Alcoholism & Drug Abuse Weekly

News for policy and program decision-makers

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Our lead stories this week look at a proposed rule to make methadone more accessible in opioid treatment programs, and concerns among addiction psychiatrists about the increase in medical marijuana despite lack of evidence.
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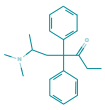
There will be no December 26 issue of *ADAW* published. Your next issue will be January 2, 2023.



OPIOID TREATMENT PROGRAMS

SAMHSA proposes reforms to methadone rules, keeps OTPs in charge

Last week, the Substance Abuse and Mental Health Services Administration (SAMHSA) released a notice of proposed rulemaking (NPRM) that would make permanent the take-home exemptions of COVID-19, making it possible for "less stable" patients to receive more take-homes. In addition, the proposal would remove the one-year requirement for opioid use disorder (OUD), remove the reliance on toxicology tests and the length of time in treatment and allow telehealth inductions by methadone.

The NPRM, issued Dec. 13, also opens up the possibility of increased interim treatment — which means medication only — of methadone.

All of these flexibilities provide that the opioid treatment program (OTP) — a methadone clinic, not an office-based physician — is the prescriber and dispenser.

> ***Bottom Line...***
> *Opioid treatment programs stay in charge under a proposed rule by SAMHSA which would remove many restrictions to methadone.*

The NPRM was released because of overdoses related to illicit fentanyl. The take-home flexibilities for methadone were originally promulgated to reduce the spread of COVID-19 (see DEA, SAMHSA relax OTP/OBOT regulations due to COVID-19, *ADAW* March 23, 2020; https://onlinelibrary.wiley.com/doi/10.1002/adaw.32664)

See **Methadone** page 2

AAAP meeting: Providers urged to voice concerns over marijuana

Having an honest, fact-based conversation with patients or policymakers about the dangers of cannabis means having to navigate an array of contradictions, panelists at a first-day symposium of the American Academy of Addiction Psychiatry (AAAP) annual meeting acknowledged. Participants in the Dec. 8 session in Naples, Florida cited these among the most prominent contradictions that complicate today's discussions around cannabis:

- A medical community that remains largely opposed to expanded access to marijuana for a public that conversely seems to have universally embraced the drug's wider availability and purported benefits.
- States' granting of permitted uses for medical cannabis that are often based on little or no evidence, while at the opposite extreme the federal government adheres to a rigid Schedule 1 designation that even

> ***Bottom Line...***
> *Though they admit it amounts to swimming against the tide, addiction specialists at an American Academy of Addiction Psychiatry symposium said physicians need to communicate more information about marijuana's risks.*

See **Marijuana** page 7

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but did not result in any overdose deaths (see No rise in methadone OD deaths with new take-home rules, *ADAW* July 25; https://onlinelibrary.wiley.com/doi/10.1002/adaw.33506), and in view of the evidence that methadone treatment reduces overdoses, are being extended permanently under this NPRM.

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"A growing body of research has demonstrated that these flexibilities facilitate access to treatment and eliminate criteria that promote stigma and discourage people from accessing care from OTPs," the executive summary to the NPRM stated in reference to the take-homes. "This proposed rule not only makes these flexibilities permanent, but also updates standards to reflect an accreditation and treatment environment that has evolved since Part 8 went into effect in 2001."

HHS is proposing to update the methadone regulations for OTPs to:

- Promote practitioner autonomy;
- Remove stigmatizing or outdated language;
- Create a patient-centered perspective; and
- Reduce barriers to receiving care.

The proposed rule also includes new definitions to expand access to evidence-based practices such as split dosing, telehealth and harm reduction activities. In addition, outdated terms such as "detoxification" have been removed.

Giving OTPs more autonomy has been something that providers have been wanting for decades. What industry doesn't want less regulation? And now, with patient demands and the fentanyl epidemic in the forefront, it's clearly time for SAMHSA to put forward these changes.

Promoting practitioner autonomy

The NPRM, if finalized, will give OTP clinicians the discretion to provide individualized treatment by:

- Allowing more take-homes, including for new patients;
- Removing the consideration of length of time in treatment as a guide for take-homes; and
- Removing "rigid reliance on toxicology testing results that demonstrate complete and sustained abstinence from all substances prone to misuse."

