions is limited to women's treatment, "We're missing the boat," said Woodford, who also is the clinical mental health coordinator at the college.

Programs also need to be aware that they should speak a different language with men. For example, "intuition" might be a concept foreign to the male patient, but "gut instinct" serves largely the same purpose, Woodford said.

He warned his NAADAC audience that his talk likely would cross into some male stereotypes, but added in his advice to professionals, "When it fits with the person's identity, use it. Don't deny parts of their self."

When treatment programs fail to serve men well, men will delay seeking help, will face worsening emotional and physical health, and likely will die prematurely, Woodford said.

Need for a national credential

NAADAC Executive Director Cynthia Moreno Tuohy told *ADAW* that another theme she heard prominently among conference attendees was their desire to see greater recognition of the counseling profession through a national credential. She supports this, while acknowledging that the move from recognizing this need to actually implementing something would take a major effort involving numerous groups.

"Everyone knows what an M.S.W. is. Everyone knows what an M.D. is," said Tuohy. "People need something they can look to and say, 'I can rely on the fact that the person who has this carries a certain amount of education and training in this area.'"

Moving from an alphabet soup of credentials in addiction practice to uniform acronyms would help to highlight the addiction-specific skills essential to serving the population with substance use disorders, Tuohy suggests. She said leaders at NAADAC and the International Certification & Reciprocity Consortium have recently participated in meetings where topics such as this and greater portability of credentials have been discussed. Tuohy hopes all affected groups can continue discussing these crucial subjects.

Schmidt added that in the area of certification, NAADAC in the coming weeks is rolling out both a credential for peer recovery specialists and a certificate in tobacco cessation prevention, education and treatment. The peer specialist credential is designed for individuals with lived experience who work in treatment programs as part of a team and who offer wraparound services, but not direct treatment or 12-Step work, Schmidt said.

He expects intense interest in pursuing the peer specialist credential, saying, "This is an up-and-coming body of providers." •

Counseling with bupe: It doesn't hurt, but does it help?

Is counseling necessary for patients on buprenorphine? For physicians prescribing buprenorphine for the treatment of opioid use disorders, the answer from the American Society of Addiction Medicine (ASAM), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the research literature is gradually coming into focus, but it's still far from clear. And while some say that's the way it should be in the practice of medicine, the fact remains that for patients in opioid treatment programs (OTPs) — clinics licensed to dispense methadone as well as buprenorphine — there is no choice. Counseling is required for all OTP patients.

Asked why counseling would be required for OTP patients but not patients in office-based opioid treatment (OBOT), David A. Fiellin, M.D., the researcher whose clinical trials got buprenorphine approved to treat opioid use disorders, said, "I have not seen research to address this." However, he did refer us to four studies that indicate from zero to modest benefits for counseling. "I don't think anyone advocates for no counseling," he told *ADAW* last week. "I think the issue is determining if outcomes are improved with counseling above and beyond physician management." Fiellin, who is professor of medicine, emergency medicine and public health at the Yale School of Medicine, used "medication management" visits with patients in trials. We read the studies (not for the first time) and summarize them briefly below.

- In 2011, a Cochrane review found no benefits conferred by psychosocial counseling in addition to agonist treatments for opioid dependence.

(Amato L, Minozzi S, Davoli M, Vecchi S. Psychosocial combined with agonist maintenance treatments versus agonist maintenance treatments alone for treatment of opioid dependence. *Cochrane Database Syst Rev* 2011 Oct 5; (10):CD004147. doi: 10.1002/14651858.CD004147.pub4.)

