HHS will revise buprenorphine regulations — cautiously

The federal Department of Health and Human Services (HHS) is going to revise the rules governing the prescription of buprenorphine for the treatment of opioid use disorder. As HHS Secretary Sylvia Burwell announced on September 17, the change is needed to expand access to treatment in the face of an opioid epidemic. However, Richard G. Frank, Ph.D., assistant secretary for planning and evaluation at HHS, explained that this is going to be done cautiously. "It’s not a wholesale lifting of the cap," Frank told ADAW last week.

Currently, physicians can treat only 30 or 100 patients at any time with buprenorphine, depending on their level of training. “We’re looking at ways of revising the regulations around the caps, and to do so in a way that both encourages evidence-based treatment, making sure that counseling and drug testing are in place, and at the same time minimizes diversion,” Frank said.

There will be a Federal Register Notice of Preliminary Rulemaking.

Bottom Line…

Interview with Richard G. Frank, Ph.D. on the forthcoming rulemaking on patient caps and buprenorphine.

Clinic chain stays the course, seeks buprenorphine-friendly locations

As the potential for wider access to buprenorphine treatment inches closer to reality, a treatment facility chain that has developed an innovative way of delivering that service finds itself in an ironic position in some communities. Sometimes in the same geographic area, CleanSlate Addiction Treatment Centers has some people desperately wanting to pull it in and others eagerly seeking to push it out.

"Because the profile has gone up, we see an increase in ‘NIMBY’ reactions,” CleanSlate medical director Kelly Clark, M.D., told ADAW. “But there also has been an increase in outreach from hospitals and health plans for us to set up services at the hospital or for plan members.”

Where there is resistance to CleanSlate, a chain with 12 clinic sites providing buprenorphine and supportive counseling in Massachusetts and one newly opened clinic in Pennsylvania, it is not always from nervous homeowners. Clark said her organization recently had to relocate...
Frank from page 1
which will have a comment period.
“We are working on getting it done as fast as we can,” said Frank.

What’s happening now?
One of the problems with the current situation is that nobody knows what physicians currently prescribing buprenorphine are doing. Are their patients getting counseling? Are they getting drug-tested? Are they getting better? These questions have been asked at several public meetings, including at the buprenorphine forum convened last year by Sen. Carl Levin, which H. Westley Clark, M.D., then director of the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA); Michael Bottonelli, director of the Office of National Drug Control Policy; and Nora Volkow, M.D., director of the National Institute on Drug Abuse, attended (see ADAW, June 23, 2014).

More recently, Clark voiced these questions at the American Society of Addiction Medicine (ASAM) conference this year, when he clearly said it was more important to increase the number of physicians providing buprenorphine than to lift the cap, and expressed concerns about the lack of regulation of buprenorphine compared to opioid treatment programs, which provide methadone along with comprehensive services (see ADAW, May 4). “Buprenorphine ‘clinics’ spawned by increasing or eliminating the caps would not have the federal and state regulatory controls that Opioid Treatment Programs have,” as his final slide noted.

These concerns are in the mind of Frank, who is viewed as the engine behind the expansion efforts. As a result, he said that HHS will “measure and evaluate very carefully what happens in response to revisions to the regulation, and we will take action.” We asked if there would be any changes to make it possible to conduct such evaluations. “We will do a lot of data evaluation,” he said.

“We’ve been doing a lot of work to understand” why so many physicians who are waivered are not prescribing buprenorphine, Frank said. “We’ve been in touch with the major medical societies, with ASAM and others, and we’re planning to do some research into what’s going on in terms of certification and prescribing patterns.”

Many physicians say the induction process and the time and work involved in treating people with substance use disorders puts off some physicians from actually providing buprenorphine treatment. “What people tell you and what the data tell you are very often different things,” said Frank. “That’s why we’re collecting data, but it’s too early to come to strong conclusions.”