Rather, patients would be eligible for unsupervised take-home doses of methadone upon entry into treatment, based on the clinical judgement of the treating OTP. "This recognizes the importance of the practitioner–patient relationship, and is consistent with modern treatment standards," HHS states in the preamble to the rule. "It also allows for greater flexibility in creating plans of care that promote recovery activities, such as employment, while also eliminating the barrier of frequent visits for individuals without access to reliable transportation."

Mobile units, interim treatment

The proposed rule also clarifies administrative issues pertaining to mobile medication units and interim

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Editor Alison Knopf
Contributing Editor Gary Enos
Copy Editor Donna Petrozzello
Production Editor Nicole Estep
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Publishing Director Lisa Dionne Lento

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treatment. These changes would make OTP treatment

- More accessible to patients,
- Easier to deliver
- Supportive of evidence-based and patient-centered care.

In proposing these changes, SAMHSA relied on published evidence, stakeholder feedback and the need to expand access to care in the face of a growing overdose epidemic, which has only been exacerbated by COVID-19.

"The proposed changes are expansive but are focused on permanently implementing existing flexibilities and updating practices," according to SAMHSA. "In this way, SAMHSA believes that much of what is proposed in the rule will not represent a significant burden for OTPs and, in fact, will offer many benefits to providers and patients. The proposed rule, therefore, supports OTPs in their on-going provision of equitable and evidence-based care to often marginalized patients with OUD. The proposed rule also is consistent with the HHS Overdose Prevention Strategy which calls for increasing access to and the uptake of evidence-based treatments for substance use disorders."

Field support

The American Association for the Treatment of Opioid Dependence (AATOD), under the guidance of president Mark Parrino, has long fought for such changes. The continued involvement of OTPs making clinical decisions in opening up more methadone treatment is crucial. AATOD and OTPs have opposed the Opioid Treatment Access Act (OTAA), a bill which, if passed, would allow office-based physicians to prescribe methadone for OUD without any involvement of OTPs.

> "AATOD is extremely grateful to SAMHSA's leadership in responding to our request to provide greater clinical flexibility in making patient centered decisions in the OTPs," Parrino told ADAW last week.

"We have advocated for these changes in our public policy statements and in numerous discussions with SAMHSA representatives. Providing these flexibilities comes at an extremely important time for OTPs as we treat a greater number of patients using fentanyl as they are admitted to treatment."

Mark Parrino

"We have advocated for these changes in our public policy statements and in numerous discussions with SAMHSA representatives," he said. "Providing these flexibilities comes at an extremely important time for OTPs as we treat a greater number of patients using fentanyl as they are admitted to treatment. I know that OTP clinicians are accelerating dosage induction schedules to the extent that they can do so safely. In our judgement, these flexibilities will provide greater opportunity for patients to enter and remain in treatment. SAMHSA has been extremely thoughtful in creating these changes and we believe that this will advance the work of our field. We enthusiastically support the balance of these new proposals and encourage the states to follow suit. We certainly hope that state regulatory policies will evolve to be in greater alignment with SAMHSA's regulatory provisions as a method of moving our field forward."

The National Association for Behavioral Health (NABH), which, like AATOD, includes OTPs among its membership, also expressed unconditional support for the NPRM. "We are very pleased with this tremendous effort by SAMHSA to expand access to opioid treatment services," said Sarah A. Wattenberg, director of quality and addiction services at NABH "We are especially gratified to see the revisions related to permitting the use of audio-visual telehealth for new patients treated with methadone. NABH has long advocated for this change, as well as many of the other revisions that were included in the proposed rule. OTPs want to expand access to care but want broadened access to take place in a thoughtful and measured manner; we think this is achieved with the new revisions."

Criteria for admission

The criteria for admission to treatment removes any reference to the Diagnostic and Statistical Manual of Mental Disorders (DSM) IV and eliminates the requirement for a one-year history of OUD. Instead, the proposed rule specifies that the patient should either:

- Meet diagnostic criteria for active moderate to severe OUD;
- Be in OUD remission; or
- Be at high risk for recurrence or overdose.

The section is amended to assure that the basis for the admission decision is documented in the patient's record.

The requirement to obtain written patient consent to treatment is removed. Consent may be provided verbally or electronically and documented as such.

The requirement that individuals under age 18 have two documented unsuccessful attempts at short-term withdrawal management

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("detoxification") or drug-free treatment is also amended to allow consent of a parent, legal guardian or responsible adult.

And the rule requiring a one-year history of OUD for people recently released from penal institutions, pregnant patients or previously enrolled individuals has been removed.

Throughout the document, "detoxification" and the corresponding definition and standards for short- and long-term detoxification treatment have been removed. "Withdrawal management" and terms for tapering from medications for opioid use disorder (MOUD) are added on behalf of individuals who seek this approach or who elect or need to reduce and/or discontinue MOUD.

However, initial doses would still be low. "The regulation of an initial dose of methadone remains at 30 mg, not to exceed 40 mg on the first day, with the incorporation of a provision for higher doses if clinically indicated and documented in the patient's record," according to the NPRM.

One thing hasn't changed: OTPs still bear the full liability for any decisions they make.

Not far enough

Despite the fact that these reforms have been what many who endorse the OTAA have been clamoring for, dissatisfaction in the ranks — not from OTPs, but from primary care physicians and others — was rumbling. There is still a hope that private office-based physicians can prescribe methadone for OUD.

The federal government — HHS and the Drug Enforcement Administration — still say no to that. The memories of the overdoses and deaths when methadone was prescribed for pain by primary care physicians within the last 20 years is too fresh.

The American Society of Addiction Medicine (ASAM), however, does support the NPRM. It did want it to go farther and is demanding that Congress do that with the OTAA.

"The American Society of Addiction Medicine applauds today's proposal by the U.S. Department of Health and Human Services, through its Substance Abuse and Mental Health Services Administration, to expand access to treatment for opioid use disorder, in particular with methadone through opioid treatment programs," said Brian Hurley, M.D., president-elect of ASAM, on Dec. 13. "The proposed changes will provide greater autonomy to OTP practitioners, as well as expand on telehealth and take-home flexibilities initially granted in connection with the nation's COVID-19 public health emergency. Several proposals are aligned with recommendations in ASAM's 2021 Public Policy Statement on Regulation of the Treatment of Opioid Use Disorder with Methadone. In the spirit of these proposed rules, now is the time for Congress to build on these regulatory efforts by creating a new statutory pathway that would allow addiction specialist physicians to prescribe methadone for OUD treatment that can be picked up from pharmacies, subject to take-home rules or guidance to be set by SAMHSA."

Some of the main reservations from ASAM and other supporters of the OTAA about the NPRM are that it didn't go far enough. For example, NAMA Recovery does support office-based prescribing by addiction physicians, saying this would be an added benefit to patients. "NAMA Recovery is still processing the nuance and full implications of the NPRM," Zachary Talbott, president of NAMA Recovery, told ADAW last week, adding "but we applaud the significant progress and move toward patient-centered care that has become evident in our first readings of the proposed draft rules."

ADAW has learned that the federal Office of National Drug Control Policy does not support OTAA and wants to take steps that are doable now. But Congress may have a different view – if it can agree on anything in 2023. Stay tuned. •

The comment period is open until tk. For the NPRM, go to https://public-inspection.federalregister.gov/2022-27193.pdf.

HHS finds removing some bupe waiver rules did not help

Earlier this month, the U.S. Department of Health and Human Services (HHS) issued a report on the impact of its new practice guideline for treating opioid use disorder (OUD) with buprenorphine. The revised practice guideline, issued in April 2021, removed two long-standing requirements for obtaining a Drug Addiction Treatment Act (DATA) waiver to treat up to 30 patients with buprenorphine for OUD, namely, the requirement for specific training, and the requirement that prescribers certify their ability to provide counseling or refer patients to counseling or other ancillary services.

The report examined changes in clinician waiver update and the number of unique patients receiving buprenorphine for OUD from pharmacies after the practice guideline took effect.

The report found that the changes did not cause any increased prescribing of buprenorphine, but did result in more waivered clinicians.

The report was issued Dec. 2 by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE).

In April 2021, HHS issued new "Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder," which removed certification requirements related to training, counseling and

other ancillary services for obtaining a DATA 2000 waiver to prescribe buprenorphine for up to 30 patients.

The researchers used an interrupted time series analysis to measure early changes in trends around the number of clinicians with a DATA waiver, and national trends in the number of people filling buprenorphine prescriptions for OUD, after the revised practice guidelines took effect.

The revised practice guidelines were associated with an acceleration in the growth of waivered clinicians, but not in buprenorphine prescriptions.

By the end of 2021, the researchers estimated that the policy change was linked to an additional 5,830 providers each certified to treat up to 30 patients — about 16% more than what would have been expected given the trend prior to the practice guideline revisions. This corresponded with an increase in potential treatment capacity of about 174,900 patients.

However, there was no acceleration in buprenorphine uptake after the revised practice guidelines took effect, as measured by national estimates of the number of unique patients filling buprenorphine prescriptions for OUD each month.

"Despite our finding of a substantial increase in potential treatment capacity following the practice guidelines change, we do not find an acceleration at a national level in the number of patients with OUD filling buprenorphine prescriptions following release of the practice guidelines," the researchers concluded. They gave several possible explanations for the discrepancy between the increase in waivered physicians and the lack of any increase in buprenorphine prescriptions.

After obtaining a waiver, it may take clinicians additional time to engage people with OUD in treatment. Therefore, positive impacts of the practice guidelines on the number of people treated with

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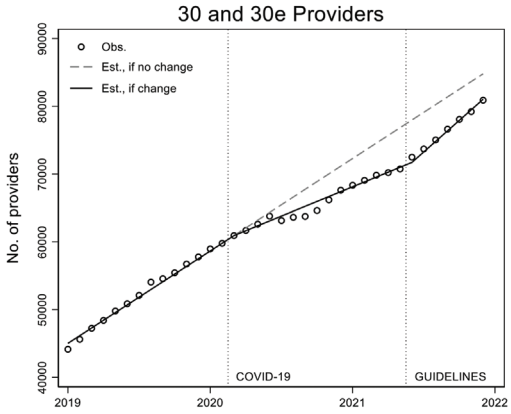
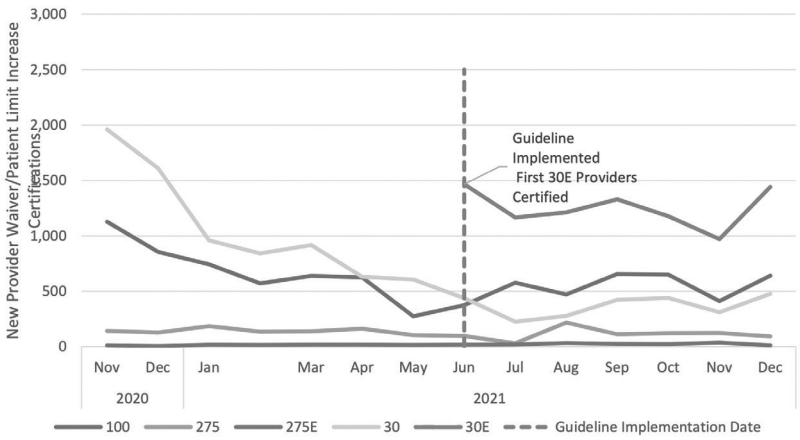
Total Number of 30 and 30E Waivered Providers Each Month, January 2019-December 2021



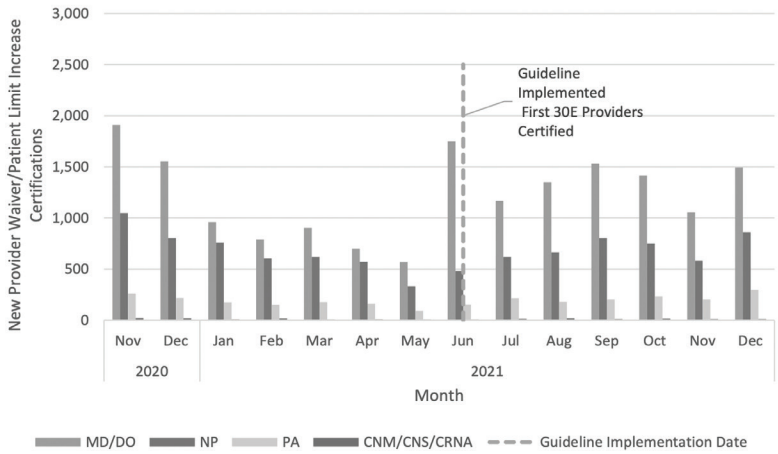
Source: HHS

Providers Newly Waivered or Certified at a Higher Patient Limit by Waiver Level, November 2020-December 2021



