Draft OTP guidelines include major role for midlevel providers

The draft guidelines for opioid treatment programs (OTPs) are out, and include a key change that is welcome by the facilities, which dispense methadone and buprenorphine for opioid addiction treatment. Under the guidelines, nurse practitioners and physician assistants (“midlevel providers”) will have the same authority as physicians for many tasks. The guidelines, issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) May 16, have a comment period ending July 16.

The rationale for the change is workforce: put simply, there aren’t enough physicians, especially in rural areas, said Robert Lubran, director of the Division of Pharmacologic Therapies at SAMHSA’s Center for Substance Abuse Treatment. “Workforce is a critical issue in terms of the ability of programs to hire physicians,” Lubran told ADW. “Rural areas tell us they can’t get doctors to work in rural areas of the state.” In addition, healthcare reform will further put pressure on the OTPs to find staff, especially in rural areas.

Even amid the chaos surrounding implementation of health reform, Medicaid expansion and other changes affecting addiction treatment centers, a consultant who co-founded an outpatient women’s treatment program is advising leaders of nonprofit facilities to give their staff members the license to sit back and dream.

“Nonprofits can have a tendency to be stuck in a rut, as they have gotten very used to managing how far their budgets can go,” Jill Gresham, a California-based coach and consultant who this July will present a 75-minute workshop for behavioral health professionals on entrepreneurship in nonprofit organizations, told ADW. “Rural areas tell us they can’t get doctors to work in rural areas of the state.” In addition, healthcare reform will further put pressure on the OTPs to find staff, especially in rural areas.

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The Business of Treatment

Nonprofit centers can ill afford to stay mired in the past

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Bottom Line…
CEOs, agency boards of directors and individual program managers all can play a pivotal role in encouraging staff members in addiction treatment organizations to be more entrepreneurial in their work.
OTP from page 1

ther increase demand for physicians, he said.

SAMHSA has already held a meeting with nurse practitioners on prescribing of buprenorphine, and with physician assistants about training, said Lubran. “There might be some pushback from the medical community,” he said. “My one concern would be that the midlevel providers have enough training and experience with addiction.”

Another concern may be the Drug Enforcement Administration (DEA), said Mark W. Parrino, president of the American Association for the Treatment of Opioid Dependence (AATOD). “The missing link is the DEA,” Parrino said of the guidelines. “These guidelines represent a significant evolution about how midlevels can be used,” he told ADAW. “I can’t imagine that the DEA would not have some response to that. The DEA has historically not supported the use of midlevels in dosage authority.”

The inclusion of midlevels represent an evolution on SAMHSA’s part as well. And while SAMHSA did share the draft with the DEA prior to releasing it, there was no response, said Lubran. “They did not express any concerns, so we went ahead and issued it,” he said. “We meet regularly with the DEA, and this is an issue that has come up before.” But SAMHSA and the DEA have different missions. “Their concern is diversion, and our concern is patient safety and quality,” said Lubran. “Once we get to the stage of finalizing it, we’ll sit down again with the DEA.”

**Telemedicine**

Another introduction to the guidelines is telemedicine, although this is the “weakest” section since it includes very little practical guidance, said Parrino. Again, the hold-up is probably the DEA, he said.

“We’ve been working with the DEA for over a year on this,” said Lubran of the telemedicine section. “There is very little in terms of rules or guidance on telemedicine in general. We’re feeling our way through this.” What is most likely to emerge is counseling, he said. “We’ll be pushing things like using technology for counseling, whether it’s mobile phones or Skype,” he said.

“There’s not a lot of research out there in terms of best practices, but there’s enough to suggest that this is an emerging field. We will encourage the use of that technology.”

A completely new area for the guidelines is Recovery Oriented Systems of Care (ROSC). This includes using peers, something that the MARS project in New York City is working on (see Resources, page 8).

**Diversion control**

Another issue that will probably draw comment from the DEA is SAMHSA’s diversion control plan, under which OTPs have randomized callbacks of patients who have been given take-home doses. Those patients, when called, must come into the clinic with their remaining medication. If they have prematurely used that medication, the clinician at the program must make a medical decision about next steps — this is left up to the physician’s discretion. But a different problem occurs when the patient has not used too much medication but is sedated. Under DEA rules, the OTP cannot take back any of the medication, because medica-
Workers’ comp insurers concerned about overuse of opioids

Insurance companies that cover workers’ compensation medical costs want to cut back on opioid prescribing, citing abuse, misuse and cost concerns, according to a comprehensive article in the current issue of Insurance Journal. Government-based solutions are shutting down pill mills and regulating prescribing via prescription drug monitoring programs, but insurance companies and pharmacy benefit managers can play a role as well.

Many workers’ compensation claims are for back injuries, and doctors frequently prescribe opioid analgesics for the pain. But Leonard J. Paulozzi, M.D., of the Centers for Disease Control and Prevention (CDC), said that long-term use of painkillers is not recommended for such injuries. Opioids should be used in the acute phase, but if they don’t help, they shouldn’t be continued, he said. One study found that 42 percent of back-pain patients were prescribed opioids during the first year, usually after the first visit, but that 16 percent of them were still getting opioids a year later.

Opioids account for 3 percent of short-term medical claims and between 15 and 20 percent of long-term medical claims, according to the Insurance Journal report. Medical costs constitute 60 percent of overall workers’ compensation claim costs, a percentage that is projected to rise.

Avoiding prolonged use

There are three main reasons for opioids being prescribed in workers’ compensation claims: catastrophic injury with chronic pain, an injury that results in surgery that requires immediate pain control and general pain control. In fact, opioids should only be prescribed for cancer-, AIDS- and surgery-related pain, the workers’ compensation insurers say, adding that for the latter, two weeks is the upper limit.

“The issue of opioid prescribing becomes even more important in workers’ compensation settings as prolonged opioid use has been shown to be associated with poorer outcomes, longer disability and higher medical costs for injured workers,” according to the 2012 Workers’ Compensation Drug Trend Report from Express Scripts.

Trey Gillespie, senior workers’ compensation director for the Property Casualty Insurers Association of America, said that opioids are being overprescribed, with long-term opioid use most prevalent in New York and Louisiana, followed by Texas, Pennsylvania, South Carolina, California and North Carolina.

Texas, which has a closed formulary, may cut back on the utilization of Schedule II drugs — which would include hydrocodone if it is rescheduled from III to II, as the...
Continued from previous page

FDA is considering doing (see AD&W, February 4).

Workers' compensation officials are concerned because they have to pay for the prescriptions, which can be very expensive, especially if patients are dependent on them on a chronic basis. "As the years progress, prescription medication becomes a bigger portion of the medical expense," Gillespie said. "This is especially true if the worker has become dependent or addicted to opioid medication to control pain. Consequently, payers are working hard to reduce the incidence of workers who become dependent or addicted to pain medication and look for better treatment alternatives to opioid pain medication to manage pain."

Getting back to work

Employers and workers' compensation insurance companies have long urged people to get back to work as soon as possible — saying that this is better for the individual, and of course it also cuts costs for the companies. In the Insurance Journal article, they expressed concern that people will feel entitled to stay away from work, and that if people are using opioids for pain relief on a long-term basis, that may interfere with their motivation to get back to work.

The opioids themselves are expensive as well. The California Workers’ Compensation Institute says opioid prescribing increased 300 percent between 2002 and 2011. In 2002, 1 percent of injured outpatients were prescribed opioids; in 2011, it was 5 percent. This meant that payments for opioid prescriptions increased accordingly — 321 percent.

Travelers recently recommended that "employers, brokers, and carriers proactively partner on timely intervention, proven return-to-work strategies and skilled case management to avoid unnecessary delays and expense in treatment."

By addressing opioid use and abuse, workers’ compensation insurance companies reduce both costs and liability — if the patient dies of an overdose, death benefits may have to be paid. "There has been case law in several states now where an injured worker overdosed on drugs that were prescribed by the work comp doctor and paid for by the work comp payer, and even though they obviously had a problem with the use of that drug — they were abusing it or misusing it," said Mark Pew, senior director of business development for PRIUM, a utilization review and cost-management company. "Ultimately, the insurance carrier had to pay for death benefits because they somewhat enabled the processor to pay for it."

"Our nation pays a huge price for bad medication-related decisions, and it is clear that the price is even more costly for those at the lowest end of the economic spectrum," said Steve Miller, M.D., chief medical officer at Express Scripts. "The good news is that our country can save billions of dollars for patients, employers and the government — and achieve healthier outcomes — simply by driving better decisions within the pharmacy benefit."

AGs ask FDA ‘black box’ warning on Rx opioids

Citing the risk of neonatal abstinence syndrome (NAS), the National Association of Attorneys General (NAAG) has sent a sign-on letter to the Food and Drug Administration (FDA) calling for a “black box” — the most serious — warning label on opioid analgesics — painkillers. Sponsored by Pam Bondi, attorney general of Florida, and Jack Conway, attorney general of Kentucky, the letter said that NAS “caused by maternal opiate use has increased at alarming levels.” NAS is the withdrawal syndrome newborn babies go through when their mothers were taking opioids — methadone or buprenorphine for addiction, or opioid analgesics for pain — on a long-term basis prior to delivery.

The letter includes a description of NAS as a “malfunction of the autonomic nervous system, respiratory system and gastrointestinal tract.” Withdrawal signs “may include: abnormal sleep patterns, tremors, vomiting, high-pitch crying, irritability, hyperactivity, seizures, weight loss and failure to gain weight.” What the letter does not say is that women who are dependent on opioids who go through withdrawal, even medically supervised withdrawal, during pregnancy put their fetus at risk.

Bondi and Conway both take a strong stance against prescription drug abuse, and as attorneys general view the problem more as one
of law enforcement than one of public health. They are the co-chairs of the NAAG substance abuse committee and are guiding the association’s substance abuse agenda, in which prescription drug abuse is elevated.

According to the letter, the black box warning “would help ensure that women of childbearing age — as well as their health care providers — are aware of the serious risks associated with narcotic use during pregnancy.” They suggest the following language for the content: “Warning: Use of narcotic analgesics in pregnant women may cause neonatal abstinence syndrome.”

The article cited a 2012 article published in the Journal of the American Medical Association on the costs of NAS — an article that gave rise to a barrage of headlines referring to babies as “addicted” (see ADAW, May 7, 2012). The letter also states that Medicaid paid for 77.6 percent of the costs.

Many studies of methadone

Stating that “there are NAS treatment protocols,” the letter added that data about optimal treatments is “sparse.” In fact, there is a solid body of literature on NAS for babies when the mothers were in methadone treatment for addiction, noted Charles P. O’Brien, M.D., professor of psychiatry at the University of Pennsylvania. “There are many studies of the use of methadone for addiction treatment in pregnant women,” he told ADAW. Methadone is so much safer for the fetus than heroin because it doesn’t have the peaks and valleys, he said. In addition, for women already on opioids, their fetus would go through a very dangerous withdrawal, he said. While there are not many studies on the use of opioids for pain for pregnant women, he said, “I think a pregnant woman in pain should be able to take opioids.”

O’Brien recalled that when he took his boards in neurology, he was given two infants to examine — both of whom had opioids in their system. “Both were being treated and were doing well,” he said.

“When top-ranking law enforcement officials make health care pronouncements it’s not surprising that they get it wrong,” said Robert Newman, M.D., director of the Baron Edmond de Rothschild Chemical Dependency Institute of Beth Israel Medical Center.

