National Association of State Controlled Substances Authorities

June 25, 2023

## Save the Date for NASCSA's Annual Conference 2023!

The 39th annual conference is a little over two months away and will take place **October 23-26, 2023** in **Minneapolis, Minnesota** at the **Embassy Suites Downtown Minneapolis**. Room rates are $149 single/double occupancy.

Our conference information including registration information, hotel information, the program and other helpful information can be found **here** and will be updated frequently. We strongly urge members to book your hotel early as this is a particularly busy time of year and the hotel is extremely popular. **Reservations must be made by September 22, 2023** to ensure attendees receive the discounted room rate. We have a number of exciting sessions during this year's conference so stay tuned and please make sure to check the 2023 conference website frequently for important updates.

We ask that all attendees take a few minutes to review the Code of Conduct found **here** established by the Executive Committee this year.

## President's Message

*Dear Colleagues and friends,*

As we battle the drug epidemic together, there is always some new challenge we face. While fentanyl dominates the conversation, Xylazine has become an ever-increasing threat and Promethazine with Codeine continues to be a sought-after drug. There seems to be no end to the combinations of chemicals and drugs we need to be knowledgeable about.

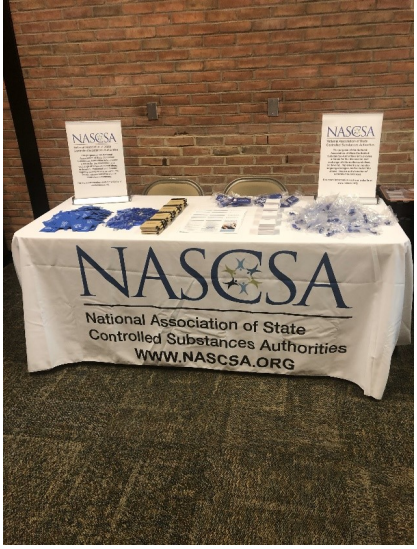
NASCSA remains committed to staying current. Our committees meet each month to bring the latest news, education, and hot topics to you. Our webinar series is going strong thanks to the Education Committee and our Executive Director. New podcasts with exciting guests and interesting discussions are in production now. And the program committee's diligent work has an exciting annual conference planned.

Ralph Orr has been a welcomed addition to the team. While Ralph served NASCSA for many years, in this new role he can advocate for our members in a way he wasn't able to before.

As always, I want to thank our members for their dedication. I also want to thank our sponsors for their contributions. This isn't only financial; they provide expertise along with time and effort on various projects. They are an important part of NASCSA, and we are lucky to have them as part of our team.

Lastly, NASCSA is always looking for new and exciting topics for our webinars and podcasts. If you have any subjects of interest or know anyone wishing to be a speaker or guest, please let us know.
I hope everyone has a happy and safe summer. I'm looking forward to seeing all of you at the annual conference in Minneapolis!

Alan




*NASCSA recently hosted a table at the Drug Diversion in Healthcare Conference at the University of Pittsburgh/Titusville campus in Pennsylvania. There were over 100 attendees and 15 vendors. The event was sponsored by Brockway Center for Arts & Technology and the Pennsylvania Office of the Attorney General*

## Mark Your Calendars!

NASCSA is pleased to announce dates and locations for both the 2024 and 2025 annual conference so please mark your calendars:

- 2024 Conference - October 28-31, 2024 - Hyatt Regency - Greenville, South Carolina
- October 20-23, 2025 - Renaissance New Orleans Arts Hotel - New Orleans, Louisiana

## Important Membership News

Dues Notices have been sent to all members in May with a subsequent reminder late last month however if you need a duplicate invoice or are sure of the status of your membership please contact the office at 617-347-1455 or **kathykeough@nascsa.org**. An electronic invoice can be generated in order to pay dues securely with a credit card.