Why the delay?
Last fall, SAMHSA held a two-
day buprenorphine summit that specifically focused on lifting the patient caps (see ADAW, Sept. 29, 2014). Why did it take so long for there to be any movement toward doing this? “First of all, the secretary didn’t get here until a year ago and it wasn’t on the top of the list until a little over a year ago,” said Frank. “There is also a level of uncertainty about what’s going on — on the one hand, we believe it’s important to expand capacity, but we need to be cautious.” The caution is because of the need for counseling and drug testing, and it’s not known whether current buprenorphine prescribers are doing this. “The effectiveness of medication-assisted treatment depends tremendously upon having all the components in place — prescriptions, counseling and drug testing — the whole comprehensive package,” said Frank.

In addition, certain providers may be better suited to buprenorphine expansion than others. For example, there is Stuart Gitlow, M.D., who has an addiction practice on Nantucket, an island off the coast of Cape Cod in Massachusetts, who told ADAW he could easily treat 300 to 500 stable patients (see ADAW, Aug. 31). On the other hand, there are providers who have little or no background in behavioral health care beyond the eight hours of training required for the buprenorphine certification. Frank said this will be key to the revisions. “We’ve been trying to understand which types of practices are best positioned to do evidence-based MAT,” he said.

Finally, HHS is concerned about the risk of diversion, said Frank. “There are a lot of different stories about diversion — literally some people come in and say, ‘There’s diversion, but it’s not dangerous diversion, because buprenorphine doesn’t give you a good high.’ Then other people say diversion contributes to the opioid epidemic because people use buprenorphine when they can’t get anything else. What is true?”

There is also the remaining question about why so few physicians who are already waivered to prescribe buprenorphine are doing it. “Why is it that so few physicians are anywhere near the cap?” he asked. “All of these things have led us to take a cautious approach.”

Meanwhile, there are several pieces of legislation under review in Congress that address the cap issue. “We are working with colleagues on the Hill to work on legislation that hits common ground,” said Frank.

AATOD and ASAM on revising buprenorphine regulations

The American Association for the Treatment of Opioid Dependence (AATOD) and the American Society of Addiction Medicine (ASAM) have decidedly different views on lifting the patient caps on treatment with buprenorphine (see story, beginning on page 1): AATOD is opposed, and ASAM is for it. The reasons are clear: AATOD represents opioid treatment programs (OTPs) that treat patients in highly regulated clinics, mainly with methadone, whereas ASAM represents office-based physicians who treat patients in their offices with buprenorphine. The Substance Abuse and Mental Health Services Administration (SAMHSA) has oversight over both methodologies. We talked to AATOD President Mark Parrino and ASAM Past President Stuart Gitlow, M.D., about the plans by the Department of Health and Human Services to revise the buprenorphine regulations. The interviews were conducted separately, but we asked the same questions.

ADA W: Why are so many physicians who are waivered to prescribe buprenorphine not doing it, and even those who are are not anywhere near the cap?

Gitlow: For every doctor out there for whom this is a significant component of their practice, all of us have coverage issues. If I go away and I’m unavailable, I want to make sure I have proper coverage. It means that two-thirds of the doctors are simply there to provide coverage. They shouldn’t be bumping up against their caps.

Parrino: When Richard Frank asked me that question, my answer was, if you authorize SAMHSA to do a randomized survey among your existing 10,000 or so physicians who are actively prescribing and ask them that question, you will be able to make an informed decision. Generally, if a physician has 50 buprenorphine patients and there’s no one else to treat them while they’re away, usually on a two-week vacation, they make sure that medication management is covered.

A: Should counseling be required as part of medication-assisted treatment?

G: There is no literature that clearly indicates that providing counseling helps.

P: I was a clinic director for 18 years and had 450 patients on any given day. I spent my time creating therapeutic approaches for the 45 counselors who worked there. Counseling does make a difference, especially if you have a trained, informed staff. And there is John Ball’s work.

A: Dr. Gitlow says he could easily treat 300 to 500 stable patients — why is this not the case for everyone?

G: I’m in a group of physicians who specialize in addiction. I’ve done nothing else for 20 years, so for us to have stable patients is not surprising. Every one of my patients is seen by two psychiatrist — I don’t know that everybody does this. It would be wonderful to take people off our waiting list.

P: Dr. Gitlow is representing his own practice based on the unique patient characteristics that he treats.