- In a study that was commissioned by ASAM and published in the *Journal of Addiction Medicine* (which is published by ASAM), Karen Dugosh, Ph.D., and colleagues summarize literature showing a modest benefit of psychosocial interventions, but conclude that the research is skimpy and more is needed. "As opioid use and overdose deaths in this country exceed epidemic proportions, the urgency for an expanded research agenda on best practices for comprehensive treatment could not be more critical," they conclude. (Dugosh K, Abraham A, Seymour B, et al. A systematic review on the use of psychosocial interventions in conjunction with medications for the treatment of opioid addiction. *J Addict Med* 2016 Mar–Apr; 10(2):93–103. doi: 10.1097/ADM.0000000000000193.)
- In a commentary on the Dugosh paper also in the *Journal of Addiction Medicine*, Robert P. Schwartz, M.D., of the Friends Research Institute writes that the review itself was flawed by using too many vague outcomes such as "retention" in treatment instead of the sole outcome of illicit opioid use. He concludes, "Physicians should be encouraged to use these medications to treat their opioid-addicted patients and not be discouraged by the fact that they cannot by themselves address all of the additional psychosocial problems a particular patient might have. If this was the way medicine was practiced, many patients would not receive medical care." (Schwartz RP. When added to opioid agonist treatment, psychosocial interventions do not further reduce the use of illicit opioids: A comment on Dugosh et al. *J Addict Med* 2016 Jul–Aug; 10(4):283–285. doi: 10.1097/ADM.0000000000000236.)
- And this summer, in *AJP in Advance*, the researchers Kathleen M. Carroll, Ph.D., and Roger D. Weiss, M.D., reviewed literature showing either no benefit or some benefit from counseling. They had some questions about research design, and concluded that there is a clear conflict between the need to expand access to buprenorphine and the need for quality care. "[W]hile efforts to expand buprenorphine access are essential and urgent, there remains considerable room for improvement, given 6-month retention rates of about 50 percent and the significantly higher risk of relapse, overdose, and death that is associated with dropout," they write. "Given these risks, we must find means of improving retention in office-based buprenorphine maintenance." (Carroll KM, Weiss RD. The role of behavioral interventions in buprenorphine maintenance treatment: A review. *Am J Psychiatry* 2017 Aug 1; 174(8):738–747. doi: 10.1176/appi.ajp.2016.16070792. Epub 2016 Dec 16.)

ACA is alive and well; GOP gives up on repeal

Congressional Republicans, despite vowing for 8 years to repeal the Affordable Care Act and having a President in the White House for whom this was a key campaign issue, last weak admitted defeat, conceding that they did not have the votes to repeal what has turned out to be a very popular health care law. A bill crafted by Sens. Lindsey Graham (R-South Carolina) and Bill Cassidy (R-Louisiana) would have drastically cut Medicaid (see *ADAW*, September 25). Using special rules that require only 50 votes to pass, the Senators had hoped to bring the bill to a vote by the deadline for that authority — Sept. 30.

In the meantime, in states that did not set up their own exchanges, the White House has pulled advertising dollars from Healthcare.gov, making it very difficult for people in those states to find out about how to enroll in ACA plans.

High-volume prescribers

While leaving physicians who treat 100 or fewer patients with buprenorphine off the hook for paperwork, those who prescribe for more than that — up to the cap of 275 — will have to at least fill out an annual form telling the government how many patients are getting some kind of counseling. Last year, when SAMHSA raised the cap — the number of patients one doctor can treat with buprenorphine — from 100 to 275, it was clear that the counseling and drug testing requirements that had been in the proposed rule were dropped (see *ADAW*, July 11, 2016). At that time, the proposal that physicians prescribing at the 275 cap would have to submit additional paperwork was temporarily put on hold.

Last September, however, SAMHSA issued a final rule calling for physicians prescribing at the cap to file paperwork indicating that they would need to "report on the number of patients provided behav-

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ioral health services and referred to behavioral health services," according to the final rule (https://www.federalregister.gov/documents/2016/09/27/2016-23277/medication-assisted-treatment-for-opioid-use-disorders-reporting-requirements). While not the same as a requirement to provide services, the reporting requirement "will strike the appropriate balance between collecting valuable information needed to assess compliance with the rule and avoiding undue burden on practitioners," according to the final rule.

