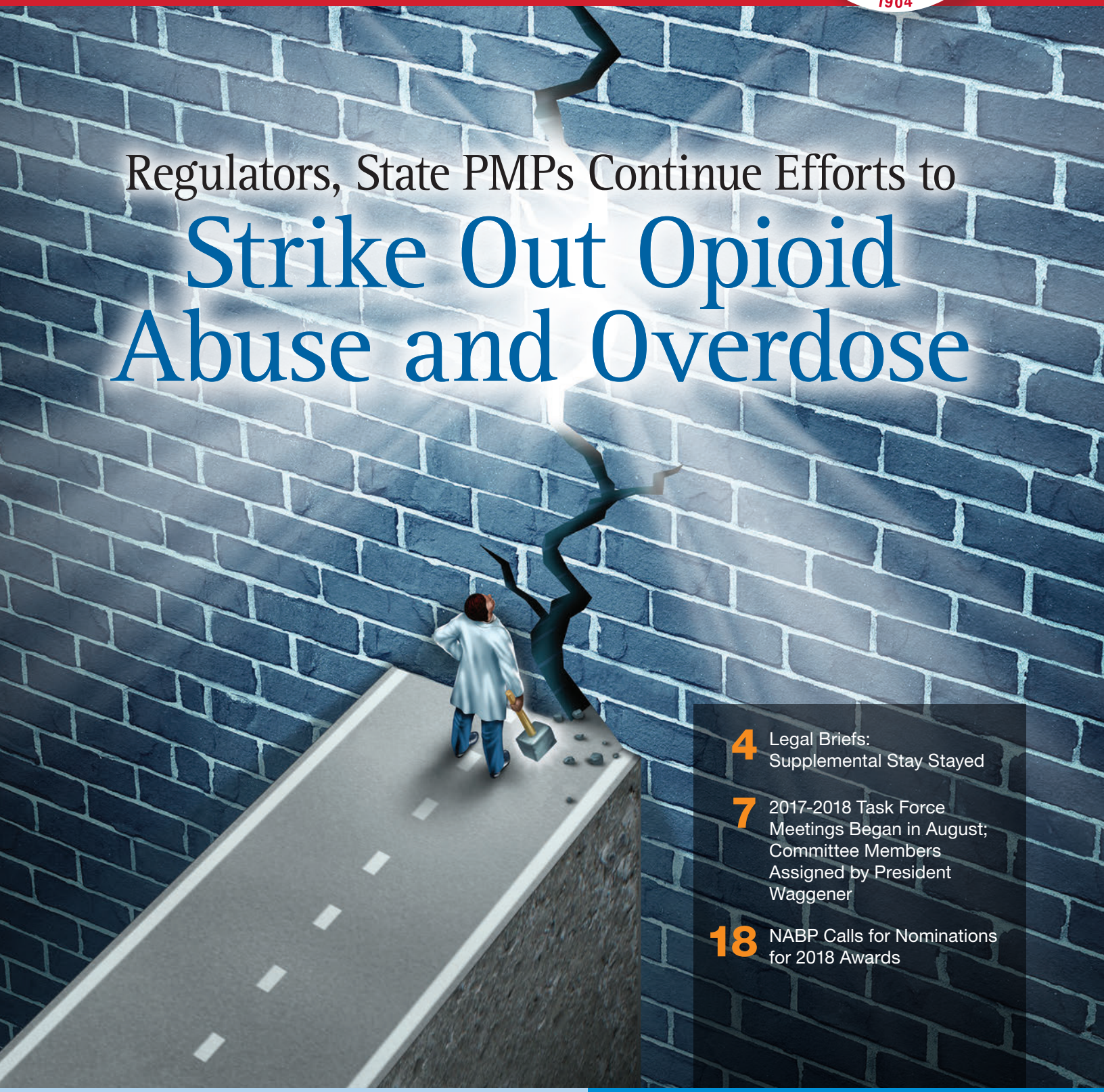
NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS®

Regulators, State PMPs Continue Efforts to

Strike Out Opioid Abuse and Overdose



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EXECUTIVE COMMITTEE

Innovations
(ISSN 2472-6850 – print; ISSN 2472-6958 – online) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 67 member boards of pharmacy.

The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $70 per year.

National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL 60056 • 847/391-4406
www.nabp.pharmacy • help@nabp.pharmacy

Carmen A. Catizone
Executive Director/Secretary

Amy Suhajda
Communications Manager

NABP Mission Statement
NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

Connect & Protect

Educating, Sharing, and Leading

Interactive Executive Officer Forum

October 3-4, 2017

Interactive Compliance Officer and Legal Counsel Forum*

November 29-30, 2017

This year's forums provide attendees a unique opportunity to discuss today's important issues with fellow pharmacy regulation experts. Highlights of the forums include:

- **Network with colleagues**
- **Participate in discussions on topics submitted by fellow attendees**
- **Discover solutions for shared challenges**
- **No registration fee**
- **Travel, hotel, and meal expenses paid by NABP**

Highlights from the Executive Officer Forum will be provided in a future issue of *Innovations*. Executive officers will receive registration information for the Compliance Officer and Legal Counsel Forum in October. For more information about the forums, contact ExecOffice@nabp.pharmacy. *One compliance officer and one legal counsel per board may attend at no charge.