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— the problem is you can’t make broad-based national policy decisions based on one practice. If he wants special rules, he can do what SAMHSA suggested to him — convert to an OTP and treat 500 patients.

**A:** If buprenorphine treatment in an office is made more accessible, will OTP patients want to leave their OTPs and go to the much less restrictive office-based setting with buprenorphine?

**G:** What would be wrong with that?

**P:** That reality has been in existence for 10 years. OTP patients already think that: “In column A is the OTP, where I have to go in every day for 90 days, I have to have counseling for 90 days, to taper off of buprenorphine, said Flattery. “Kevin was required to taper off of buprenorphine in one week,” he said. “After the abstinence-only facility, without his MAT support, he overdosed.”

**Enforcement**?

Whether the guideline will be codified and enforced is another question, which ADAW posed to Frank at the press conference. He responded that HHS will “make use of information such as what is contained in the guidelines to allow us to better direct the money that we spend on grant programs that are best equipped to deliver evidence-based treatment,” so following this guideline might be tied to certain federal grants.

That means that private addiction treatment programs that don’t get any grants can continue to provide “abstinence-only” treatment, with no enforcement of the guide-

Federal officials join ASAM in guideline announcement

On September 24, when most of Washington was transfixed by the papal visit, a core group of “stakeholders” was at the National Press Club, where the American Society of Addiction Medicine (ASAM) released an app and pocket guide to go with its *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*. The actual guideline was released last spring (see *ADAW*, June 15), so the real purpose of the gathering was not the guideline itself, but a broader discussion about medications to treat opioid use disorders.

“This is a problem that has not been treated well in our country,” said Margaret Jarvis, M.D., chair of ASAM’s quality improvement council, which led the development of the guidelines.

Jarvis, along with Nora Volkow, director of the National Institute on Drug Abuse (NIDA); Kana Enomoto, acting administrator of the Substance Abuse and Mental Health Services Administration; Richard Frank, Ph.D., assistant secretary for planning and evaluation at the Department of Health and Human Services (HHS); and June Sivilli, treatment branch chief at the Office of National Drug Control Policy, all declared the same thing: medications to treat opioid use disorders — methadone, buprenorphine and naltrexone — are effective and should be used by treatment programs. Thomas R. Frieden, M.D., MPH, director of the Centers for Disease Control and Prevention, talked about his agency’s

### ‘Kevin was required to taper off of buprenorphine in one week. After the abstinence-only facility, without his MAT support, he overdosed.’

Don Flattery

Don Flattery’s voice broke when talking about his 26-year-old son, Kevin, who died just over a year ago from an opioid overdose. “He tried inpatient detox, 28-day abstinence only, but like many others in pursuit of recovery, he was in a cycle of recovery and relapse,” Flattery said. “Painfully I have learned about evidence-based treatment, and the most significant lesson was about medication-assisted treatment [MAT].” Kevin had gone to AA and NA meetings, where he got “lectures about self-control, and appealing to a higher power,” said Flattery. “Few if any other diseases are treated this way.” ASAM’s practice guidelines makes it clear that it takes months, not days, to taper off of buprenorphine, said Flattery. “Kevin was required to taper off of buprenorphine in one week,” he said. “After the abstinence-only facility, without his MAT support, he overdosed.” It is indeed well-documented that people who are no longer in MAT are at their highest risk of an overdose after discharge, noted Flattery. He now travels around “telling people to avoid abstinence-only facilities, which are only contributing to opioid overdose deaths.”
A tale of two sectors

By John de Miranda, Ed.M., L.A.A.D.C.

Early in my career it seemed that many who worked in the alcohol and drug problems field wanted to find jobs in the private employee assistance (EA) sector. Those folks were at the top of the workforce status hierarchy in the 1980s, and it was easy to conjure visions of working in an executive suite for United Airlines or Chevron Oil and pulling down a six-figure salary. Lurking in the background were the ethical issues associated with the EA professional’s primary allegiance to the corporation, and the individual client only secondarily.

The reality for many of us, however, was to find work on the other side of town in public-sector, community-based nonprofits where a suit, tie and briefcase were definitely not part of the dress code. We could console ourselves with the belief that working with low-income, indigent and/or homeless individuals was a morally superior calling, but wouldn’t it be nice to do this work and be paid more than just a living wage?

