NASCSA
National Association of State Controlled Substances Authorities

NASCSA News

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DEA Establishes Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2023

The US Drug Enforcement Administration (DEA) has issued its Final Order regarding DEA's 2023 aggregate quotas for Schedules I and II Controlled Substances and list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. It is scheduled for publication in the Federal Register on Friday, December 2 and is effective upon publication. A copy is found here.

President's Message

It's always bittersweet when our annual conference ends. It's good to see everyone, especially in such a beautiful place like Salt Lake City. What an amazing venue, both the hotel and location. I want to thank Dave Furlong and his colleagues for the hospitality enjoyed by all in their home state.

On behalf of the Executive Board and the Association, I want to thank our sponsors. NASCSA relies on their financial support as well as the many contributions they make. So many of our sponsors serve on committees as valuable partners which makes everything a success. We could not do any of this without them.

All of our committees put in another remarkable year. Holding meetings each month to complete the important work we do. All of us together as an association dedicated to making the lives of our loved ones, friends, family, and community better.
So many of you took the time to comment on the success of this year's conference. The program committee, led by our Executive Director, did another fabulous job making it a great one. This is a reminder of what can be achieved when we work together.
I was excited to see the many friends and colleagues I have come to know over the years. And encouraged by new members and first-time attendees. This is always good, and I hope to see more of this in the coming years.

I looked forward to our future as an association. There are many exciting webinars, podcasts, and learning experiences moving forward.

On behalf of the Executive Board, we wish you a safe and happy holiday season. We hope to see you at next year's conference in Minneapolis!

Warmest Regards,

Alan McGill
President

Attorneys General Propose DEA and SAMHSA Extend Telehealth Flexibilities for Buprenorphine

Forty-five attorneys general sent a letter to the leaders of Drug Enforcement Administration (DEA) and Substance Abuse and Mental Health Services Administration (SAMHSA) urging the agencies to permanently extend flexibilities that have allowed telehealth services for prescribing buprenorphine during the coronavirus disease 2019 public health emergency. The letter indicates that these flexibilities have made buprenorphine accessible to 2.5 million United States adults as treatment for opioid use disorder and that extending these allowances is urgent in helping to reduce opioid overdose deaths. A copy of the letter is found here.

Save the Date!

It's not too late to block off your calendars for NASCSA's annual conference held each fall. Below are the conference dates and locations:

- **2023 Conference** - October 23-26, 2023 - Embassy Suites Minneapolis - Downtown Minneapolis, Minnesota - Online Hotel reservations can already be made here.
- **2024 Conference** - October 28-31, 2024 - Hyatt Regency - Greenville, South Carolina
- **2025 Conference** - October 18-23, 2025 - Renaissance New Orleans Arts Hotel - New Orleans, Louisiana

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NASCSA Webinars

NASCSA Hires Ralph Orr as Policy and Communications Director

Responding to an ongoing need voiced by NASCSA's membership, the Executive Committee has hired Ralph Orr who will serve as Policy and Communications Director. Ralph is an honorary member of NASCSA and previously served as President among other positions on the Executive Committee. Ralph has extensive experience with Prescription Monitoring Program (PMP) and controlled substance issues, with over 20 years of experience at the Virginia Department of Health Professions. While there he implemented and administered the state's PMP and worked with the Board of Pharmacy, other licensing boards and several state agencies on controlled substances issues. We are delighted to welcome Mr. Orr in his new role at NASCSA. He can be reached at ralphorr@nascsa.org.

2022 Annual Conference Recap

The 38th annual conference took place in October in Salt Lake City with attendance at pre-pandemic levels. In addition to attendees from over 41 states as well as industry leaders, there were representatives from a variety of federal agencies including the Drug Enforcement Administration (CDC), the Food and Drug Administration (FDA) as well as the Centers for Disease Control and Prevention (CDC). In an effort to "go green" presentations are posted online and can be found here.

We would like to offer our deep appreciation of this year's sponsors who recognize the value of partnership with NASCSA. A complete listing of sponsors is located here.