FDA Training for Compliance Officers

Prior to the start of the Interactive Compliance Officer and Legal Counsel Forum, compliance officers will have the opportunity to attend an educational session on compounding facility inspections presented by Food and Drug Administration (FDA). This session will begin the afternoon of November 28 and conclude the morning of November 29.

Supplemental Stay Stayed

Attorney Dale J. Atkinson, JD, outside counsel for NABP, is a partner in the law firm of Atkinson & Atkinson.

> **"While the entry of a stay in administrative rulings is rare, such requests can trigger interesting legal issues as well as create complex circumstances."**

On a regular basis and based upon administrative prosecutions, state boards of pharmacy enter final adverse actions against persons and entities alleged to be found guilty of violating state law. These prosecutions involve providing the respondent with notice of and an opportunity to respond to the allegations. If not resolved through agreement, the matter proceeds to an administrative hearing before a final determination is rendered. In the event of a ruling against the respondent and an order imposing sanctions, the respondent may seek a "stay" of the execution of the sanctions. A stay may be sought through an administrative ruling and/or before a circuit court. If granted, the sanctions imposed are not enforced pending an appeal of the administrative ruling. While the entry of a stay in administrative rulings is rare, such requests can trigger interesting legal issues as well as create complex circumstances. Consider the following.

In October 2016, the Alabama State Board of Pharmacy (Board) entered an administrative order against a pharmacist (Licensee), suspending her license for five years and levying a $27,000 fine against her. In addition, the order placed two pharmacy permits of pharmacies owned by the Licensee on probation for five years. (Where applicable, the pharmacist and pharmacies will be collectively referred to as Respondents.) The adverse actions were based upon 46 counts of various improper practices.

In November 2016, the Respondents sought judicial review of the Board order and, at the same time, filed a motion to stay the Board's decision pending the outcome of the judicial review. In a procedural twist and two days before the hearing on the original motion to stay, the Respondents filed an emergency motion to stay the administrative order. In this emergency motion, the Respondents argued that the suspension of her license was causing her "irreparable harm" because medical suppliers were unwilling to provide supplies to the pharmacies. She alleged that "the personal suspension of me taints and sullies my pharmacies and is making it extremely difficult, if not impossible, for my pharmacies to continue in business so long as I am suspended." Two affidavits were filed in support of this emergency motion.

On December 1, 2016, the circuit court entered an order staying the suspension of the Licensee's license pending the appeal and subject to compliance with certain conditions, including that the Licensee would not dispense legend or controlled substances (CS) and that a specified pharmacy (owned by the Licensee) hire a pharmacist-in-charge who must be approved by the Board. On December 14, 2016, the Licensee filed an "emergency supplemental motion to stay" seeking the removal of language from the website of the National Practitioner Data Bank (NPDB) relating to the now stayed suspension. The language sought to be removed was not specified in the motion, but the allegation stated that the NPDB language resulted in the revocation of the Licensee as a provider under the Alabama Medicaid program, again resulting in a refusal of suppliers selling to the pharmacies.

The Respondents asked for a modification of the previous stay to apply to the NPDB website.

During various motions to extend the hearing date of the supplemental emergency motion, the circuit court entered an order that stated:

1. [Licensee], whose suspension was lifted by this court's order of December 1, 2016, is hereby allowed to work as a pharmacist until further order of this court.

2. [The Board] is hereby ORDERED to immediately clear and remove all language in its entirety sent to the [NPDB] concerning [the pharmacies] and [Licensee].

Based upon this supplemental order, the Board filed a petition for a writ of mandamus. A writ of mandamus seeks a court order that compels action by an entity or court based upon an abuse of discretion standard. In this case, the Board asked that the court of appeals compel the removal of the supplemental emergency motion order by the lower court. As noted by the court of appeals, a writ of mandamus is an extraordinary legal remedy.

In its appeal, the Board argued that the lower court must allow the Board, under the Alabama Administrative Procedure Act (AAPA), to present evidence related to the request for a modification of conditions of a previously ordered stay. The pertinent part of the AAPA allows for the Board to present evidence of a probable danger to public health, safety, and welfare in a case whereby a licensee seeks a stay of an order removing a suspension or revocation of licensure.

The Board argued that the lower court, by allowing the Licensee to practice pharmacy pending the outcome of the appeal, removed the prohibition of dispensing legend and CS without an opportunity by the Board to present evidence related to public health, safety, and welfare. The Respondents argued that the Board attorneys did not appear at the relevant emergency hearings thereby justifying the lower court order.

