



National Association of State  
Controlled Substances Authorities



## NASCSA NEWS

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### Consider Donating to NASCSA

Did you know that you can contribute to NASCSA online? As a 501(C)(3) nonprofit is a great organization to consider donating to.

To donate please click [here](#).

### State Regulatory Developments

Did you know that NASCSA publishes a monthly compilation of state regulatory actions related to pharmacy and controlled

## NASCSA Testifies Before FDA's Opioid Steering Committee/Meetings with Congressional Leaders

NASCSA President Barbara Carter testified before the Food and Drug Administration's [Opioid Steering Committee](#) last month on how the FDA might under its authority, improve the safe use of opioid analgesics by curbing overprescribing to decrease the occurrence of new addictions and limit misuse and abuse of opioid analgesics. Ms. Carter testified that NASCSA is opposed to any initiative or program that duplicates or replaces individual state prescription drug monitoring programs. A copy of NASCSA's testimony is found [here](#). To view the proceedings, click [here](#).

Given discussions before Congress of the future direction of state Prescription Drug Monitoring Programs (PDMP's), Ms. Carter also met with a number of key leaders in Congress to discuss NASCSA's position on PDMP's (see [resolution 2017-03](#)).

## Save the Date for NASCSA's Annual Conference

The 34th annual conference will take place at the [Hotel Valley Ho](#) October 30-November 2, 2018 in Scottsdale, Arizona. Registration information as well as information on hotel accommodations is available on our website. We strongly urge members to book your hotel early as this is a particularly busy time of year and the hotel is extremely popular. Check the [website](#) on a regular basis for updates.

substances. State Regulatory Developments is located on the website [here](#).

### Follow NASCSA on Twitter

NASCSA is pleased to announce that it is now on Twitter and the number of followers continues to grow each month so please follow us at @NASCSA.

On behalf of NASCSA we wish to extend a very special thanks to our sponsors who help support us during the conference and throughout the year. A list of sponsors can be viewed [here](#).



*The 2017 President's Award was presented to Ralph Orr, Director of the Virginia Prescription Monitoring Program for his many years of support to NASCSA and his tireless support of the organization over the years. Mr. Orr was presented the award from David Dryden, past president of NASCSA.*

## Near Record Attendance at 2017 Annual Conference

The 33rd annual conference took place in October in San Antonio, with over 160 attendees from over 42 states as well as industry representatives. In an effort to "go green" presentations were posted online in advance of the conference and we continue to receive positive feedback to this change. Presentations and attendance lists from the conference are found [here](#).



Officers and Executive Committee members were sworn into office by the membership.

Highlights of the 2017 conference include:

### Election of Officers:

The following slate of officers and executive committee members were approved at this year's conference:

- Barbara Carter (MN) - President
- Joseph Fontenot (LA) - Vice President
- Larry Pinson (NV) - Secretary/Treasurer
- Joshua Vinciguerra (NY) - Executive Committee (2 year term)
- Christie Frick (SC) - Executive Committee (2 year term)

## NASCSA is on Twitter

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## Staff Changes

The following changes in personnel have occurred. If you know of any changes/updates in personnel please contact Kathy Keough at [KathyKeough@nascsa.org](mailto:KathyKeough@nascsa.org).

**California** - Tina Farales is now the PDMP manager for the California Department of Justice, filling the position vacated by Mike Small.

**Delaware** - Geoffrey Christ has been named as the Executive Secretary to the Board of Pharmacy.

**New Mexico** - Cheranne McCracken has assumed the role of Executive Director/Chief Drug Inspector, replacing Ben Kesner who retired after 30 years of service. In addition, Peter Ryba has been hired as the new PMP Director in New Mexico.