## Policy & Communications Update

*Ralph Orr, Policy & Communications Director*

NASCSA and affected state members continue to work on issues surrounding grant funding from the Bureau of Justice Assistance (BJA) for FY2021 and FY2022. In February, several states participated in a conference call with BJA leadership to discuss concerns with not being able to access funding from approved grant awards. The biggest issue of concern is the determination by BJA that the long-standing practice of identifying PMP vendors as contractors needs to be changed to sub-awardee status. As a result of this meeting, BJA has begun to release some funds not related to the unresolved vendor issues. NASCSA is continuing outreach and discussion with BJA, member states and other partners on these very important issues to facilitate the release of the remaining funds.

CDC released information for the second round of Overdose to Action funding during this last quarter. While concerns about specific special conditions seem to have been resolved, the level of funding available is significantly different for PDMPs and for state departments of health. CDC has put a cap of twenty percent of prevention dollars that a state may use for PDMP activities which may increase to thirty percent if the PDMPs are deemed "qualified". There are still unresolved questions as to what specific requirements are necessary to be determined "qualified" for this increased percentage of funding. PDMPs that have benefited from CDC funding in the past may not have access to the same level of funding under this new iteration.

*NASCSA's Executive Committee held its midyear meeting at the Renaissance Hotel Arts Warehouse District Hotel in New Orleans, which will be the site of the annual conference in 2025. The in-depth meeting took place to review NASCSA's policies, discuss a 5 year strategic plan, as well as conduct a site visit at the property.*

## NASCSA PMP Administrators Work to Assist DEA to Establish Aggregate Production Quotas

## NASCSA Webinars

NASCSA Education Committee is pleased to announce a number of exciting webinars that are offered for members and sponsored in the coming months. We will be adding additional webinars so please make sure to check the website periodically as well as communications from NASCSA. Webinars include the following:

- September 13 2023 3-4 pm ET - Objects in the Mirror are Closer than they Appear: Little Known Facts about the Drug Enforcement Administration (DEA)
- September 27, 2023 3-4 pm ET – NASCSA Town Hall
- January 31, 2024 3-4 pm ET - Controlled Substance Management in Veterinary Medicine 101

Registration for each of the upcoming webinars is found **here**. Note Attendance is solely limited to members and sponsors.

## DEA Revises Its Rules Regarding Theft/Loss of Controlled Substances

DEA just published a final rule amending its theft and loss reporting regulations to require registrants to submit a "Report of Theft or Loss of Controlled Substances," DEA Form 106 ("DEA-106"), electronically to the agency within 45 days of discovery of a theft or significant loss. Reporting Theft or Significant Loss of Controlled Substances, 88 Fed. Reg. 40707, 40708 (June 22, 2023) (to be codified at 21 C.F.R. §§ 1301.74(c) and .76(b)). Attached **here**.

The rule now requires registrants to first report a theft or significant loss in writing within one business day of discovery (step 1), followed literally by a DEA-106 filed through the agency's secure network application "within 45 calendar days" (for non-practitioners) and "within 45 days" (for practitioners) after discovery (step 2). Id. at 40712. DEA will no

NASCSA was pleased to partner with the US Drug Enforcement Administration (DEA) in order to assist in obtaining participation by state Prescription Monitoring Programs in providing data to establish aggregate production quotas (APQ) for certain drugs as required by Congress.

DEA is required under the Controlled Substances Act (CSA) to establish aggregate production quotas (APQ) for each basic class of controlled substance in schedules I and II, and the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, to be manufactured to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks.

Since 2021, NASCSA has played a pivotal role in DEA's ability to comply with these statutory requirements and we value our partnership with DEA. This year more than 32 states participated in the project, a record and one we hope to continue working with our federal partners.

## Resolutions/Bylaws Update

The Resolutions/Bylaws Committee has been hard at work over the past several months reviewing proposed resolutions for consideration by regular members at this year's annual conference and business meeting. The Committee is chaired by Eric Griffin, Ohio Board of Pharmacy, Vice President of NASCSA and consists of members Terri Witkowski-Iowa Board of Pharmacy/PMP, Larry Houck – Hyman, Phelps & McNamara, Stephanie Mueller – MS Board of Pharmacy and Shannon Tonn – Minnesota Board of Pharmacy. To date there are is one proposed change to the bylaws found **here**.

However the committee has put forth a number of Resolutions for consideration which will be posted next month. Per Article XXII of the **Bylaws** resolutions must be presented 45 days in advance of the annual meeting. In order to streamline the Business Meetings at the Annual Conference (agenda **here**) NASCSA will be holding a Town Hall on September 27, 202 at 3 pm ET to review the proposed resolutions and Bylaw change in advance of the meeting. To register for the Town Hall meeting for regular members register **here**.

## DEA Issues Final Rule on Partial Filling of Schedule II Prescriptions

longer accept hardcopy DEA-106s as of July 24, 2023. Id. at 40708. For a comprehensive review of the law please see a blog posted by Hyman, Phelps & McNamara **here**.

## FDA and White House Outline Plan to Combat Illicit Xylazine Entering the US

Xylazine, the veterinary sedative that is unsafe for human consumption, continues to be detected in the illicit drug supply as it is mixed in with fentanyl and other drugs. To address the growing public health concern, FDA has placed restrictions on shipments of xylazine entering the country. So far, four shipments of unapproved xylazine have been found entering the US, and FDA has issued alerts for US Customs and Border Protection (CBP) to detain any shipments of xylazine that appear to be adulterated or misbranded. Furthermore, **FDA's Center for Veterinary Medicine** and CBP are working to identify xylazine shipments that are packaged and declared as other products.

In addition to FDA's actions, the Biden Administration developed a National Response Plan to address the emerging threat, which includes testing; expanding data collection; implementing and expanding evidence-based prevention, harm reduction, and treatment; identifying sources distributing the non-opioid tranquilizer; investigating scheduling and other regulatory options under the Controlled Substances Act; and increasing research. See the report **here**.

## Have You Checked Out NASCA's Youtube Channel?

We understand that often members and sponsors are not always able to participate in our periodic webinars

On July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) was signed into law. One provision of CARA amended the Controlled Substances Act to allow the partial filling of schedule II prescriptions under certain conditions. DEA last week amended its regulations to conform to this statutory provision, as well as to provide direction on gaps not addressed by the legislation.
This Final Rule becomes effective 30 days after publication in the Federal Register. A copy of the notice, published on July 21, 2023 is found **here**.
Changes will allow a pharmacist to partially fill a Schedule II prescription when requested by the prescribing practitioner or the patient provided that all of the following conditions are satisfied:
(1) The partial filling must not be prohibited by State law;
(2) The prescription must be written and filled in accordance with the CSA, DEA regulations, and State law; and
(3) The total quantity dispensed in all partial fillings must not exceed the total quantity prescribed.
In addition, the remaining portions of a partially filled Schedule II prescription must be filled no later than 30 days after the date on which the prescription is written, unless the prescription is issued as an emergency oral prescription, in which case the remaining portion must be filled no later than 72 hours after it was issued.

## House Energy and Commerce Panel Holds Subcommittee Hearing on the Opioid Crisis

Last month, the House Energy and Commerce Subcommittee on Health held a hearing titled "Responding to America's Overdose Crisis: An Examination of Legislation to Build Upon the SUPPORT Act." The subcommittee featured witnesses from the Drug Enforcement Agency, the Centers for Medicare & Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), and other mental healthcare stakeholders. The witness panel discussed many opioid treatment bills, including:

- **H.R. 824**, the Telehealth Benefit Expansion for Workers Act of 2023 (Reps. Tim Walberg, Suzan DelBene, Angie Craig, Ron Estes, Mikie Sherrill, Rick Allen)
- **H.R. 3892**, the Improving Mental Health and Drug Treatment Act (Reps. Michael Burgess and Ritchie Torres)
- **H.R. 4091,** the Combatting Substance Use Disorder Act (Reps. David Valadao and Mike Garcia)
- **H.R. 3736**, the Extending Access to Addiction Treatment Act (Reps. Paul Tonko and Kelly Armstrong)
- **H.R. 4096**, a bill to amend Title XIX of the Social Security Act to expand the application of Medicaid State programs to monitor

(work and life get in the way!), so NASCSA has created a Youtube Channel. While all webinars are open solely to members and sponsors, several of our webinars are often posted on our Youtube Channel, typically about 6 weeks after the webinars. So visit our Youtube Channel to see what you might have missed **here**.

## NDEWS Hotspot Alerts: June 22 – 28, 2023: Opioid, Heroin, Methamphetamine, and Non-Opioid 911 Dispatches

This week's NDEWS Hotspot Alerts report includes 33 counties with higher-than-expected drug-related 911 dispatch counts over the previous 7-day period. To view the report click **here**. Click **here** to read more about NDEWS Hotspot Alerts.

## NDEWS and CFSRE Collaboration: Will Assist in Investigations of Exposures Involving Novel or Unknown Substances

NDEWS recently partnered with the Center for Forensic Science Research & Education (CFSRE)'s NPS Discovery to assist in investigations of exposures involving novel or unknown substances. Requests for assistance can be submitted to NDEWS, and NPS Discovery will facilitate the comprehensive testing of biospecimens and drug paraphernalia/materials for the identification of drugs and adulterants, including a wide array of novel psychoactive substances (NPS). **Complete the query form here**.

antipsychotic medications to all Medicaid beneficiaries. (Reps. Buddy Carter and Jan Schakowsky)

- **H.R. 4056**, the Ensuring Medicaid Continuity for Children in Foster Care Act of 2023 (Reps. Gus Bilirakis and Kathy Castor)
- **H.R. 3074**, the Due Process Continuity of Care Act (Reps. David Trone and Michael Turner)
- **H.R. 2400**, the Reentry Act of 2023 (Reps. Paul Tonko and Michael Turner)
- **H.R. 4089**, the Safer Response Act (Reps. Anthony D'Esposito and Josh Harder)
- **H.R. 4063**, the FIND Fentanyl Act of 2023 (Reps. Debbie Dingell and Gus Bilirakis)
- **H.R. 4079**, the Substance Use Disorder Treatment and Recovery Loan Repayment Program Reauthorization Act of 2023 (Reps. Hal Rogers and Abigail Spanberger)
- **H.R. 4100**, to amend the Public Health Service Act to reauthorize a monitoring and education program regarding infections associated with illicit drug use and other risk factors. (Reps. Lori Chavez-DeRemer and Lori Trahan)
- **H.R. 4101**, the Road to Recovery Act (Reps. John James and Tony Cardenas)
- **H.R. 4099**, the RECONNECTS Act of 2023 (Reps. Morgan Griffith and Angie Craig)
- **H.R. 4088**, the CAREER Act (Reps. Andy Barr and Sharice Davids)
- **H.R. 1502**, the Comprehensive Opioid Recovery Centers Reauthorization Act of 2023 (Reps. Brett Guthrie, Scott Peters, Larry Bucshon, Paul Tonko)
- **H.R. 4098**, the Communities of Recovery Reauthorization Act (Reps. Brittany Pettersen and Zach Nunn)
- **H.R. 4095**, the Save Children from Trauma Act (Reps. Monica De La Cruz and Greg Landsman)
- **H.R. 4097**, the Mental Health Improvement Act (Reps. Emilia Sykes and John Joyce)
- **H.R. 1839**, the Combating Illicit Xylazine Act (Reps. Jimmy Panetta and August Pfluger)
- **H.R. 4053**, the Studying Suboxone Act (Reps. Anne Kuster and Buddy Carter)
- **H.R. 4057**, the Keeping Kids Safe Act (Reps. Lisa Blunt Rochester and Brian Fitzpatrick)
- **H.R. 4080**, the Trauma-Informed Care Task Force Reauthorization Act of 2023 (Reps. Raul Ruiz and Bob Latta)
- **H.R. 4092**, the Protecting Moms and Infants Reauthorization Act (Reps. Marie Gluesenkamp Perez and Young Kim)
- **H.R. 4054**, the Trauma Support and Mental Health in Schools Reauthorization Act (Reps. Nikki Budzinski and Michelle Steel)
- **H.R. 4093**, the Remote Opioid Monitoring Act of 2023 (Reps. Troy Balderson and Robin Kelly)
- **H.R. 4007**, the HEAL Act (Reps. Kelly Armstrong and Paul Tonko)