The court of appeals held that the characterizations by the Respondents of impropriety by the Board attorneys in not appearing at the emergency hearings was "wholly unsupported" by the record. In fact, the Board attorneys were in consistent contact with the court and, due to identified medical issues, requests for continuances were appropriate. Based upon the fact that the Board was not given an opportunity to present evidence challenging the supplemental stay allowing the Licensee to practice pharmacy pending the appeal, the court of appeals found that the lower court erred. It further noted that the lower court failed to give the Board an opportunity to address the NPDB language issue. Thus, the court of appeals granted the writ of mandamus and ordered the lower court to vacate the supplemental order. The court also directed the lower court to hold a hearing whereby the parties can present evidence and arguments regarding the supplemental relief sought by the Respondents.

Board or court orders that stay the enforcement of sanction rendered after an administrative proceeding can be challenging. However, with the public health, safety, and welfare at stake, opportunities for Board rebuttal to the requests for a stay are essential to fulfill the mission of a regulatory system. While this case turned on a procedural issue of notice and opportunity to be heard by the Board, the substantive issue remains whether and how a court can order a board of pharmacy to take action related to the NPDB.

Ex Parte Alabama State Board of Pharmacy, 2017 Ala Civ App LEXIS 120 (App Ct AL 2017) ■

Free Resources Available to Member Boards on NABP Website

Check out the following resources available to member boards for download in the Publications and Reports section of the NABP website at *www.nabp.pharmacy*.

- *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*
- *The NABP State Boards of Pharmacy Member Manual*

Task Force Addresses the Assessment of Pharmacy Candidates' Communication Skills

During the Task Force on the Pharmacist Integrated Communication Skills Examination (PICSE) held on December 13-14, 2016, in Rosemont, IL, members addressed the concept of assessing the communication skills of candidate pharmacists. The task force members reviewed information collected from the 2014 NABP Pharmacy Practice Analysis Survey and the analysis by the Advisory Committee on Examinations, and discussed the current competency assessment measures for written and oral communication skills through multiple-choice examination items. The task force members made two recommendations and resolved to have NABP study whether a PICSE would be beneficial for evaluating United States pharmacist candidates.

The task force members recommended that NABP and the state boards of pharmacy collaborate with the Accreditation Council for Pharmacy Education (ACPE), American Association of Colleges of Pharmacy (AACP), and other stakeholders to encourage standardization within the pharmacy school curriculum and review how the standards for accreditation concerning communication skills, specifically the *ACPE Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016)*, are being implemented by the schools and colleges of pharmacy. During their discussions, task force members referenced both the *Standards 2016* and the AACP Center for the Advancement of Pharmacy Education (CAPE) Educational Outcomes 2013. Because patient-centered care is grounded on good communication skills, the members indicated that boards of pharmacy may wish to consider the necessity to assess and validate this skill in the interest of public welfare and protection.

Additionally, the task force members recommend that NABP consider the feasibility of developing a PICSE and incorporating it into the competency assessment of pharmacist candidates. Members envisioned NABP working with ACPE and AACP to standardize the communication skills education in pharmacy schools and to create a progression model similar to the model used in the US medical school system, in which medical students cannot progress to clinical clerkship without passing some standardized assessment of communication skills.

The Task Force on PICSE was established in response to the results of the 2014 NABP Pharmacy Practice Analysis Survey, which provided strong evidence that pharmacist communication skills are an integral component for safe and effective contemporary pharmacy practice. NABP regularly conducts a survey of pharmacy practice in accordance with examination development standards and recommendations from the testing industry. For the 2014 survey, NABP convened a panel of pharmacist regulators, practitioners, academicians, and representatives from ACPE and AACP to conduct a critical review of the North American Pharmacist Licensure Examination® competency statements.

Members of the Task Force on the PICSE included Roger Fitzpatrick, RPh, chair; Daphne Bernard, PharmD, RPh; Michael Bertagnolli, MBA, RPh, FACHE; Jim Bracewell, BBA; Rebecca Deschamps, RPh; Randy Forbes, JD; Maria Marzella Mantione, PharmD, RPh, CGP, FAPhA; John Marraffa, Jr, RPh; Brenda McCrady, RPh; Richard A. Palombo, RPh; Rebecca "Suzette" Tijerina, RPh; Stuart Williams, JD; and Caroline D. Juran, RPh, DPh, Executive Committee liaison.

More details about the NABP Pharmacy Practice Analysis Survey can be found in the January 2014 *NABP Newsletter,* available in the Publications and Reports section at *www.nabp.pharmacy*. The task force report was approved by the Executive Committee during its May 19, 2017, meeting and is available in the Publications and Reports section at *www.nabp.pharmacy.* ■

Task Force Charges

The Task Force on the Pharmacist Integrated Communication Skills Examination met on December 13-14, 2016, and accepted the following charges:

1. Review the present status of pharmacy competency assessment as it relates to pharmacists' communication skills.
2. Discuss the concept of a pharmacist integrated communication skills examination.