Highlights of the 2022 conference include the following:

Election of Officers:

The following slate of officers and executive

NASCSA has several upcoming webinars that are open to members and sponsors that will be taking place in the next several months.

For more information click here.

Volunteers Needed

Want to give back to NASCSA, have fun, and meet new colleagues? Several Committees are looking for additional members to join this year including the Program Committee, Controlled Substances Committee, Education Committee, Membership, Survey/Data and Resolutions/Bylaws Committee. If you are interested please contact the office or let one of the members of the Executive Committee know as soon as possible. Each committee sets their own schedule and makes an attempt to accommodate the members' schedule. Most committees meet no more than monthly.

Volunteers Needed - 40th Anniversary Committee

It's hard to believe but NASCSA will be celebrating its 40th Anniversary in 2024. We are looking for volunteers who would be willing to serve on our 40th Anniversary Committee that will offer recommendations to celebrate this important milestone.

If you are interested please contact the office at 617-347-1455 or email kathykeough@nascsa.org.

DEA Publishes New Diversion Headquarters Org

committee members were approved at this year's conference:

- Alan McGill (PA) -President
- Eric Griffin (OH) - Vice President
- Sidney Seal (MS) - Secretary/Treasurer
- Melissa DeNoon (SD) -Member at large
- Jason Slavoski (DE) - Member at large
- Rodrick Marriott (CT) - Member at large
- Stella Bailey (NC) - Member at large
- Joe Fontenot (LA) - Chair of the Executive Committee

Biographies of the Executive Committee are found here.

Adoption of Resolutions:

The membership voted to approve four resolutions at the annual conference:

- Resolution 2022-01 - A Resolution Relative to Scheduling Gabapentin as a Schedule V Controlled Substance
- Resolution 2022-02 - A Resolution Relative to Prescription Monitoring Program Data Integrity
- Resolution 2022-03 - A Resolution Encouraging the Expanded Role of Pharmacists to Address the Opioid Crisis
- Resolution 2022-04 - A Resolution Recognizing Ralph Orr
- Resolution 2022-05 - A Resolution Recognizing Sherry Green
- Resolution 2022-06 - A Resolution Recognizing Terry Woodworth

Copies of these resolutions as well as all resolutions adopted by NASCSA's members can be found here.

2022 President's Award Recipient Joe Fontenot Recognized

At this year's annual conference, President Alan McGill presented the President's award to recipient, **Joe Fontenot,** Executive Director of the Louisiana Board of Pharmacy, who has served in

Chart

The Drug Enforcement Administration (DEA) recently pushed its Diversion Headquarters Organizational Chart that includes names and titles. The listing can be found here.

A Special Thanks to our Sponsors

NASCSA wishes to extend a very special thanks to our sponsors who help support NASCSA during the conference and throughout the year.

Check out our sponsors **here**.

Sponsor Spotlight - IQVIA

IQVIA has been an industry expert in DEA and state operational compliance and a leading provider of regulatory services since 1991. Our long-standing compliance solutions support the industry and the health care community in the areas of the Controlled Substance Act, Prescription Drug Marketing Act and more specifically, state pharmacy and wholesale distribution regulatory issues, as well as operational best practices.

Staffed by former DEA investigators, policy makers, and industry experts, IQVIA offers comprehensive solutions to support Registrants at any stage of the journey to achieve regulatory compliance. Our expert services also include:

- Unparalleled experience

many leadership roles in NASCSA over the years and presently serves as Board Chair. Joe Fontenot is currently the Assistant Executive Director-Chief Operations Officer for the Louisiana Board of Pharmacy. Joe is directly responsible for the Board's Compliance, Licensing, PMP, and Administrative Divisions. The licensing division includes both pharmacy licensing as well as the state's Controlled Dangerous Substance (CDS) license. Joe was licensed as a Louisiana Pharmacist in 1991 and after practicing in both independent and chain pharmacy for 11 years he was selected in 2002 as a Compliance Officer for the Louisiana Board of Pharmacy. In 2008, he was chosen by the Board to be the PMP Director and in 2012 was selected as the Assistant Executive Director and has served the Board in that capacity to the present. Joe has been attending NASCSA Conferences since 2008 and served on the Executive Committee as a Member-at-Large from 2013-2015. Since 2017 Joe has served NASCSA as Vice-President and has served on several NASCSA committees, which includes being Chairman of the Resolutions and Bylaws Committee since 2017.