Source: HHS

Providers Newly Waivered or Certified at a Higher Patient Limit by Provider Type, November 2020-December 2021



Source: HHS

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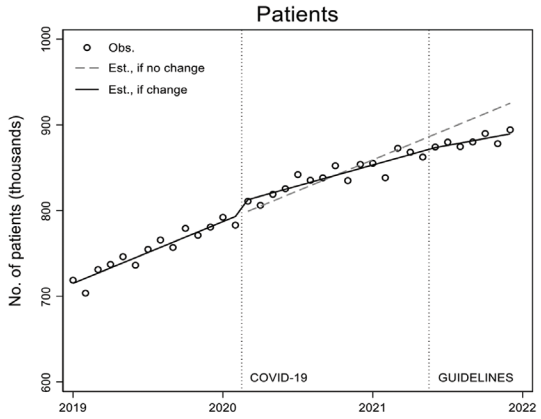
buprenorphine are expected to lag behind the increase in the number of waivered clinicians, so it may be too early to detect these changes in the first seven months following implementation (recall that this report, even though it was just issued, was prepared with data received up to January 2022).

It is also possible that additional barriers to the use of buprenorphine to treat OUD beyond the availability of waivered clinicians could be hindering treatment uptake.

Several barriers that have been documented in the research literature include stigma towards people with SUDs, insufficient knowledge among health care providers about the effectiveness of medications to treat opioid use disorder (MOUD), providers' lack of clinical experience in diagnosing and managing OUD, administrative burdens associated with providing MOUD (e.g., prior authorizations), insufficient reimbursement for SUD treatment, and inadequate institutional supports including limited integration of OUD treatment into clinical workflows.

Total Number of Patients (thousands) with Buprenorphine Fills Per Month, January 2019-December 2021



Source: HHS

Finally, some states may have existing policies in place (e.g., training and attestation requirements) that do not align with HHS's 2021 practice guidelines and could create confusion and persistent barriers for providers who otherwise would be eligible to prescribe buprenorphine under the new guidelines.

The researchers stated that additional time and policy efforts may be necessary for increased provider capacity to result in greater numbers of patients treated. •

The report is still under "Section 508" review, which means that it needs to be accessible to people with disabilities.

For the report, go to "Early Changes in Waivered Clinicians and Utilization of Buprenorphine for Opioid Use Disorder After Implementation of the 2021 HHS Buprenorphine Practice."

Endocarditis among injecting drug users increased markedly: Study

The incidence rate of a rare but often fatal inflammation of heart valves in patients with cocaine use disorder or opioid use disorder increased markedly from 2021 to 2022, according to a new study funded by the National Institute on Drug Abuse (NIDA). Physicians have been aware of the increase in infective carditis over the last decade, but recently the condition, which is a significant health concern for people who inject drugs, has been growing. The culprit is not only the injecting, but exacerbation during the COVID-19 epidemic, according to the study, published last week in *Molecular Psychiatry*.

Patients with either cocaine or opioid use disorder who were diagnosed with COVID-19 faced a higher risk of a new endocarditis diagnosis, as well as hospitalization following this diagnosis, than those without COVID-19, the study, "Association of COVID-19 with endocarditis in patients with cocaine or opioid use disorders in the US," found.

Additionally, over the full 12-year study period beginning in 2010, the rate of endocarditis was three-to-eight times greater in patients with opioid and cocaine use disorder than in those without.

The findings also showed that Black and Hispanic people faced a lower risk of COVID-19-associated endocarditis than non-Hispanic white people. This is consistent with the higher prevalence of injection drug use in non-Hispanic white populations, compared with Black or Hispanic populations.