2017-2018 Task Force Meetings Began in August; Committee Members Assigned by President Waggener

NABP provides guidance on current topics of interest to the state boards of pharmacy through the commissioning of single-issue task forces. When an issue arises that requires special expertise or a commitment of time and funds, a task force is appointed to address an explicit charge and to report its findings to the NABP Executive Committee. When finalized, task force reports are published on the NABP website. For 2017-2018, NABP commissioned three single-issue task forces pertaining to the following topics:

- best practices for veterinary compounding;
- long-term care pharmacy rules; and
- definition of a patient-pharmacist relationship.

NABP President Jeanne D. Waggener, RPh, DPh, made the following appointments for task forces and standing committees for 2017-2018.

2017-2018 Task Forces

The **Task Force on Best Practices for Veterinary Compounding** met on August 14-15, 2017, at NABP Headquarters in Mount Prospect, IL. The task force was established in response to Resolution No. 113-1-17, passed at the NABP 113th Annual Meeting. The resolution states that the purpose of the task force is to develop model regulations for the compounding of animal products.

The task force is charged with the following objectives:

1. Review existing state laws and regulations addressing compounding of animal (non-food-producing) products.
2. Review existing federal laws and regulations pertaining to the compounding of animal (non-food-producing) products.
3. Determine the applicable role of state boards of pharmacy in regulating the compounding of animal (non-food-producing) products and develop model regulations to amend the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* accordingly.

Chairperson of this task force was Mark J. Hardy, PharmD, RPh, executive director, North Dakota State Board of Pharmacy.

Individuals appointed to serve as members included:

- Jillian Foster, MBA, PharmD, RPh, Mississippi Board of Pharmacy
- Diane Halvorson, RPhTech, CPhT, North Dakota State Board of Pharmacy
- Brenda McCrady, PD, RPh, Arkansas State Board of Pharmacy
- William "Bill" Mixon, MS, RPh, FIACP, FACA, North Carolina Board of Pharmacy
- Patti Smeelink Keim, RPh, Michigan Board of Pharmacy
- Krystal Brashears Stefanyk, North Carolina Board of Pharmacy
- Jenny Downing Yoakum, RPh, Texas State Board of Pharmacy
- Anita Young, EdD, RPh, Massachusetts

Michael Blaire, RPh, of the Arizona State Board of Pharmacy, and Leigh Briscoe-Dwyer, RPh, of the New York State Board of Pharmacy served as alternates. The Executive Committee liaison was Timothy D. Fensky, RPh, DPh, FACA.

The **Task Force on Long-Term Care Pharmacy Rules** met on August 16-17, 2017, at NABP Headquarters. The task force was established in response to Resolution No. 113-4-17, passed at the NABP 113th Annual Meeting. The goal of this task force is to study long-term care pharmacy rules and to review and amend, if necessary, the *Model Act* accordingly.

The task force is charged with the following objectives:

1. Review existing state laws and regulations addressing the practice of long-term care pharmacy.
2. Review current requirements for long-term care pharmacy practice contained within the Controlled Substances Act (CSA) and Code of Federal Regulations (CFR).
3. Recommend, if necessary, amending the *Model Act* addressing applicable state regulation of long-term care pharmacy practice.
4. Recommend, if necessary, revisions to the CSA and CFR.

Chairperson of this task force was Malcolm J. Broussard, RPh, executive director, Louisiana Board of Pharmacy.

Individuals appointed to serve as members included:

- Traci Collier, RPh, South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy
- Janet Hart, RPh, Pennsylvania State Board of Pharmacy
- Joshua G. Kohler, North Carolina Board of Pharmacy
- Richard A. Palombo, RPh, New Jersey State Board of Pharmacy
- Tejal Patel, RPh, Delaware State Board of Pharmacy
- Doug Robichaux, RPh, Louisiana Board of Pharmacy
- Kari Shanard-Koenders, RPh, South Dakota State Board of Pharmacy

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Committee, Task Force Appointments

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- Mitch G. Sobel, MAS, RPh, FASHP, New Jersey State Board of Pharmacy
- Robert Stout, RPh, New Hampshire Board of Pharmacy

James Bialke, MA, of the Minnesota Board of Pharmacy, Gary Merchant, MBA, RPh, of the New Hampshire Board of Pharmacy, Ronald Moore, RPh, of the Louisiana Board of Pharmacy, and Suzette Tijerina, RPh, of the Texas State Board of Pharmacy served as alternates. The Executive Committee liaison was Mark D. Johnston, RPh, DPh.

The **Task Force on the Definition of a Patient-Pharmacist Relationship** met on September 18-19, 2017, at NABP Headquarters. The task force was established in response to Resolution No. 113-2-17, passed at the NABP 113th Annual Meeting. The task force convened to examine the adoption of a definition of a patient-pharmacist relationship.

The task force is charged with the following objectives:

1. Review existing state laws and regulations that address the patient-pharmacist relationship.
2. Examine information related to the definition of patient relationships with pharmacists concerning the pharmacist's role in patient care services, such as, but not limited to, disease state manager and patient care advocate.
3. Recommend, if necessary, amending the *Model Act* to include a definition of a patient-pharmacist relationship.

Chairperson of this task force was Dennis F. Wiesner, RPh, member, Texas State Board of Pharmacy.