This kind of private-treatment envy has occurred for some of us more recently as we’ve heard about the astronomical rates charged by so-called high-end treatment facilities. The onslaught of television ads for facilities that “cure” addiction and the glossy photos in our trade publications are never-ending. Wouldn’t it be nice to work in a beachfront treatment program, eat gourmet meals with the clients and provide insightful consultation drawing from our own recovery path?

Unfortunately, recent press accounts indicate that the high end of the substance use disorder (SUD) field is also ethically challenged. The private sector’s shady marketing practices, substandard care and chronic overpromising have all been documented in recent press accounts, books and documentary films. The low point has been reached with the California Department of Justice charging several high-end treatment administrators with homicide for a patient death allegedly caused by negligence.

Contrast this with the thousands of SUD professionals who go to work every day in public-sector programs to share their “experience, strength and hope” with those on the lower rungs of the socioeconomic ladder. There the ethical challenges are more likely to involve the distribution of limited resources to a population with unlimited needs or, perhaps, how to finesse governmental regulations that can be both labyrinthine and burdensome.

Similarly, while professional counselor codes of conduct strongly encourage attention to self-care, most of the counselors I know work long hours for low pay, and regularly put their own health at risk in order to carry the message.

New prospects improving for California to build a more effective public-sector addiction treatment service because of the recent approval of a Section 1115 waiver from the federal Center for Medicare & Medicaid Services (see ADAW, Sept. 14). While the devil is always in the details, those of us working in the public-sector trenches may finally have some new tools to improve supports for our clients and create the “good and modern addiction treatment system” that is needed.

So, all things considered, today I’m glad to be working on the public-sector side of town.

John de Miranda, Ed.M., L.A.A.D.C., is associate director of Door to Hope, a comprehensive behavioral health organization based in Salinas, California. The opinions expressed do not necessarily reflect the opinions of his employer. He can be reached at (650) 218-6181 or solanda@sbcglobal.net.
Study calls for integrating housing with treatment

Integrating housing with treatment and recovery support would improve outcomes for people with substance use disorders (SUDs), according to a report from the Corporation for Supportive Housing (CSH) and the National Council on Behavioral Health. The report, released last week, comes a year after the two organizations met in a remarkable meeting devoted to housing and people with SUDs (see ADAW, Nov. 10 and 17, 2014).

“Over the past decade, addiction treatment providers across the U.S. have shifted to treatment plans focused on self-management skills with a goal of lifelong recovery,” said Becky Vaughn, vice president of Addictions for the National Council, in releasing the report September 22. “There also is growing knowledge that housing status is a determinant of all health, and we need to ensure those seeking treatment for SUDs have access to both to underpin their stability and progress.”

“Medicaid expansion, health homes and other initiatives arising out of the Affordable Care Act (ACA) are creating unprecedented opportunities to finance integrated models of housing and recovery support services for individuals with substance use disorders,” said Janette Kawachi, CSH director of innovations and research and Vaughn’s co-author of the report. “ACA provisions have expanded Medicaid to provide benefits for individuals with low incomes experiencing homelessness and SUDs. All of this is moving the discussion on integration forward.”

Key recommendations for policymakers in the report include:

- **Systems Change:** Promote integration of housing, treatment and recovery support systems at the federal, state and local levels by hosting summits; providing technical assistance; educating the supportive housing community about integrating recovery; shifting SUD services from acute care to a model that fosters quality of life and wellness; working with the Substance Abuse and Mental Health Services Administration to increase the role of housing systems in its Recovery-Oriented Systems of Care efforts, and incorporating housing supports in funding mechanisms; and reducing stigma for people with SUDs.

- **Education:** Cultivate and disseminate models in the housing field for best practices for serving people with SUDs, including families, by reviewing evidence on different models such as supportive housing, Housing First (in which people with SUDs do not have to be in recovery before getting housing), harm reduction and recovery housing.

- **Practice Change:** Improve practice by building the capacity of supportive housing and recovery housing providers, including facilitating the intake and assessment process, providing technical assistance in the areas of housing development and best practices, and developing a practice manual on how to service individuals and families with SUDs in supportive housing.