## DEA Practitioner's Manual Released

On June 14, 2023, DEA posted its newly revised Practitioner's Manual on its Diversion website. A copy of the guide is attached to this email for your convenience. The manual is current and includes the recent elimination of the requirement for a special registration to treat opioid use disorder (DATA-Waiver). **https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf** The 2023 edition replaces all previous versions of the Practitioner's Manual issued by DEA, both hard copy and electronic.

## CDC Issues New Report on Overdose deaths with detected Xylazine

The Centers for Disease Control and Prevention (CDC) late last month released a report entitled "Illicitly Manufactured Fentanyl–Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022" showing a significant increase in overdose deaths over the past three years. The report is found **here**.

## FDA and SAMHSA Issue Joint Letter Clarifying Buprenorphine Prescribing Recommendations

Last week, the U.S. Food and Drug Administration and the Substance Abuse and Mental Health Services Administration issued a joint letter affirming both agencies' commitment to addressing the overdose crises by reducing barriers to accessing evidence-based treatments and providing person-centered care for substance use disorders. You may already be

The subcommittee will mark up the bills at a later date. Additional details are available on the House Energy and Commerce **website**.


## Sponsor Spotlight

COMPASS Pathways is delighted to be a sponsor of NASCSA and looks forward to both engaging with controlled substances authorities, NASCSA leadership, and members to learn about their important work, and educate about our company's mission and the innovations underway using novel therapies.

COMPASS Pathways is a mental health care company dedicated to **accelerating patient access to evidence-based innovation in mental health**. Our focus is on improving the lives of those who are suffering with mental health challenges and who are not helped by current treatments.
We are developing innovative therapies and, when appropriate, combining them with psychological support and next-generation digital tools to forge new, sustainable mental health care pathways.

Our investigational COMP360 psilocybin therapy is currently undergoing phase 3 investigation in treatment-resistant depression. We are also assessing COMP360 in anorexia nervosa and post-traumatic stress disorder, across multiple clinical studies. Learn more **https://compasspathways.com**

aware that a separate waiver is no longer required to dispense certain controlled medications, including buprenorphine. An often-cited barrier to prescribing buprenorphine for the treatment of opioid use disorder (OUD) is the perception that patients must engage in counseling and other services to start or continue receiving the medication. The decision as to when counseling and other services, such as case-management and peer support, are to be provided should be made in collaboration with each individual patient. Read more about our recommendations for providing person-centered intervention **here**.

## Industry News

- On May 22 Indivior announced that the US Food and Drug Administration (FDA) approved OPVEE® (nalmefene) nasal spray, a new medication for the reversal of overdose by natural or synthetic opioids. A copy of the **press release** and the approved prescribing information for OPVEE can be found **here**.
- Braeburn received U.S. FDA approval of BRIXADI™ (buprenorphine) extended-release injections for subcutaneous use for the treatment of moderate to severe opioid use disorder (OUD). BRIXADI should be used as part of a complete treatment program that includes counseling and psychosocial support. A copy of the **press release** and the approved prescribing information can be found **here**.

## NASCSA in the Media

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## Have you listened to our NASCSA Podcasts?

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