Individuals appointed to serve as members included:

- Sabrina Beck, PharmD, RPh, Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit
- Fiona Karbowicz, RPh, Oregon State Board of Pharmacy
- Timothy R. Koch, RPh, CHC, Arkansas
- Sam Lanctin, BScPharm, MBA, New Brunswick College of Pharmacists
- Leo Lariviere, MS, RPh, Rhode Island Board of Pharmacy
- Dennis K. McAllister, RPh, FASHP, Arizona State Board of Pharmacy
- Jeff Mesaros, PharmD, JD, RPh, Florida Board of Pharmacy
- Steven Saxe, RPh, FACHE, Washington State Pharmacy Quality Assurance Commission
- Deena Speights-Napata, MA, Maryland Board of Pharmacy
- Christian Tadrus, PharmD, RPh, AE-C, Missouri Board of Pharmacy
- Donna S. Wall, PharmD, RPh, Indiana Board of Pharmacy
- Cynthia "Cindy" Warriner, RPh, Virginia Board of Pharmacy

Buford T. Abeldt, Sr, RPh, and Kerstin Arnold, JD, of the Texas State Board of Pharmacy, Greg Braylock, RPh, of Arizona, Patricia F. Donato, RPh, of the New York State Board of Pharmacy, and Kevin Robertson, PharmD, RPh, BCPS, of the Arkansas State Board of Pharmacy served as alternates. The Executive Committee liaison was Susan Ksiazek, RPh.

2017-2018 Standing Committees

As authorized by the NABP Constitution and Bylaws, the Association's standing committees annually perform specific responsibilities that are essential to the success of NABP's programs. Once a committee has explored its assigned issues, the members submit recommendations or resolutions to the NABP Executive Committee for consideration.

The **Committee on Law Enforcement/ Legislation** will meet on January 22-23, 2018, at NABP Headquarters. The committee is charged with the following tasks:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Steven W. Schierholt, Esq, executive director, State of Ohio Board of Pharmacy, will serve as the committee chairperson. Committee members include:

- Allison Vordenbaumen Benz, MS, RPh, Texas State Board of Pharmacy
- Lee Ann F. Bundrick, RPh, South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy
- Lemrey "Al" Carter, MS, PharmD, RPh, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy
- Debbie Chisolm, RPh, Connecticut Commission of Pharmacy
- Virginia "Giny" Herold, MS, California State Board of Pharmacy

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Task Force on Long-Term Care Pharmacy Rules Meets

The Task Force on Long-Term Care Pharmacy Rules met August 16-17, 2017, at NABP Headquarters to study long-term care pharmacy rules and to review and amend, if necessary, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. Pictured are (front, left to right) Janet Hart, RPh, Pennsylvania State Board of Pharmacy; Tejal Patel, RPh, Delaware State Board of Pharmacy; Joshua G. Kohler, North Carolina Board of Pharmacy; (center, left to right) William "Fitz" Fitzpatrick, Texas; Traci Collier, RPh, South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy; Kari Shanard-Koenders, RPh, South Dakota State Board of Pharmacy; Ross Brickley, RPh, MBA, CGP, North Carolina Association of Pharmacists; (back, left to right) Doug Robichaux, RPh, Louisiana Board of Pharmacy; Malcolm J. Broussard, RPh, Louisiana Board of Pharmacy (chairperson); Richard A. Palombo, RPh, New Jersey State Board of Pharmacy; Robert "Bob" Stout, RPh, New Hampshire Board of Pharmacy; Mitch G. Sobel, MAS, RPh, FASHP, New Jersey State Board of Pharmacy; and Mark D. Johnston, RPh, DPh, NABP Executive Committee liaison.

Committee, Task Force Appointments

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- Deborah C. Mack, PD, RPh, CHC, CCEP, Arkansas State Board of Pharmacy
- Lenora Newsome, PD, RPh, Arkansas State Board of Pharmacy
- Jeenu Philip, RPh, Florida Board of Pharmacy
- Penny Reher, RPh, Oregon State Board of Pharmacy
- Gayle D. Ziegler, RPh, North Dakota State Board of Pharmacy

Christopher M. Dembny, RPh, and Chip Thornsburg of the Texas State Board of Pharmacy will serve as alternates. The Executive Committee liaison is Jack W. "Jay" Campbell IV, JD, RPh.

The **Committee on Constitution and Bylaws** will meet on March 28, 2018, via conference call. The charge of this committee, as defined by the NABP Constitution and Bylaws, is to review proposed amendments to the Constitution and Bylaws, suggest changes where appropriate, and issue a recommendation for each proposed amendment.

Stuart T. "Stu" Williams, JD, member, Minnesota Board of Pharmacy, will be the committee chairperson. Committee members include:

- L. Suzan Kedron, JD, Texas State Board of Pharmacy
- John M. Marraffa, Jr, RPh, New York State Board of Pharmacy
- Bradley A. Miller, PhTR, Texas State Board of Pharmacy
- Katy Wright, RPh, DPh, Tennessee Board of Pharmacy

Alice G. Mendoza, RPh, of the Texas State Board of Pharmacy and Mark Mikhael, PharmD, RPh, of the Florida Board of Pharmacy will serve as alternates. The Executive Committee liaison is Philip P. Burgess, MBA, DPh, RPh.