**Oklahoma** - Brian Veazy is

Eric Griffin (OH) - Executive Committee (1 year term)

- Alan McGill (PA) - Executive Committee (1 year term)
- Ralph Orr (VA), - Chair of the Executive Committee

## Adoption of Resolutions:

A number of resolutions were adopted by the membership at the annual conference. Those adopted at this year's conference include:

- A Resolution Endorsing the Enactment of Legislation Entitled the Synthetics Trafficking and Overdose Prevention (STOP) Act of 2017.
- A Resolution Encouraging the United States Department of Defense to Submit Controlled Substance Dispensations to State Prescription Monitoring Programs.
- A Resolution in Support of State Prescription Monitoring Programs (PMP's) and in Opposition to Any Initiatives to Duplicate or Replace PMP's.
- A Resolution Recognizing Lisa Adams.
- A Resolution Recognizing David Dryden.
- A Resolution Recognizing Peg Clifford.
- A Resolution Recognizing Chad Zadrzil.

Copies of these resolutions as well as all resolutions adopted by NASCSA's members can be found [here](#).

## Revised Bylaws Adopted:

Several changes to the bylaws were enacted by the membership, a copy of which is found [here](#).

## NASCSA Committees Hard at Work

NASCSA President Barbara Carter created nine committees that have been hard at work on a variety of projects. Committee members, comprised of volunteers from member states as well as associate members are the backbone of the organization. We encourage all members to consider volunteering. For a list of committee members click [here](#).

**Grants, Sponsorships and Membership** - In addition to developing the criteria for this year's travel scholarship, members of the committee will be review the applicants and

the point of contact at the Prescription Monitoring Program until a permanent replacement has been named following the departure of Don Vogt, who recently joined Appriss Health as a Senior PDMP Specialist.

**Texas** - Allison Vordenbaumen Benz has been named as Executive Director/Secretary of the Board of Pharmacy, replacing Gay Dodson who retired late last fall.

**Arkansas** - Jim Myatt, Section Chief of the Arkansas Department of Health retired at the end of January.

### **FDA Requests Comments on Ways to Ease Appropriate Opioid Prescribing**

The Food and Drug Administration (FDA) is requesting stakeholder input on how to use Risk Evaluation and Mitigation Strategies (REMS) to aid in the appropriate prescribing of opioid pain relievers. According to the FDA [notice](#), the agency's Opioid Policy Steering Committee will consider using REMS to require sponsors to ensure that opioid analgesic prescriptions exceeding a certain amount document medical necessity and/or use a nationwide prescription history database to prevent misuse or abuse. The

make recommendations to the Executive Committee. Travel Scholarship applications and instructions will be available later this Spring. The committee will also be identifying other individuals and organizations to expand its membership and sponsorship base to continually ensure that NASCSA continues to be self-sustaining in the future. If you are aware of potential organizations please contact us!

**Program Committee** - Members of the committee are hard at work working on the 2018 conference, taking into consideration feedback from last year's conference evaluation to ensure yet another successful conference. It is not too late to provide suggestions for conference speakers and/or topics for consideration. If you are interested in participating as a speaker or panelist at this year's conference please let us know. We are always looking for volunteers from our own membership to highlight the important work our members are doing.

**Survey/Data/IT Committee** - The committee has begun its work of developing potential surveys of the membership and will also be working with our webmaster Bill Ward on additional enhancements to our new database management software. The software has helped NASCSA update contact information quickly as well provide updates on various regulations/statutes. We ask that state agencies check the state profile page [here](#) for their respective states and let us know whether any information needs updating. If there is information you feel would be helpful, please forward those suggestions.

**Prescription Monitoring Program Committee** - The committee is meeting on a monthly basis and has a number of important tasks. Several committees have been formed. More information will be provided on these initiatives as they progress.

**Policy and Procedures** - A committee has been formed to review NASCSA's written policies and procedures to ensure that these documents are up to date. These policies ensure the smooth operation of the organization and provide a roadmap for overall operations of the organization.

**Finance Committee** - A committee has been formed to review NASCSA's finances on an ongoing basis and to make any recommendations to the Executive Committee.