"Based on law and regulation, health care professionals have varying levels of responsibility with regard to assuring patients receiving buprenorphine receive psychosocial services," said Melinda Campopiano, M.D., medical officer for SAMHSA's Center for Substance Abuse Treatment, in an email to *ADAW* last week. "Prescribers with the lower patient limits must be able to provide a referral for appropriate services," she said. "Prescribers with the higher patient limit must coordinate these services or provide them directly. The training health professionals must complete to obtain a waiver to prescribe buprenorphine for opioid use disorder covers not only pharmacotherapy, but also the need and importance of psychosocial services to establishing and maintaining recovery." Asked how SAMHSA knows if providers are complying, she responded, "This, like many other aspects of medical practice, can be enforced by state medical boards if standards are not being met."

Interestingly, Indivior, which makes the Suboxone brand of buprenorphine, does insist on counseling, regardless of how many patients are being treated by one physician. "Suboxone Film, a prescription medicine indicated for treatment of opioid dependence, should be used as part of a complete treatment plan to include counseling and psychosocial support," a company spokesman told *ADAW* last week. "Treatment should begin under the supervision of a doctor. The doctor must be qualified under the Drug Addiction Treatment Act of 2000. In appropriate patients, treatment may continue at home with follow-up visits to a doctor at reasonable intervals."

Coming up...

The **International Drug Policy Reform Conference** will be held **Oct. 11–14** in **Atlanta**. Go to **www.reformconference.org/sites/reformconference.org/files/2017-09/2017_dpa_reformconf_program_v3_0.pdf** for more information.

The **Association for Medical Education and Research in Substance Abuse** will hold its 41st annual national conference **Nov. 2–4** in **Washington, D.C.** For more information, go to **https://amersa.org**.

ASAM view

ASAM, which has consistently opposed caps and other regulations that would limit access to buprenorphine, and which in review courses tells physicians counseling is not necessary, suggested we talk to Yngvild Olsen, M.D., M.P.H., for more information on the topic of counseling. Olsen, who is medical director for the Institutes for Behavior Resources/REACH Health Services in Baltimore City, has both OBOT and OTP patients, and uses both methadone and buprenorphine in treatment. "The DATA 2000 law essentially says that a DATA 2000 waivered physician needs to be able to refer a patient to counseling," she said. "But by law, counseling is not required, unlike with the rules for OTPs, where counseling is part of the regulation, something that is required."

"In office-based treatment, there are patients with different degrees of severity of opioid use disorder," she said. Isn't this also true in OTPs? "I don't know that you can equate OTPs and office-based models, because the severity of the patients may be different," she said. "Even in the OTP world, when you try to make it one-size-fits-all, it doesn't always work. In the OTP world, if you don't attend your mandated counseling sessions, you get kicked out of care, and that isn't good either."

ASAM, for its part, refers prescribers to its guideline, which states that "psychosocial treatment is recommended for patients being treated with buprenorphine," said Susan Awad, ASAM director of advocacy and government relations. The guideline also notes, however, that "the evidence for benefits of such psychosocial treatment is mixed," she said. "But it still recommends clinicians should consider providing or referring patients to services such as cognitive behavioral therapy, contingency management, relapse prevention and/or motivational interviewing." Awad added that ASAM has "opposed payer policies that would require counseling as a condition for covering the prescription costs of buprenorphine," she said. "While clinically recommended, it should not be made a barrier to pharmacologic treatment." •

In case you haven't heard...

It's not only the alcohol that can hurt your liver — in fact, diet, not total alcohol consumption, can affect the severity of liver disease, according to a new study published in *Alcohol and Alcoholism*. In particular, saturated fat may protect your liver, according to the study, which was conducted on rodents. While high alcohol content is definitely bad for your liver, your gut "microbiome" may play a critical role. The study is titled "Use of a Crossed High Alcohol Preferring (cHAP) Mouse Model with the NIAAA-Model of Chronic-Binge Ethanol Intake to Study Liver Injury."