"People with substance use disorder already face major impediments to proper health care due to lack of access and stigma," said NIDA Director and co-corresponding study author, Nora D. Volkow, M.D. "Proven techniques like syringe service programs, which help people avoid infection from reused or shared injection equipment, can help prevent this often fatal and costly condition."

One in 10 hospitalizations for endocarditis is associated with injection drug use.

Many drugs, when injected, cause infection because of inadequate access to sterile injection equipment, according to NIDA. Reusing injection equipment also increases the risk of HIV and hepatitis.

Study results

For the study, Volkow and a team of scientists at Case Western Reserve University in Cleveland, Ohio, analyzed electronic health record data of more than 109 million unique patients collected from January 2011 through August 2022. Patient data were derived from 77 hospitals nationwide across the entire U.S., covering diverse geographic locations, age groups, racial and ethnic groups, income levels and insurance types. The electronic health records were de-identified to ensure privacy.

- In 2011, there were four cases of endocarditis per day for every one million people with opioid use disorder;
- In 2022, there were 30 cases of endocarditis per day per one million people with opioid use disorder;
- In 2011, for people with cocaine use disorder, cases increased from five per one million people to 23 cases in 2022.

COVID-19

A clinical diagnosis of COVID-19 more than doubled the risk for new diagnosis of endocarditis in patients with either cocaine or opioid use disorder. Among these patients, the risk of hospitalization within 180 days following diagnosis of endocarditis was about 68% in patients with COVID-19, compared to 59% in those without. Moreover, the mortality risk within 180 days following new diagnosis of endocarditis was 9% in those with COVID-19, compared with 8% in patients without.

"As the scientific understanding of long COVID develops, we can now include endocarditis as one long-term effect on key organ systems for people who inject drugs," said Rong Xu, Ph.D., co-corresponding author of the study. "It's critical that we continue to monitor long-term, broad impacts of COVID-19 on people who use drugs." •

Marijuana from page 1

conflicts with its own approvals of cannabis-derived and cannabis-related products for some uses.

- Claims from leaders in legalization states that the cannabis market is being highly and effectively regulated, while data on the explosive growth of attractively packaged edibles that can produce dangerous effects for an ill-informed public suggest otherwise.

"It's easier for states just to copy what other states have done," said symposium speaker Kevin Hill, M.D., director of addiction psychiatry at Beth Israel Deaconess Medical Center and author of multiple books about marijuana and marijuana research. "Policies have not gotten better."

But given that a cold rendering of the facts about the risks of marijuana increasingly is falling on deaf ears with the public (a common refrain at the AAAP symposium was "the horse has left the barn"), speakers urged the addiction specialists in attendance to aim for nuanced conversations with patients.

"Don't discard their interest in cannabis," Hill said, suggesting instead that an open conversation about risks and possible benefits could eventually lead patients to explore alternative options for addressing issues such as anxiety (for which there has been some research evidence of benefit from cannabis) or depression (where no such evidence exists).

Speakers tied much of the troubling trend to commercial interests that have fueled soaring demand without contributing much to broadening the understanding of marijuana's risks and possible benefits.

Numbers on the rise

Presenters at the symposium, titled "Cannabis Policy: Misaligned with Science?", cited numerous data points suggesting a growing presence of marijuana's insidious effects both in the general public and among those presenting for treatment for a substance use disorder.

Smita Das, M.D., Ph.D., a clinical associate professor at the Stanford University School of Medicine and senior medical director of psychiatry at technology-driven provider organization Lyra Health, said the prevalence of marijuana use disorders in the U.S. population rose from 1.8% in 2018 to 5.1% in 2020. While treatment admissions for a primary marijuana issue remain relatively uncommon, marijuana continues to be the most commonly reported drug of use among those being admitted to a treatment program, she said. Co-presenter Arthur Robin Williams, M.D., assistant professor of psychiatry at Columbia University's Division on Substance Use Disorders, also pointed out high rates of cannabis use among patients who receive medications for opioid use disorder.