**Education Committee** - The committee is in the process of identifying additional educational offerings for NASCSA members including but not limited to webinars for members. We welcome any suggestions for the committee to consider.

**Nominating Committee** - In order to streamline the nominating process for election of officers, a formal committee has been formed.

**Resolutions/Bylaws** - The committee is in the process of preparing reviewing the bylaws for any revisions at this year's annual business meeting. Bylaw changes must be distributed 60 days in advance of the meeting. In addition, the committee will be reviewing potential resolutions for

agency will hold a Jan. 30 public hearing on the issue. Comments are due March 16.

### **Department of Veterans Affairs Publicly Posts Opioid Prescribing and Dispensing Data**

The Department of Veterans Affairs (VA) will be publicly posting opioid-prescribing and -dispensing rates from VA pharmacies in an effort to be the most transparent government agency. The data also includes changes in opioid prescribing rates between 2012 and 2017. Ninety-nine percent of VA facilities have decreased prescribing rates since 2012, according to the department. The latest data can be viewed on the department's [website](#).

### **SAMHSA to Award New Grants to States Hit Hardest by Opioid Epidemic**

As part of the Opioid State Targeted Response (STR) Supplements program, Substance Abuse and Mental Health Services Administration (SAMHSA) will award new grants to states with the highest overdose death rates. This funding follows last year's announcement of \$1 billion in grants, which SAMHSA distributed to states and

consideration at the annual conference. All members are strongly encouraged to provide their suggestions on possible resolutions and proposed language as soon as possible. All members are permitted to submit proposed resolutions in accordance with our [Bylaws](#), found at Article XI. Draft resolutions will be distributed in early September (45 days prior to the annual meeting). The committee will also be developing guidelines for voting on resolutions and election of officers at this year's meeting.

### **Energy and Commerce Committee Announces Legislative Hearings on Opioid Epidemic Feb. 28**

The House of Representatives Committee on Energy and Commerce will be holding a series of legislative hearings on possible solutions to the opioid epidemic beginning Wednesday, February 28, 2018 at 1 p.m. in room 2123 of the Rayburn House Office Building. The hearings will consider legislative measures aimed at fighting opioid abuse, an issue that has received bipartisan attention as deaths caused by opioids continue to rise, notes a Committee [press release](#). The following bills are some of the proposals to be considered:

**The Empowering Pharmacists in the Fight Against Opioid Abuse Act.** The bill would require leaders of HHS and the Drug Enforcement Administration to develop and disseminate programs and materials for training pharmacists, healthcare providers and patients on properly filling prescriptions for controlled substances. The bill also requires DEA, as it develops training materials, to seek input from national, state and local associations, boards of pharmacy, medical societies, licensing boards, healthcare practitioners, and patients.

**Opioid Preventing Abuse through Continuing Education (PACE) Act of 2017.** The bill would develop requirements for practitioners to complete, every three years, 12 hours of training on pain management treatment guidelines and best practices, early detection of opioid addiction, and treatment and management of opioid-dependent patients. DEA will fund enforcement of the requirements, and HHS will establish or support one or more training modules.

**Stop the Importation and Trafficking of Synthetic Analogues (SITSA) Act.** The SITSA Act would add a new and sixth schedule category - Schedule A - to the Controlled Substances Act. Schedule A substances have a chemical structure of a controlled substance in schedule I, II, III, IV or V, the bill explains, and they also have "an actual or predicted stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or

territories based on the number of overdose deaths and the number of people needing treatment.

SAMHSA is accepting grant applications from the Opioid STR grantees for the Opioid STR

Supplements program through January 16, 2018. The eligible states include Kentucky, Massachusetts, New Hampshire, New Mexico, Ohio, Pennsylvania, Rhode Island, Tennessee, Utah, and West Virginia. The purpose of the supplemental funding is to bolster efforts already being made through the STR grant program. More details about the new grants can be found in SAMHSA's [announcement](#).

### **CDC Releases Drug Overdose Deaths in the United States, 1996-2016**

The Centers for Disease Control and Prevention (CDC) released its annual overdose death report in December 2017. The report uses data from the National Vital Statistics System (NVSS) to illustrate trends in overdose deaths in the US, describe demographic and geographic patterns, and identify the types of drugs involved. A link to the report is found [here](#).

### **Senate Subcommittee Releases Report on**

greater than the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled substance" under any of the other five schedules. The bill names 13 substances that would be listed under schedule A: 4-fluoroisobutyryl fentanyl, valeryl fentanyl, 4-methoxybutyryl fentanyl, 4-methylphenethyl acetyl fentanyl, 3-furanyl fentanyl, ortho-fluorofentanyl, tetrahydrofuranyl fentanyl, ocfentanil, 4-fluorobutyryl fentanyl, methoxyacetyl fentanyl, meta-fluorofentanyl, isobutyryl fentanyl and acryl fentanyl.

Ensuring Patient Access to Substance Use Disorder Treatments Act of 2018. The bill would allow a pharmacy to deliver a controlled substance to a practitioner to be administered to a patient for maintenance or detoxification treatments.

**The Tableting and Encapsulating Machine Regulation Act of 2018.** The bill would add encapsulating and tableting machines to the definition of a controlled substance. An encapsulating machine is any manual, semi-automatic or fully automatic equipment used to fill shells or capsules for human consumption. A tableting machine is any manual, semi-automatic or fully automatic piece of equipment that compacts or molds powdered or granular solids to produce solid tablets for human consumption.

**The Safe Disposal of Unused Medication Act.** The bill would allow hospice program employees to handle controlled substances in the residence of a deceased hospice patient to assist with disposing of the medication.

Improving Access to Remote Behavioral Health Treatment Act of 2018. The bill would allow community mental health and addiction treatment centers to register to dispense controlled substances.

### **DEA Issues Temporary Drug Scheduling Orders on Synthetic Drugs**

The US Drug Enforcement Administration (DEA) recently issued temporary scheduling order to schedule the synthetic opioids.

- Temporary Placement of Fentanyl-Related Substances in Schedule I (February 6, 2018)
- Temporary Placement of Seven Fentanyl-Related Substances in Schedule I (February 1, 2018)
- Proposed Rule: Placement of MAB-CHMINACA Into Schedule I (January 30, 2018)
- Extension of Temporary Placement of MAB-

## Online Orders and Shipments

Last month the Senate Permanent Subcommittee on Investigations released a staff report entitled "Combatting the Opioid Crisis: Exploiting Vulnerabilities in International Mail." The release of the [report](#) precedes a subcommittee hearing on this issue held January 25th. The 100-page report focuses on the ease in which American citizens are able to order and ship synthetic, illicit, and counterfeit opioids into the United States through online orders and shipments via national post.

## NABP Releases Report on Online Sales of Counterfeit Drugs

The National Association of Boards of Pharmacy® (NABP®) published the February 2018 [Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators](#). The report provides an update on the internet drug buying landscape and how the online sale of counterfeit medications is exacerbating the opioid epidemic in the United States.

In a recent study, NABP evaluated 100 websites selling medications to patients in the US, and all of them were found to be operating illegally. The study found that:

- 54% of the sites were

CHMINACA in Schedule I of the Controlled Substances Act (January 30, 2018)

- Temporary Amendment; Temporary Scheduling Order: Temporary Placement of Cyclopropyl Fentanyl in Schedule I (January 4, 2018)

For more information click [here](#).

Additionally, DEA recently placed all illicit fentanyl analogues not already regulated by the Controlled Substances Act into Schedule I-the category for substances with no currently accepted medical use-for two years, with the possibility of a one-year extension. This action is expected to reduce these substances' flow into the country and slow the alarming increase in overdose deaths linked to synthetic opioids. The Federal Register notice is available [here](#).

## FDA to Limit Number of Loperamide Doses in Packaging to Encourage Safe Use

Despite the addition of a warning label and previous communication, FDA continues to receive reports of serious heart problems and deaths primarily among people who are intentionally misusing or abusing the over-the-counter (OTC) anti-diarrhea drug loperamide by taking much higher than the recommended dose. To foster safe use of loperamide, FDA is working with manufacturers to use blister packs or other single dose packaging and to limit the number of doses in a package. The maximum approved daily dose for adults is 8 mg per day for OTC use and 16 mg per day for prescription use.

Some individuals are taking high doses of loperamide to treat symptoms of opioid withdrawal. Health care professionals should be aware that using much higher than recommended doses of loperamide, either intentionally or unintentionally, can result in serious cardiac adverse events. As noted in a [safety alert](#), health care professionals should counsel patients to take loperamide only as prescribed or according to the OTC Drug Facts label, and advise patients that drug interactions with commonly used medicines may increase the risk of serious cardiac events.

FDA is continuing to evaluate this safety issue and will update the public when more information is available. Health care professionals are encouraged to report adverse events or side effects related to the use of these products to FDA's [MedWatch Safety Information and Adverse Event Reporting Program](#).

selling controlled substances (CS). This is a substantial jump from the 13% of all sites NABP has reviewed and listed as "Not Recommended" in the past nine years that were selling CS.

- 98% of the sites did not require a valid prescription.
- 76% of the sites offered foreign or non-Food and Drug Administration-approved drugs.
- 40% of the sites were selling CS, including opioids frequently linked to fentanyl-related overdoses. The most common CS being offered with no prescription was Xanax®, a drug whose counterfeit could contain fentanyl.

### NABP Adds New States to National Network of Prescription Drug Monitoring Programs

The National Association of Boards of Pharmacy (NABP's®) recently announced that North Carolina and Oregon are now participating in in PMP InterConnect initiative. These two states have joined the secure national network of PMPs that allows authorized prescribers and pharmacists to access information about their patients' controlled

## DEA Enables Mid-Level Practitioners to Prescribe and Dispense Buprenorphine

Drug Enforcement Administration (DEA) recently announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices, indicates a DEA news release. This final rule took effect January 22, 2018. More details about DEA's amendments related to the dispensing of narcotic drugs for opioid use disorder are available in a Federal Register [notice](#).

## State Regulatory Developments

**Georgia** - Proposed rule of the Composite Medical Board would adopt regulations under GAC 360-38 to provide guidance to physicians on the Prescription Drug Monitoring Program (PDMP). The rule would establish requirements for enrollment, access, and checking the PDMP. The rule also would specify grounds for disciplinary action. A hearing is scheduled for April 14, 2018, in Atlanta. Comments are due April 4, 2018. Contact: Diane Atkinson; CMB; 404-656-3913; [matkinson@dch.ga.gov](mailto:matkinson@dch.ga.gov)

**Illinois** - Effective January 1, 2018, prescribers who possess an Illinois controlled substances (CS) license must register with the state prescription monitoring program (PMP) and must consult the PMP when prescribing Schedule II narcotics. These requirements are part of amendments to the Illinois Controlled Substances Act with the passage of Senate Bill 0772. The amendments also require prescribers or their designees to document the attempt to access patient information in the PMP when providing an initial prescription for a Schedule II narcotic. This requirement excludes prescriptions for oncology treatment or palliative care, or a seven-day or less supply provided by a hospital emergency department when treating an acute, traumatic medical condition. The attempt to access must be documented in the patient's medical record. In addition, if an unsolicited report is issued to a prescriber or prescribers, then the report must also be sent to the applicable dispensing pharmacy. Within one year of the effective date of the amended Act, the Illinois Department of Human Services must adopt rules requiring all electronic health record systems to interface with the PMP application

substance prescriptions across state lines. There are now 44 states live in the program with plans for an additional PMP, St Louis County, Missouri, to be made live in early 2018.