The meeting and report were sponsored by the Melville Charitable Trust, which has the goal of ending homelessness.

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one of its clinics from a medical building shortly after it began operation, because other medical professionals practicing at the site did not want to be co-located with an office that served the opioid-addicted.

“This was simply a matter of stigma,” said Clark, who declined to identify the Massachusetts community where this occurred. “We had been asked to come to the area by the local hospital, which is helping us to relocate.”

Supporting HHS move

Clark supports the spirit of the federal government’s intent to revisit the current federal rule governing buprenorphine treatment in order to expand access to care (see top story, page 1). “Any restrictions that get in the way of access to good quality care need to be changed,” she said.

It doesn’t appear that the Department of Health and Human Services’ announcement will alter CleanSlate’s own growth plans in the immediate term. Clark said that without seeing the specifics of a revised rule, it is impossible to know what kinds of treatment facilities or initiatives might emerge from the changed landscape — and therefore whether and what kind of new competitors might eventually surface.

CleanSlate (see ADAW, April 20, 2015; Oct. 20, 2014) is the only organization of its type serving the opioid-ravaged Northeast.

CleanSlate, which next month will open its second Pennsylvania site (a Scranton location will join a Wilkes-Barre clinic that began operation earlier this month), continues to look for states and health plans with which to partner. This is in keeping with its perspective to go to communities where its services are wanted.

“Some states really understand the evidence base of medicine,” she said, with particular leadership from health and Medicaid department...
Current services

Clark said CleanSlate is currently serving around 4,400 patients, with the vast majority using buprenorphine and around 150 taking injectable naltrexone (Vivitrol). It does not favor use of oral naltrexone because of challenges around patient compliance. It is using a variety of formulations of buprenorphine, often dependent on the preferred agent listed on the formulary for the patient’s health plan.

The company’s structure of using part-time doctors who visit its clinic sites to see patients in group settings means it could ramp up the number of patients it serves considerably, regardless of whether current federally imposed patient limits are loosened.

Clark says the most common pathway to one of the clinics involves a patient who has been treated in a detox and/or inpatient drug-free setting in the past and received no medication support at discharge. Also, some individuals who have received methadone treatment in an opioid treatment program may decide based on convenience that they would prefer to go to the buprenorphine clinic a couple of times a week rather than the methadone program daily, she said.

For her business, some of the factors that have changed in the six years since it has been open include the positive of a stronger evidence base for the treatment and the negative of more problems with diversion. Clark said she does not believe buprenorphine patients should be singled out in how a prescription drug monitoring program is applied. If a patient is seen at a clinic twice a week, such a requirement would be “unduly burdensome,” she said.

DiGirolamo says he certainly does not want to do away with buprenorphine treatment altogether. But he adds, in reference to the way it is generally being delivered in his state, “I think it’s way off course.”

Warnings from legislator

Even in the state CleanSlate chose as its second location, not all leaders are relishing the thought that patient limits for buprenorphine treatment could be relaxed. Pennsylvania State Rep. Gene DiGirolamo, who chairs the House Human Services Committee and has sponsored numerous addiction-related initiatives over the years, says buprenorphine diversion has become a major problem in the state, fueled by prescribers establishing cash-only practice sites and patients shopping for doctors and distributing the drug to others.

“One hundred [patients] was too many,” DiGirolamo told ADAW, referring to the maximum limit in the current federal regulations.

DiGirolamo says he sees very little counseling or drug monitoring associated with most of the buprenorphine treatment that physicians are delivering in Pennsylvania. He has introduced two bills in the legislature. One would add buprenorphine to the work plan of the methadone death and incident review team that comes under the auspices of the state Department of Alcohol and Drug Programs. The other would require prescribers of buprenorphine to check the state’s prescription drug monitoring database every time a script is written for a patient, not just the first time that a patient is seen.

Clark said she does not believe buprenorphine patients should be singled out in how a prescription drug monitoring program is applied. If a patient is seen at a clinic twice a week, such a requirement would be

‘Because the profile has gone up, we see an increase in “NIMBY” reactions.’

Kelly Clark, M.D.
Continued from previous page
the case applies equally to substance use disorders and mental illness.
For a copy of the ruling, go to www.nypsych.org/assets/docs/ubh%20decision%208-20-15.pdf.

Hospital chain to buy Foundations
For-profit Foundations Recovery Network will be purchased by Universal Health Services (UHS) for $350 million, according to a September 18 press release from the Pennsylvania-based acquiring hospital company. There will be 322 additional residential beds in four facilities and eight additional outpatient centers, according to the press release, which cited the “sophisticated direct to consumer marketing model which includes a call center, a national sales team and an industry leading web marketing program.” The acquisition “will serve as a platform for growth in a new substance use disorder service line” for Universal Health Services. “We were attracted to their proven track record of providing high quality treatment and reputation for excellence in this very attractive market segment,” said Alan B. Miller, CEO and chairman of the board of Universal Health Services, of Foundations. “Demand for evidence-based, high quality substance-use treatment is driving the immediate need for additional services nationwide,” said Rob Waggener, CEO of Foundations. “With access to UHS’s broad market presence, we hope to ramp our pace of growth exponentially.” Joby Pritzker, spokesperson for the Pritzker family, the majority shareholder of Foundations, said, “UHS is a company which we trust to further our commitment to the treatment of addiction.”

Resources
AATOD presents webinars on patient exception requests
The American Association for the Treatment of Opioid Dependence (AATOD) is offering webinars on the use of an extranet for patient exception requests using form SMA-168. These requests, in which opioid treatment programs (OTPs) ask for exceptions to rules about take-home methadone for certain patients and other issues, are being made simpler through the Web-based OTP extranet system operated by the Substance Abuse and Mental Health Services Administration (SAMHSA), which regulates OTPs. Utilizing SAMHSA’s extranet system will be faster than the fax method currently in use by many OTPs. By using one of the four types of accounts — counselor, program physician, program sponsor and program director — the turnaround will be faster. This is particularly important because SAMHSA anticipates getting a greater number of exception requests, all of which will need to be coordinated through the State Opioid Treatment Authorities. The extranet requests go directly to SAMHSA. The newly updated electronic manuals are being developed by the American Institutes for Research, which will conduct the webinars. Each presentation will be followed by a 10-minute Q&A session. The first webinar was Thursday, September 24, for counselors. Upcoming will be webinars for program physicians (October 8, 1:30–2:30 p.m. ET), program sponsors (October 15, 1:30–2:30 p.m. ET) and program directors (October 19, 1:30–2:30 p.m. ET). To register, go to www.aatod.org/four-role-specific-otp-extranet-account-webinar-series.

Coming up…
NAADAC, the Association for Addiction Professionals will hold its 2015 annual conference and Hill Day October 9–13 in Washington, D.C. For more information, go to www.naadac.org/annualconference.
The annual educational conference of the International Nurses Society on Addictions will be held October 21–24 in Charlotte, North Carolina. For more information, go to www.intnsa.org/conference.
The 39th annual national conference of the Association for Medical Education and Research in Substance Abuse will be held November 5–7 in Washington, D.C. Go to www.amersa.org for more information.
The National Prevention Network Conference will be held November 17–19 in Seattle. For more information, go to www.npnconference.org.

In case you haven’t heard…
Last week, eight select reporters, including the editor of ADAW, received an email from public relations giant Edelman about participating in voluntary interviews to help a federal health agency with its “messaging” — a word that lends itself more to advertising than news. It turns out the agency was the Substance Abuse and Mental Health Services Administration (SAMHSA), which had engaged the firm to do the outreach. Reporters who volunteered would be allowed to designate a charity to which Edelman would donate $175. The catch? All of the information obtained in the interview — which ADAW did not do — would be “confidential.” In this space, we would like to commend Bradford Stone and his colleagues for the help they provide as press officers at SAMHSA, as well as Mark Weber, deputy assistant secretary for public affairs at the Department of Health and Human Services. If any health agency needs guidance about what to tell reporters, they don’t need to pay a public relations agency to find out. They can just be transparent, answer questions directly and provide sources without minders. Nobody needs another layer of spin.