Regulators, State PMPs Continue Efforts to Strike Out Opioid Abuse and Overdose

On August 10, 2017, President Donald Trump issued instructions for his administration to use all appropriate emergency and other authorities to respond to the crisis caused by the opioid epidemic. In a brief statement, the President referred to the crisis as "a serious problem – the likes of which we've never had [. . .] This is a national emergency, and we are drawing documents now to so attest."

This announcement comes after the governors of Alaska, Arizona, Florida, Virginia, Maryland, and Massachusetts declared emergencies in their own states to address the opioid crisis. The efforts being made by both state and federal officials are the latest in a series of ongoing efforts to address the opioid overdose epidemic that has resulted in the deaths of tens of thousands of Americans over the last decade.

"The efforts being made by both state and federal officials are the latest in a series of ongoing efforts to address the opioid overdose epidemic that has resulted in the deaths of tens of thousands of Americans over the last decade."

Opioid Abuse Trends

More than 33,000 people died of opioid overdoses in 2015, reports the Centers for Disease Control and Prevention (CDC). Deaths from drug overdoses rose sharply in the first nine months of 2016, and the rate of overdose deaths increased every three months in that period, reaching a record of 19.9 per 100,000 people in the third quarter, up from 16.7 for the same three months in 2015.

State-specific data for opioid overdoses in 2016 is also alarming. In Pennsylvania, there was a 37% increase from 2015 to 2016 in drug-related overdoses reported by coroners and medical examiners, according to a report released by Drug Enforcement Administration's Philadelphia Field Division. The report also identified heroin as the most frequently reported drug involved in an overdose in 2015, with total instances increasing 23% from 2015 to 2016. Prescription opioids were involved in 25% of deaths.

One piece of good news amid this health crisis is that overall misuse and abuse of prescription drugs, including opioids, appears to have leveled off. According to the 2015 National Survey on Drug Use and Health (NSDUH), an estimated 6.4 million Americans (2.4% of the population) age 12 or older were "current misusers of psychotherapeutic drugs." The largest subset of abused prescription drugs were prescription painkillers, particularly opioids such as morphine and fentanyl. While not directly comparable to last year's NSDUH statistics due to methodology changes, similar estimates from previous versions of the survey estimated a slightly higher rate of abuse, ranging as high as 2.9%. Data also show a possible slowing of prescription drug overdoses. Specifically, a February 2017 National Center for Health Statistics Data Brief showed that the percentage of drug overdose deaths involving "natural and semisynthetic opioid analgesics, which include drugs such as oxycodone and hydrocodone," decreased by 5% from 2010 to 2015. However, the percentage of drug overdoses involving heroin tripled in that same period.

Many experts now believe that the abuse of prescription opioids and heroin use are interconnected and that prescription drug abusers who lose access to a preferred opioid painkiller may turn to heroin. Approximately 808,000 people over 18 used heroin within the last year, according to the NSDUH. The number of heroin-related overdose deaths "nearly quadrupled" between 2002 and 2013, according to CDC.

Federal Legislative and Executive Branch Action Is Ongoing

Both the executive and legislative branches of the federal government have taken recent steps to address the opioid crisis. In 2016, the 21st Century Cures Act was signed into public law by President Barack Obama after being passed by the 114th Congress. The Act provided National Institutes of Health funding to support efforts to reduce opioid abuse, including medical research and drug development. Specifically, $1 billion was designated to this agency over two years to be provisioned for fighting the epidemic.

This money will primarily be used to fund state efforts to prevent and treat opioid addiction, including making treatment programs more accessible, training health care providers to better care for addiction patients, and conducting research into the most effective ways to prevent opioid addiction.

In addition, the Comprehensive Addiction and Recovery Act (CARA) became law in 2016, with the intention of promoting many strategies to reduce the impact of the opioid crisis. These strategies include increased access to the overdose reversal drug naloxone and state prescription monitoring programs (PMPs); however, the Act did not provide any federal funding to implement those strategies. The money allocated by the 21st Century Cures Act may be used to supplement CARA.

In March 2017, President Trump signed an executive order establishing the President's Commission on Combating Drug Addiction and the Opioid Crisis, led by New Jersey Governor Chris Christie. The group was charged with studying ways to "combat and treat the scourge of drug abuse, addiction, and the opioid crises."

The initial report of that commission, published to the White House website in August 2017, noted the CDC finding that an estimated 142 Americans die each day from drug overdoses, and that, in 2015, nearly two-thirds of those overdoses were linked to opioids. The commission made multiple recommendations, but recommended "first and most urgent[ly]" that the President declare a national emergency under the Public Health Service Act or the Stafford Act.

According to the commission, an emergency declaration would "empower [Trump's] cabinet to take bold steps and would force Congress to focus on funding and empowering the Executive Branch even further to deal with this loss of life."

As of press time, the White House has not indicated the next steps to address the crisis. The Stafford Act is usually activated for natural disasters and normally requires a request from a governor. An emergency of this nature would allow the Federal Emergency Management Agency to provide financial and technical assistance to states and cities. By contrast, the Public Health Service Act allows the secretary of health and human services to declare a public health emergency and deploy medical staff to areas in need.

The presidential commission's other recommendations included rapid increases to treatment capacity, mandating prescriber education initiatives with medical and dental schools, and immediately establishing a federal incentive to enhance access to medication-assisted treatment.

States Expand Access to Naloxone

Among the six states that have already declared emergencies related to the opioid epidemic, several other actions have been taken. In Maryland, practices for those prescribing opioids have been tightened, and the state has received a waiver to allow Medicaid to pay for residential drug treatment. In addition, officials in Florida have allocated an additional $27 million in federal funds for drug treatment and prevention, while officials in Arizona are gathering data on the crisis that can be used to shape public policy.

In Massachusetts – the first state to declare an emergency – former Governor Deval Patrick took steps in accordance with the recommendations of a special task force. The recommendations included directives to prohibit the prescribing and dispensing of all hydrocodone-only medications, mandating prescriber and pharmacist use of the state's PMP, and permitting all first responders to carry and administer naloxone.

To reduce the negative outcomes associated with opioid overdoses, all 50 states and the District of Columbia have now passed some form of legislation to increase access to those who may prescribe, dispense, and administer naloxone. Many states have also passed so-called "Good Samaritan" laws, which provide some protection from arrest or prosecutions for individuals who report an overdose in good faith.

State PMPs, NABP Continue Efforts to Combat Epidemic

PMPs continue to be an effective resource that helps health care providers protect their patients from prescription drug abuse. NABP PMP InterConnect® enhances state PMPs by allowing states to share data with other PMPs.

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Opioid Abuse Prevention Tools for Pharmacists

The AWAR$_x$E® Prescription Drug Safety Program offers pharmacists numerous tools to help them educate themselves, colleagues, and patients on preventing opioid abuse and misuse. Find videos, educational flyers in English and Spanish, federal agency resources, a drug disposal locator, and more on the AWAR$_x$E page in the Initiatives section at *www.nabp.pharmacy*.

Task Force on Best Practices for Veterinary Compounding Convened in August

The Task Force on Best Practices for Veterinary Compounding met August 14-15, 2017, at NABP Headquarters to develop model regulations for the compounding of animal products and amend, if necessary, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. Pictured are (front, left to right) Krystal Brashears Stefanyk, North Carolina Board of Pharmacy; Jenny Downing Yoakum, RPh, Texas State Board of Pharmacy; Anita Young, EdD, RPh, Massachusetts; (center, left to right) Gigi Davidson, BSPh, DICVP, North Carolina State College of Veterinary Medicine; Patti Smeelink Keim, RPh, Michigan Board of Pharmacy; (back, left to right) Jim Penrod, American Association of Veterinary State Boards; Diane Halvorson, RPhTech, CPhT, North Dakota State Board of Pharmacy; Jillian Foster, MBA, PharmD, Mississippi Board of Pharmacy; Timothy D. Fensky, RPh, DPh, FACA, NABP Executive Committee liaison; Mark Hardy, PharmD, RPh, North Dakota State Board of Pharmacy (chairperson); Brenda McCrady, RPh, Arkansas State Board of Pharmacy; and Bill Mixon, North Carolina Board of Pharmacy. Kent McClure, DVM, JD, American Veterinary Medical Association, is not pictured.

Opioid Abuse

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In July 2017, NABP announced that St Louis County and other participating Missouri jurisdictions had signed a memorandum of understanding with NABP to participate in the PMP data sharing system. These jurisdictions joined a network of 42 state PMPs exchanging data securely. PMP InterConnect currently processes more than 10 million requests and 18.5 million responses per month for consolidated multistate PMP reports. The system is available to states, free of charge, and can be used to identify trends so that problems with prescription drugs can be addressed early. (For more information about PMP InterConnect, including its Steering Committee, see pages 14-15 of this issue.)

At the 2015 NABP Annual Meeting in New Orleans, NABP stakeholders discussed strategies for preventing prescription drug abuse while providing effective patient care at the pre-meeting continuing pharmacy education (CPE) session, "Combating Prescription Drug Abuse – Together We Are Making a Difference." A summary of this session is available in the 2015 Special Issue of the *NABP Newsletter*.

At the 2017 NABP Annual Meeting in Orlando, FL, attendees were able to learn about pharmacists' ability to prescribe and dispense naloxone without a prescription to patients at risk for an opioid overdose during the Executive Officer and Board Member CPE session, "Naloxone and Beyond: Can Expanded Scopes Impact the Opioid Epidemic?"

The Tri-Regulator Collaborative, an initiative that includes NABP, the Federation of State Medical Boards, and the National Council of State Boards of Nursing, met in July 2017 and also addressed the opioid crisis.