Noting that addiction is a medical problem, he said that “what should have been advocated is widespread public service announcements that dependence on opioids — prescription painkillers as well as illicit drugs such as heroin — can be treated with excellent outcomes for both mother and child, and that no treatment has been found to be as safe and effective as maintenance with methadone or, more recently, buprenorphine,” he said.

“Furthermore, with regard to the neonatal abstinence syndrome, the attorneys general seem oblivious to the fact that at the first signs of occurrence long-standing, evidence-based treatment protocols exist that can preclude the suffering they spell out in such detail in their letter,” he said. “When suffering does occur, it generally is an indication of inappropriate and/or inadequate care of the newborn.”

AGs urge ‘prevention’ of NAS

The AGs’ letter said that the “best course of action” is “prevention” of NAS, implying that pregnant women should not take opioids.

We contacted the press office of New York Attorney General Eric Schneiderman, who did not sign the letter, and the press office of Massachusetts Attorney General Martha Coakley, who did. Schneiderman’s office did not get back to us, and Coakley’s press officer declined to comment, except for saying they would let the letter “speak for itself.”

NAAG Communications Director Marjorie Tharp explained the sign-on process for letters. First, each letter needs two sponsors — a Democrat (Conway) and a Republican (Bondi). The two sponsors, who are also co-chairs of the association’s substance abuse committee, crafted the letter, and then asked NAAG to send it out to all 56 AGs — in all states and territories. “All the AG offices get a cover letter from the two sponsors explaining the topic, and then giving them the deadline by which to sign, or not sign, the actual letter,” Tharp told ADAW. If there are 36 or more signers, the letter is then sent.

There is no significance to an AG not signing a letter, said Tharp. “We don’t know what their reasons are,” she said.

The FDA did not respond to requests for information about their response to the AG letter.

‘When top-ranking law enforcement officials make health care pronouncements it’s not surprising that they get it wrong.’

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Nonprofits can innovate

Sara Moscato Howe, CEO of the Illinois Alcoholism and Drug Dependence Association (IADDA), does not believe that organizations that have historically operated one way cannot adopt a culture of change. Nor does she think that today’s tumultuous times should prevent organizations and their leaders from finding the time for creative thinking and planning.

“There are so many changes already happening right now that this might be the perfect time for organizations to think outside the box, and ask questions such as ‘What is our market?’ and ‘What other organizations should we align ourselves with in the community?’” Howe told ADAW.

Howe’s organization represents just over 50 addiction treatment organizations that have mainly served a public-sector treatment population; the overall number of members has decreased slightly in recent months because of provider agency mergers and consolidations. Another topic on the minds of most Illinois agency executives right now is preparing to serve more patients under Medicaid, as state legislators in late May approved a Medicaid expansion after much debate.

‘The nonprofits that have relied more on government funding have tended to have more risk aversion and be less likely to dream.’

Jill Gresham

Executives in IADDA member organizations acknowledge to Howe that their employees are worried about the implications of change, but many have seen the need to press on with efforts to innovate. She cited as a couple of examples Gateway Foundation, which has moved to become less dependent on government-funded services, and Haymarket Center, which has remained public-sector-focused but continues to establish innovative new programs in areas such as integrated care in partnership with a federally qualified health center (FQHC).

Howe does see some variation in the degree to which member agency CEOs are willing to consider out-of-the-box ideas, but she says that often serves more as a reflection of the agency board’s perspective than of the CEO’s own philosophy.

“The common denominator is in how the boards are directing them,” said Howe. “Some boards will communicate to the CEO, ‘We have 100 percent faith in you,’ while others will say, ‘This is who we are, and this is what we’ve always done.’”

In cases such as the latter, Howe often will be invited by a CEO to make presentations to the board on the changing healthcare market and why it might make sense to rethink traditional assumptions. IADDA also uses its annual conference and Howe’s periodic electronic communications to members to highlight emerging market opportunities, such as treatment for eating disorders that clinically resemble substance addictions, she said.

“The message is that the world is a lot bigger potentially than your current piece of the pie,” Howe said. •

Briefly Noted

Club drug ketamine may hold promise as antidepressant

A new experimental drug called esketamine may provide rapid — but short-term — relief from debilitating, suicidal depression, Reuters reported May 24. While it’s not news that ketamine holds promise for mental disorders, it is news that a major pharmaceutical company, Johnson & Johnson (J&J), will be seeking approval for a ketamine-derived depression treatment by 2017. Ketamine is also abused, as a “club drug,” along with Rohypnol and GHB (see ADAW, Dec. 22, 2008). Ketamine is used for conscious sedation for pediatric patients, and is injected. But the J&J product would be used intranasally. “Today you basically treat people and lock them up until the drugs take effect,” said Husseini Manji, head of neuroscience at J&J. But ketamine may completely change that process; usually antidepressant medication takes days or weeks to take effect. Last year, a National Institutes of Health (NIH) trial found the same thing: the agent, which was called AZD6765, works via the brain’s glutamate chemical messenger system, according to the NIH. Side effects include hallucinations. “Our findings serve as a proof of concept that we can tap into an important component of the glutamate pathway to develop a new generation of safe, rapid-acting practical treatments for depression,” said Carlos Zarate, M.D., of the NIH’s National Institute of Mental Health, which conducted the research. They reported their results online Dec. 1, 2012, in the journal Biological Psychiatry. In the NIMH small-scale (n=22) trial, about a third of the patients infused with the drug had a clinical response within 80 minutes, and the effects lasted half an hour.

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In this trial, there were only minor side effects — nausea and dizziness — that were no different from the patients on placebo. AZD6765 works like ketamine by blocking the same receptor — the NMDA. The J&J announcement, however, came out during an all-day meeting with financial analysts at the company’s headquarters in New Brunswick, New Jersey.

Lawyer: Soldier accused of Afghan killings was given alcohol, steroids
Staff Sgt. Robert Bales, accused of killing 16 Afghan civilians last year, was given alcohol and steroids by special operations troops, according to John Henry Browne, Bales’ lawyer, CNN reported May 29. Last year Browne said that “steroid use is going to be an issue in this case, especially where Sgt. Bales got steroids and how he got steroids.” Bales will plead guilty in exchange for avoiding the death penalty, said Browne. The argument about steroids and alcohol will be used to mitigate a life sentence, he said. A military hearing is scheduled for June 6. According to Browne, Bales has post-traumatic stress disorder, a traumatic brain injury, and is a “broken man” who never should have been in Afghanistan.

In case you haven’t heard...
A former Microsoft executive is starting a different kind of business in Seattle: his own medical marijuana brand, Reuters reported March 30. Jamen Shively, former corporate strategy manager for the software company, wants to become the Starbucks of medical marijuana dispensaries. He was at Microsoft for 6 years before he left in 2009. He is looking for $10 million in investment money for the marijuana startup. Two states, Washington and Colorado, have legalized marijuana for medical use, and one for recreational use. “It’s a giant market in search of a brand,” said Shively. “We would be happy if we get 40 percent of it worldwide.” Part of Shively’s vision includes importing marijuana legally from Mexico. He said he would be willing to meet with federal officials, but basically would prefer to buy dispensaries that comply with state laws. Mark Kleiman, Washington’s marijuana consultant, was skeptical. “It’s very hard for me to understand why anybody seriously interested in being in the marijuana business, which after all is against the federal law, would so publicly announce his conspiracy to break that law,” said Kleiman, a professor of public policy at the University of California, Los Angeles. But Washington state Representative Reuven Carlyle said the enterprise holds promise. “The fact that an entrepreneur is publicly pushing the envelope around a branding and value-based pricing opportunity, I would say that’s in the water in Seattle,” said Carlyle, chairman of the House Finance Committee. “That’s in our DNA... We could have predicted that as much as the rain.” Shively plans to create two brands of marijuana: one for medical use, and one for recreational use.

For more addiction information, visit www.wiley.com