2022 Bill Ward Education Award Recipient Recognized

Kari Shanard-Koenders was the recipient of the 2022 Bill Ward Education Award which recognized an individual who has gone above and beyond to volunteer for NASCSA. Ms. Shanard-Koenders holds a pharmacy degree from the University of Kansas. In 2020, Kari completed a Master of Science Degree in Jurisprudence from Seton Hall Law School.

Kari has had a diverse career working as Consultant Pharmacist/Medical Facilities Surveyor for the SD Department of Health, in staff and management roles in hospital, retail, psychiatric, and long-term care pharmacies in Kansas and South Dakota.

Kari joined the South Dakota Board of Pharmacy in July 2012 to become the PDMP Director and in 2015 became its Executive Director/Secretary. She has and

developing SOM solutions;
- State services for licensing assistance and other requirements;
- Proactively monitor the regulatory and enforcement landscapes; and
- Bridge the gap between regulation and practice.

Social Media Update

Did you know that NASCSA is now on most social media platforms?

Linkedin - follow here

Youtube - follow here **(we will be posting some (but not all) webinars that will be available for viewing.**

Twitter @NASCSA

Please follow us and share this information widely.

In addition, NASCSA offers several podcasts of significant interest to our members available on most podcast platforms.

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continues to serve on a variety of committees, boards and taskforces for NABP, her church, local non-profits, hotel and hotel management company, and NASCSA. Kari currently chairs the Education Committee for NASCSA and is excited about continuing to bring excellent webinar content to its members.

MDScripts Receives Special Recognition Award

President Alan McGill presented representatives from MDScripts with a special recognition on behalf of the membership of NASCSA for their contribution in developing, maintaining and hosting the website. Shown receiving a citation and gifts are Theo Antoniou, Chief Technology Officer, Gary Mounce, President and Jessie Criswell.

DEA Laboratory Testing Reveals that 6 out of 10 Fentanyl-Laced Fake Prescription Pills Now Contain a Potentially Lethal Dose of Fentanyl

WASHINGTON – The U.S. Drug Enforcement Administration is alerting the public of a sharp nationwide increase in the lethality of fentanyl-laced fake prescription pills.
The DEA Laboratory has found that, of the fentanyl-laced fake prescription pills analyzed in 2022, six out of ten now contain a potentially lethal dose of fentanyl. This is an increase from DEA's previous announcement in 2021 that four out of ten fentanyl-laced fake prescription pills were found to contain a potentially lethal dose.

"More than half of the fentanyl-laced fake prescription pills being trafficked in communities across the country now contain a potentially deadly dose of fentanyl. This marks a dramatic increase –

from four out of ten to six out of ten – in the number of pills that can kill," said Administrator Anne Milgram. "These pills are being mass-produced by the Sinaloa Cartel and the Jalisco Cartel in Mexico. Never take a pill that wasn't prescribed directly to you. Never take a pill from a friend. Never take a pill bought on social media. Just one pill is dangerous and one pill can kill."

Last year, the DEA issued a Public Safety Alert on the widespread drug trafficking of fentanyl-laced fake prescription pills in American communities. These pills are largely made by two Mexican drug cartels, the Sinaloa Cartel and the Jalisco (CJNG) Cartel, to look identical to real prescription medications, including OxyContin®, Percocet®, and Xanax®, and they are often deadly. In 2021, the DEA seized more than 20.4 million fake prescription pills. Earlier this year, the DEA conducted a nationwide operational surge to target the trafficking of fentanyl-laced fake prescription pills and, in just over three months, seized 10.2 million fake pills in all 50 states. Through its One Pill Can Kill campaign, the DEA is working to alert the American public of the dangers of fake prescription pills.