Speakers tied much of the troubling trend to commercial interests that have fueled soaring demand without contributing much to broadening the understanding of marijuana's risks and possible benefits. Williams showed the slides of scheduled speaker Rosalie Pacula, Ph.D., president of the International Society for the Study of Drug Policy (she was not able to attend), stating her view

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that "industry-led policies have not promoted moderate consumption." This becomes clear when looking at the fastest-growing segment of the cannabis market in edibles, many of which have questionable levels of THC and are not packaged with consideration of proper "dosing" standards.

According to Pacula, "We need to start thinking seriously about policy relevant for the cannabis products we have today or think about limiting the cannabis products we make available in the market."

State-level policies lacking

The reality, however, is that regulations governing the medical and recreational cannabis markets have not been steeped in science to say the least, symposium presenters suggested. Hill said a study he co-authored this year found that just over 10% of the 42 qualifying conditions that have been included in one or more states' medical marijuana regulations has substantial or conclusive evidence supporting a benefit from cannabis.

He did add, however, that it isn't helpful for medical professionals to insist there is no benefit at all from products derived from cannabis, given approved indications of cannabidiol (CBD) for the treatment of seizures associated with two rare forms of epilepsy. Also, the fact that the researchers who demonstrated the evidence for those indications were able to get their studies published in renowned journals contradicts the argument among cannabis interests that it is too burdensome for them to conduct such studies, Hill said.

In December 2019, AAAP issued a proposed model state law designed to reduce harms associated with expanded access to cannabis. The model law includes six tenets that the academy sees as important elements of state initiatives to expand legal access (initiatives that AAAP points out it does not endorse). While states have adhered to the first tenet — that legal recreational sales should be limited to adults — few if any states have embraced other principles, such as not including mental health or substance use disorders as qualifying conditions for medical marijuana or ensuring proper testing and labeling of cannabis-derived products.

AAAP associate executive director Michelle Dirst told *ADAW* that the academy wants to work with other medical groups to make sure more evidence-based information is getting to the public. Dirst also pointed out the value of other authoritative voices to the discussion, such as when the U.S. Surgeon General issued a statement about risks of marijuana use in pregnancy around the time AAAP's model state law was released.

Academy medical director Karen Drexler, M.D., told *ADAW* that AAAP and other groups are looking for ways to help providers initiate sound informed consent and shared decision-making with patients. These discussions should bring up information that often doesn't get addressed in areas such as medication interactions with cannabis.

Symposium presenter Das urged the addiction specialists in the AAAP audience to take a motivational interviewing approach with their patients. In a non-judgmental way, practitioners should ask patients how their use patterns may have changed over time and how their use is affecting the key dimensions of their life, she said. •

Coming up...

The CADCA 2023 **Leadership Forum and SAMHSA's Prevention Day** will be held **Jan. 30–Feb. 3** in Washington, D.C. For more information, go to **https://www.aaap.org/training-events/annual-meeting/2022-annual-meeting/**

The 2023 **Rx and Illicit Drug Summit** will be held **April 10-13** in Atlanta, Georgia. For more information, go to **https://www.rx-summit.com/**

The 2023 **ASAM conference** will be held **April 13-16** in Washington, DC. For more information, go to **https://annualconference.asam.org/**

The 2023 **American Psychiatric Association conference** will be held **May 20-24** in San Francisco, California. For more information, go to **https://www.psychiatry.org/psychiatrists/meetings/annual-meeting**

In case you haven't heard...

Now that marijuana is legalized in so many places, guess what's cropping up in those same places? Illegal marijuana shops — in other words, shops that sell what they say is marijuana, but don't have a license, don't pay fees to the state, don't guarantee the safety of their product, and have now aroused the ire of citizens. For example, in Buffalo, New York, local lawmakers just passed a resolution to write rules and regulations for marijuana stores. The state legalized recreational use of the drug, but that leaves cities to work out details. Buffalo legislators have asked the New York Office of Cannabis Management — a state agency paid for by taxpayers — to step in and take action against unregulated stores. The lawmakers in Buffalo — as in many jurisdictions — who look at marijuana stores as a source of revenue, tourism, and part of a hospitality industry, are not opposed to legal marijuana. They just want any store that opens before it has a license to be banned. Meanwhile, how does one know if what they are buying is safe and legal? Questions to answer next year. Maybe.