PMP InterConnect currently processes over 15 million requests and 18.5 million responses per month. It is free of charge for participating states. For more information about PMP InterConnect, click [here](#).

## Industry News

### **FDA Approves First Once-Monthly Buprenorphine Injection -**

The U.S. Food and Drug Administration today approved Sublocade, the first once-monthly injectable buprenorphine product for the treatment of moderate-to-severe opioid use disorder (OUD) in adult patients who have initiated treatment with a transmucosal (absorbed through mucus membrane) buprenorphine-containing product. It is indicated for patients that have been on a stable dose of buprenorphine treatment for a minimum of seven days. For more information click [here](#).

**RxOrbit Launches New Platform** - RxOrbit recently issued two press releases.

program on or before January 1, 2021. These rules must also address the electronic integration of pharmacy records with the PMP to allow for faster transmission of the information.

**Kentucky** - Final rule of the Cabinet for Health and Family Services, Office of Inspector General, amends regulations under 902 KAR 55 regarding the Kentucky All-Schedule Prescription Electronic Reporting (KASPER) system that establishes reporting requirements for all dispensers of controlled substances. The rule adds a definition of "suspected drug overdose" and mandatory hospital reporting requirements via the Kentucky Health Information Exchange for all positive toxicology screens. The rule also removes obsolete reporting time frames, clarifies KASPER error remediation procedures, clarifies that drug testing is "ordered" by hospital emergency departments, and updates certain forms. The rule is effective Jan. 5, 2018. Contact: Tricia Orme; CHFS, Office of Legal Services; 502-564-7905; [Tricia.Orme@ky.gov](mailto:Tricia.Orme@ky.gov)

**New Hampshire** - Final rule of the Board of Pharmacy readopts with amendment regulations under NHAR Ph 1501 through 1506 regarding the Controlled Drug Prescription Health and Safety Program. The program authorizes the board to establish and contract with a third party for the implementation and operation of an electronic system to facilitate the confidential sharing of information relating to the prescribing and dispensing of Schedule II, III, and IV controlled substances by prescribers and dispensers within the state. The rule updates reporting procedures and classifications of registered users, adds waiver procedures, and clarifies prescriber and dispenser access to the program. The rule also clarifies requirements concerning medical records and protected health information and updates the definitions of "dispenser" and "practitioner." The rule is effective Jan. 23, 2018. Contact: Robert Lamberti; Office of Professional Licensure; 603-271-3103; [Robert.lambertijr@nh.gov](mailto:Robert.lambertijr@nh.gov)

**Texas** - Final rule of the Department of State Health Services adopts regulations under 25 TAC 95 to establish the Prescription Drug Donation Program, where individuals donate unused prescription drugs to providers who will distribute them to eligible recipients. The rule sets eligibility criteria for participating providers and directs the department to create and maintain a database of participating providers on the program's website. The rule also implements standards and procedures for donating or accepting prescription drugs and for inspecting, storing, and dispensing donated prescription drugs. In addition, the rule prohibits prescription drugs under this program from being resold; limits liability for donors and providers; addresses the handling fee providers may charge to cover the costs of inspecting, storing, labeling, and dispensing donated

One for the launch of its [RxOrbit](#) PDMP platform and the second their partnership/launch for the Overdose Fatality Review ([OFR](#)) workflow tool. The former was also recently covered in

[Healthcare IT News.](#)

prescription drugs; and addresses recordkeeping requirements for providers. The rule is effective March 1, 2018. Contact: Francela Brazil Williams; DSHS, Pharmacy Branch; 512-776-7489; [francela.williams@dshs.texas.gov](mailto:francela.williams@dshs.texas.gov)

To view all state regulatory developments which are compiled monthly by NASCSA click [here](#).

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