Fentanyl remains the deadliest drug threat facing this country. It is a highly addictive synthetic opioid that is 50 times more potent than heroin and 100 times more potent than morphine. Just two milligrams of fentanyl, the small amount that fits on the tip of a pencil, is considered a potentially deadly dose. According to the CDC, 107,622 Americans died of drug poisoning in 2021, with 66 percent of those deaths involving synthetic opioids like fentanyl. The Sinaloa Cartel and Jalisco Cartel in Mexico, using chemicals largely sourced from China, are primarily responsible for the vast majority of the fentanyl that is being trafficked in communities across the United States.

For more information on the dangers of fentanyl, please visit Fentanyl Awareness (dea.gov).

FDA Announces Preliminary Assessment that Certain Naloxone Products Have the Potential to be Safe and Effective for Over-the-Counter Use

The U.S. Food and Drug Administration issued a Federal Register notice, Safety and Effectiveness of Certain Naloxone Hydrochloride Drug Products for Nonprescription Use, that may help facilitate the development and approval of certain nonprescription naloxone drug products, including through the switch of certain naloxone drug products from prescription status to nonprescription status. Naloxone is a medicine that can help reduce opioid overdose deaths and when administered timely, usually within minutes of the first signs of an opioid overdose, can counter the overdose effects.

The Federal Register notice includes a preliminary assessment that certain naloxone drug products–up to 4 milligrams (mg)

nasal spray and up to 2 mg autoinjector for intramuscular (IM) or subcutaneous (SC) use–may be approvable as safe and effective for nonprescription use. This preliminary assessment is intended to facilitate development and approval of nonprescription naloxone products; however, it is not a final determination that certain naloxone drug products are safe and effective for nonprescription use, and it does not mandate an immediately effective switch to nonprescription/over-the-counter (OTC) availability for naloxone.

To make its final determination, the FDA needs additional data, such as product-specific data on the nonprescription user interface design, including packaging and labeling. These data would usually be submitted to the agency in an application for a proposed nonprescription naloxone product.
By issuing this notice, the FDA is making application holders of certain prescription naloxone drug products aware of the preliminary assessment and the possibility that the agency may make a conclusive determination, through approval of a nonprescription naloxone drug product, that such products are safe and effective for use without a prescription.
The notice does not cover all naloxone products, as more data are needed on the safety and efficacy for nonprescription use of higher dose naloxone products and naloxone supplied in other presentations (including vials, ampules or syringes without integrated needles) before a preliminary assessment with respect to those products can be reached. The notice requests comments from the public on whether there is data to support safe and effective nonprescription use of higher dose naloxone products and on potential consequences of a switch from prescription to nonprescription status.

Over the last several years, the FDA has taken a number of steps to improve access to naloxone products. In September, the agency issued an immediately in effect guidance to clarify that certain Drug Supply Chain Security Act requirements do not apply to distribution of naloxone to harm reduction programs during the Opioid Public Health Emergency. Additional efforts include development of a model Drug Facts Label, which is required for OTC drug products, with easy-to-understand pictograms on how to use the drug to encourage manufacturers to pursue approval of OTC naloxone products; requiring drug manufacturers for all opioid pain relievers and medicines to treat opioid use disorder to add new recommendations about naloxone to their prescribing information; and extending the shelf life of naloxone nasal spray from 24 months to 36 months.

The FDA continues to make progress implementing the new FDA Overdose Prevention Framework – our vision to undertake impactful, creative actions to prevent drug overdoses and reduce deaths. The agency remains focused on responding to all facets of substance use, misuse, substance use disorders, overdose, and death in the U.S. through the four priorities of the framework, including: supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing; encouraging harm reduction through innovation and education; advancing development of evidence-based treatments for substance use disorders; and protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks.