# Alcoholism & Drug Abuse Weekly

News for policy and program decision-makers

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## In This Issue...

This week on page 1 we write about the federal government's denial of a request to allow contingency management, the best treatment for stimulant use disorders, to proceed, and a recent study showing that if patients with druglcohol use disorders engage in 12-step groups, the outcomes are far better for

. . . *See stories, this page*

GAO: Role of pharmacists in access to bupe shots and implants

. . . *See page 5*

McCance-Katz urges school reopenings

. . . *See page 6*

Claims against Purdue far exceed bankrupt company's assets

. . . *See page 8*




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## HHS OIG doubles down on constraints against contingency management

Stimulant use disorders are on the rise resulting in exacerbation of the opioid epidemic, with stimulants often present in opioid overdoses.. Subcontractors are lining up to implement the new stimulant use disorder treatment provisions of the $1 billion annual State Opioid Response (SOR) federal grant program. And contingency management (CM), in which patients are given monetary rewards for not using drugs, is the best — by far — treatment for stimulant use disorder.

Against this backdrop, with tone-deaf timing, the federal government is insisting that CM is not an allowable cost, leaving SOR grantees and their patients with less than optimal treatment options. The federal Department of Health and Human Services (HHS) has held, and last week upheld, that these rewards are actually "kickbacks," because they come out of funding that goes to the treatment provider. Last month a group headed by H. Westley Clark, M.D., J.D., dean's executive professor at Santa Clara University, wrote

See **Contingency management** page 2

### *Bottom Line...*

*The request to increase allow payments to patients in contingency management for stimulant use disorder was rejected by the federal government, which calls it a "kickback."*

## 12 Steps benefit drug use clients, but engagement proves challenging

It may be more difficult to engage individuals with illicit drug use disorders into 12-Step participation compared with those with alcohol use disorders, but newly published data suggests that the effort carries a significant payoff.

Pooled data from six randomized trials found that 12-Step facilitation strategies had a limited ability to increase group participation in patients with drug use disorders. However, for those who were able to engage successfully in mutual-help groups, greater attendance predicted fewer problems with illegal drugs, even for those who attended Alcoholics Anonymous (AA) more than a drug-focused support group such as Narcotics Anonymous (NA).

Moreover, the research shows that the benefits of 12-Step group attendance extend to women and minorities, calling into question the notion that a group culture that was originally shaped by white males might not resonate for women or persons of color. The study was published online Aug. 4 in the journal *Drug and Alcohol Dependence*.

It appears that at least some sufficient level of functioning is

See **12 steps** page 7

### *Bottom Line...*

*The benefits of 12-Step group attendance extend to individuals with drug use disorders, but the greater degree of dysfunction in their lives often challenges their ability to engage in group support.*

**Contingency management** from page 1

HHS to waive the sanctions for contingency management for two years, so the treatment could go ahead (see "CM, only effective treatment for stimulants, on the ropes as methamphetamine surges," *ADAW*, June 8, https://onlinelibrary.wiley.com/doi/10.1002/adaw.32742).

Last week, the group, called the Motivational Incentives Policy Group, got its answer from the HHS Office of Inspector General (OIG): no waiving of the rules. Treatment providers getting federal funds using financial rewards are subjected to "administrative sanctions" — meaning financial penalties. HHS views contingency management financial rewards as "inducements" to patients to go to treatment, thereby benefiting the treatment provider. In fact, as proven for decades by Richard Rawson, Ph.D., research professor at the University of Vermont and professor emeritus at UCLA's Department of Psychiatry and Biobehavioral Sciences. Rawson developed the Matrix Model during the cocaine epidemic of the 1980s, and contingency management is its centerpiece.

The OIG is not using the specific language sometimes heard about contingency management — "we don't want to pay people not to use drugs" — but rather interpreting the rewards to patients under a narrow analysis of the kickback statute.

"The Policy Group's [July 24] letter requests that the Department of Health and Human Services waive the imposition of administrative sanctions under the Federal anti-kickback statute, 42 U.S.C. § 1320a–7b(b), and the civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP), 42 U.S.C. § 1320a-7a(a)(5), for two years in connection with contingency management for the treatment of stimulant use disorders," according to the letter from Robert K. DeConti, assistant inspector general for legal affairs at OIG. (The OIG is the HHS entity authorized to impose administrative sanctions under the anti-kickback statute and the civil monetary penalty.) "At this time, OIG declines to waive the imposition of administrative sanctions under the Federal anti-kickback statute and Beneficiary Inducements CMP for two years in connection with the contingency management for the treatment of stimulant use disorders."

The OIG letter went on to cite the risk of "fraud and abuse" related to providing incentives to patients: "For example, depending on the nature and value of the incentives, such incentives could inappropriately steer a patient to a particular provider or result in improper utilization of items and services reimbursed by Federal health care programs. We note that patient incentives used to promote adherence or healthy behavior modification do not necessarily implicate or violate the Federal anti-kickback statute or Beneficiary Inducements CMP; they would need to be evaluated under these statutes on a case-by-case basis, including the intent of the parties."

The letter, a copy of which was obtained by *ADAW*, went on to recommend that Clark's policy group "submit questions to OIG that it can consider adding to its FAQ website." The letter also said "the Policy Group, or its members, may request an advisory opinion from OIG to determine whether a specific contingency

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management arrangement is sufficiently low risk under the Federal anti-kickback statute, Beneficiary Inducements CMP, or both to receive prospective immunity from administrative sanctions by OIG."

## $75 a year per patient

Currently, only $75 a year is allowed per patient, whether the payer is Medicaid or a SOR grant (the limitation is written into the SOR application; see box below). But states where stimulants are an increasing problem want to use treatment methods that work, and grantees are investigating which ones they should use now that stimulants are covered in SOR (see "SAMHSA to write new application for new SOR with stimulants included," *ADAW*, Jan. 13, https://onlinelibrary.wiley.com/doi/10.1002/adaw.32587).

There are only three proven treatment methods — motivational interviewing (MI), medication-assisted treatment and CM — for all substance use disorders.

Overdose death rates associated with cocaine and methamphetamine use are up, partly because these drugs are added to illicit fentanyl, and the street price of cocaine and methamphetamine is down. There are no medications approved for stimulant use disorder.

Clark, former director of the Center for Substance Abuse Treatment at the Substance Abuse and Mental Health Services Administration (SAMHSA), which administers the Substance Abuse Prevention and Treatment block grant and the SOR grants, is opposed to kickbacks. But COVID-19 could justify an exemption for CM, he said. Just as HHS — via SAMHSA and the Center for Medicare and Medicaid Services — has accepted waivers of rules to expedite treatment of opioid use disorder with methadone and buprenorphine, it could do so for stimulant use disorders.

The OIG issued a notice of proposed rulemaking (NPRM) in December asking for opinions about modifying its view. However, they have not published the rules associated with that NPRM, and in the meantime COVID-19 kicked in.

The waiver proposed by Clark would last for two years and allow incentives up to $200/month per patient per year. Other safeguards are included, including the requirement that individualized care plans be documented accounting for every payment, purpose and status of behavioral expectation.

## Making lemonade out of lemons

Rawson is practical and not one to give up. In what he has jokingly referred to as "making lemonade out of lemons," states need to figure out other allowable ways to treat stimulant disorders. Rawson is providing consultation to states on such strategies including the use of CM, especially in terms of complying with current rules from the OIG. There is some evidence for combining MI, cognitive behavioral therapy (CBT), the community reinforcement approach (CRA) and physical exercise, along with the $75 incentive, delivered over a few months. Data will be collected.

"I am also very familiar with the challenge of states who want to use their SOR money to scale up treatment for individuals with stimulant use disorder using evidence-based treatments," Rawson told us last week. He has given dozens of talks since 2017 on overviews of new information on cocaine and methamphetamine, and the status of treatment. "My main message was that while there are some data to support CBT, CRA, MI and my own study, to support physical exercise, the overwhelming conclusion is, supported by five excellent meta-analyses, contingency management/motivational incentives has by far the most robust evidence of support," he said. "At the end of those talks, I would often mention the OIG obstacle, but often I would not go into mind-numbing detail."

After doing those talks, he said, he got emails from state directors and others asking how they should go about using CM. At that point, he would go into detail about the HHS-OIG challenge. The state directors, advised by their lawyers, would invariably say "No chance," he said. "And the issue would be dead."

The question from some of those states was: "If we can't use CM, what should we develop as treatment?" With the SOR money issue coming to the forefront, all of the states are asking.

## Matrix Model not updated

"Of course, these folks realized I have been the primary author on

Continues on page 4

## State Opioid Response limitation on CM

P. 6 of the FY 2020 SOR Funding Opportunity Announcement: "Recipients are also permitted to address issues related to stimulant use in their jurisdictions. SAMHSA requires that only evidence-based approaches are implemented to address stimulant use as well. SAMHSA will monitor use of these funds to assure that they are being used to support evidence-based treatment and recovery supports and will not permit use of these funds for non-evidence-based approaches."

P. 9, under Allowable Activities: "Develop and implement contingency management strategies to engage patients in care. Contingencies may be used to reward and incentivize treatment compliance with a maximum contingency value being $15 per contingency. Each patient may not receive contingencies totaling more than $75 per year of his/her treatment."

Continued from page 3

the Matrix Model, and they asked if I recommended they use it," Rawson said.

The Matrix Model was sold and is no longer run by Rawson. "We wrote the Matrix Model in 1989–1990," Rawson said. "That was 30 years ago, when we were only just beginning to understand stimulant use disorder." Much new knowledge has been acquired since then, but to Rawson's frustration, "the folks at Matrix have not updated the approach," he said.

While the Matrix Model has some CBT elements that are still useful, it is "badly out of date," said Rawson. "So my answer has been 'No, I don't recommend the Matrix Model' for that reason."

## Alternatives

The next question is: What does he recommend?

Rawson's suggestion is to use the currently allowed $75 incentive amount for a small incentive program, combined with elements of CBT, CRA, MI (with a focus on specific stimulant-related scenarios) and a program of exercise, which might allow for a core "protocol" of evidence-based elements. Programs could add other strategies as they choose. "This would need pilot testing and further research, but in 2020 with the limits on CM, this is the best I could come up with," he said.

He outlined such a protocol for Virginia and agreed to do a pilot trial. What started as a 25-page outline has become a 175-page manual with worksheets to guide sessions, he said. "We incorporate material from the Matrix manual, from the NIDA [National Institute on Drug Abuse] CRA manual, and we developed some stimulant-specific case examples for how to use MI to address frequently encountered issues with individuals who use stimulants." There are also steps to help encourage and structure an exercise program as a formal component of treatment.

**"How to incorporate the $75 incentive is still under debate. We could set up some kind of fishbowl method using a maximum reward of $25, and when a patient gets to a total of $75, it ends. Or we could choose a behavior like attendance and give a flat $5 or $10 gift card for each attended session until $75 is reached....We're still working on it."**

Richard Rawson, Ph.D.

"How to incorporate the $75 incentive is still under debate," he said. "We could set up some kind of fishbowl method using a maximum reward of $25, and when a patient gets to a total of $75, it ends. Or we could choose a behavior like attendance and give a flat $5 or $10 gift card for each attended session until $75 is reached. Or…" he trailed off. "We're still working on it."

It's not enough money. But if Clark's effort is successful, the materials in the manual may still be of use, along with a robust CM program, said Rawson.

There is no charge for the manual, which is still being written, said Rawson last week. "We will send it electronically to whomever would like it. People can use any and all of it and modify it to fit their population and setting." The manual has not been evaluated, but anyone's use of the materials in whatever way they think will help is great, he said. "We did not develop this manual as a commercial product and we have no intention of developing a 'cottage industry' selling manuals," said Rawson. "We developed it to help groups try to use some EBPs [evidence-based practices] in practice." The manual is simply one way to do that.

## Specific plans

West Virginia will train six pilot sites in September, with Rawson colleague Al Hasson doing Zoom training sessions over a month, followed by coaching and implementation sessions over the next 11 months. In January 2021, California will do the same. A group in Montana is developing a training agreement with Rawson, and several other states are considering it.

"And if the limit is lifted on CM amounts so that a robust CM program can be used, I recommend people immediately consider using established CM strategies, including the NIDA-SAMHSA Blending manual and new companies with app-based CM, including DynamiCare and reSET."

## 'Better than nothing'

The $75 may be "better than nothing," whether for Medicaid or SOR beneficiaries, said Clark. "But the ultimate question is what form of CM works for which population," he said. Moving from research to practice requires the data from treatment programs that have specific populations such as women in general, pregnant and postpartum women in specific, Latinx, Blacks, Native Americans, Asians, rural patients, seniors, LGBTQ patients, those with unique physical or cognitive needs and others," he said. "Given the reluctance of HHS to adequately address the issue of stimulant misuse by

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permitting a reasonable approach to CM, it appears that this matter needs to be addressed by the White House or the Congress."

We asked SAMHSA, NIDA and HHS for a response. The SAMHSA press office responded that our email was received but gave no further response (as Clark noted, SAMHSA is constrained by the OIG interpretation of the anti-kickback statute). The NIDA press office, always responsive, directed our question directly to HHS press. An HHS spokesman said he would check. We received no response by press time.

"We recognize the concerns of the OIG," Clark told *ADAW*. "However, our proposal contained safeguards that minimize the potential for waste, fraud and abuse while permitting clinicians the necessary flexibility to design CM programs to meet the needs of their patients," adding "without that flexibility, programs may not be able to address the unique needs of patients." •

Also see https://www.asam.org/docs/default-source/advocacy/letters-and-comments/asam_comments_hhs-oig-anti-kickback_12-2019.pdf and

https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-statehealthcare-programs-fraud-andabuse-revisions-to-safe-harborsunder-the.

# GAO: Role of pharmacists in access to bupe shots and implants

Pharmacists could help with the coordination of getting buprenorphine implants or injections, which is less divertible than the oral medication, according to a report out this month from the Government Accountability Office (GAO). Providers are responsible for prescribing, storing and administering these medications, while pharmacies are responsible for dispensing them. Dispensing means giving them to the patient, who then takes them to the provider for placing the implant (a surgical procedure) or injection.

Interviews by the GAO of provider groups and pharmacies showed that the steps involved in treating patients with injectable or implantable buprenorphine were not difficult overall. However, "careful and timely coordination with each other and patients is needed at key steps of the process to ensure that the patient receives treatment," the report, which was reviewed by the Department of Health and Human Services and the Department of Justice, states.

Key points from provider groups and pharmacies were that diversion of injectable or implantable buprenorphine is "unlikely." In addition, three of the six provider groups said the specific design of these formulations "reduces opportunities for diversion due to how they are administered."

Oral — either in strip or tablet form — buprenorphine can be diverted easily, meaning given or sold to people for whom it wasn't prescribed. However, Elinore McCance-Katz, M.D., Ph.D., director of the Substance Abuse and Mental Health Services Administration, told *ADAW* two years ago that just because a medication isn't divertible doesn't mean it can be used as the only form of treatment. "If you give someone a long-acting injectable, all well and good," she told *ADAW* then. "But how many people with opioid use disorder have no other substance use problem? You've done nothing about the other substances. In fact, they may, because they still have those other behaviors which are not being addressed in treatment, move on to start using other substances." (see "SAMHSA's McCance-Katz says no to 'medication alone,'" *ADAW*, Aug. 6, 2018, https://onlinelibrary.wiley.com/doi/10.1002/adaw.32055).

About 7,250 prescriptions were issued for injectable and implantable buprenorphine in 2019, compared to more than 700,000 patients who received oral buprenorphine prescriptions for

Continues on page 6

**Flow from prescriber to pharmacist to administration of buprenorphine**


**PRESCRIBE**
Provider prescribes implantable or injectable buprenorphine to a patient.

**DISPENSE**
Pharmacy reviews the prescription and dispenses it to the provider.

**STORE**
Provider stores the medication prior to administration.

**ADMINISTER IMPLANT OR INJECTION**
Provider administers the implant or injection to the patient.

**CONTINUE TREATMENT**
Patient, in consultation with their provider, continues treatment, as appropriate.

Source: GAO