Through the AWAR$_x$E® Prescription Drug Safety Program, NABP continues its efforts to provide prescription drug safety resources to pharmacists and to educate the public on the safe purchase, use, and disposal of both prescription and over-the-counter medications. For more information on AWAR$_x$E, visit the Initiatives section on the NABP website at *www.nabp.pharmacy*.

NABP will continue to monitor trends and provide updates in the interest of protecting the public health. ■

Coming April 2018:
New Member Database, Customer Applications

NABP Streamlining Processes, Creating User-Friendly Interface for e-Profile Connect

NABP is transitioning its online applications and the corresponding databases to a Windows-based platform to provide a streamlined, user-friendly interface for member boards of pharmacy, schools and colleges of pharmacy, and customers. Improvements users will see when the system launches on April 2, 2018, are as follows:

- The NABP e-Profile Connect will have an improved interface that is more intuitive and easier to navigate.
- Licensure transfer via the Electronic Licensure Transfer Program® will be entirely online and paperless.
- Improved login system features self-service "forgot password" functionality with secure two-step verification.
- New two-step registration process for the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® puts focus on boards' eligibility requirements.
- Schools and colleges of pharmacy will be able to order Pre-NAPLEX® vouchers online through e-Profile Connect.
- New online application process for the Foreign Pharmacy Graduate Examination Committee™ Certification.

Implementation of this new system positions NABP to begin offering more services to boards of pharmacy. In addition, the Association will be able to automate and streamline processes that it currently uses to implement some of the programs used by the boards and schools of pharmacy.

Several accreditation programs – Verified Internet Pharmacy Practice Sites®, Verified-Accredited Device Integrity Program®, Verified-Accredited Wholesale Distributors®, and durable medical equipment, prosthetics, orthotics, and supplies – will be transitioned at a later time.

Boards of pharmacy, schools, and customers will receive detailed, program-specific information in a variety of communication methods as the launch approaches.

DEA to Hold 14th Prescription Drug Take-Back Day on Saturday, October 28, 2017

Drug Enforcement Administration (DEA) will hold a National Prescription Drug Take-Back Day event on Saturday, October 28, from 10 AM to 2 PM, at participating locations nationwide. DEA will list collection sites on its website. Consumers unable to visit a location on the Take-Back Day can find permanent disposal locations using the AWAR$_x$E® Prescription Drug Safety Program's drug disposal locator, which can be found in the Initiatives section on the NABP website at *www.nabp.pharmacy*. Those pharmacies that offer permanent disposal sites may submit their location for inclusion in the locator tool by downloading and emailing the form per the instructions on the site.

State PMPs Discuss PMP InterConnect, Data Sharing, and More at July Steering Committee Meeting

The NABP PMP InterConnect® Steering Committee met on July 19-20, 2017, to provide governance and policy direction as it relates to the implementation of the program. Thirty-eight attendees, including 35 states, one ex-officio state, and two guest states, attended the meeting at NABP Headquarters in Mount Prospect, IL.

The two-day event began with a brief history and overview of PMP InterConnect by NABP staff. Next, Appriss, Inc, NABP's technology provider for PMP InterConnect, provided the group — which included nine members new to the Steering Committee meeting — with an update and reviewed key features of the software used by all program participants.

The Future of PMP InterConnect

NABP staff presented an update to attendees on the current federal landscape, including recent activities by the federal government such as the President's Commission on Combating Drug Addiction and the Opioid Crisis, the proposed federal budget, the changing roles of the US Department of Justice and US Department of Health and Human Services, the 21st Century Cures Act, and the Comprehensive Addiction and Recovery Act, as well as opportunities and challenges they may pose for NABP and PMP InterConnect participants.

The discussion then transitioned to how PMP InterConnect can advance, from both an administrative and a public relations perspective. Participants discussed the various perceptions they face from their own states, as well as at the national level. Regarding technical enhancements, Appriss stated it would commit to two new software releases per year at the direction of the Steering Committee.

PMP Gateway and Data Sharing

NABP staff and Appriss personnel presented an overview of PMP Gateway, its purpose, and its functionality during a discussion focusing on the importance of and movement toward standards for data sharing. Launched in 2014, PMP Gateway works with PMP InterConnect to automate requests for patients' prescription monitoring program (PMP) data, bringing it into the workflow of health care providers' electronic health information systems.

Following the presentation, Steering Committee members from Kansas, Massachusetts, Michigan, and Ohio shared some of the successes and challenges they are experiencing with statewide integration into the health care systems of prescribers and pharmacies.

Steering Committee members also received updates on the activities of two subcommittees. A representative for the Policy Subcommittee described a number of outreach and education activities over the past year and said the group is continuing to look for ways to reach out to more professional associations and organizations to educate them about the accomplishments of the PMPs and PMP InterConnect. The Research Subcommittee recommended that states consider participating in a research project it had evaluated involving monthly, data-filled reports created by health consulting firm Pinney Associates.

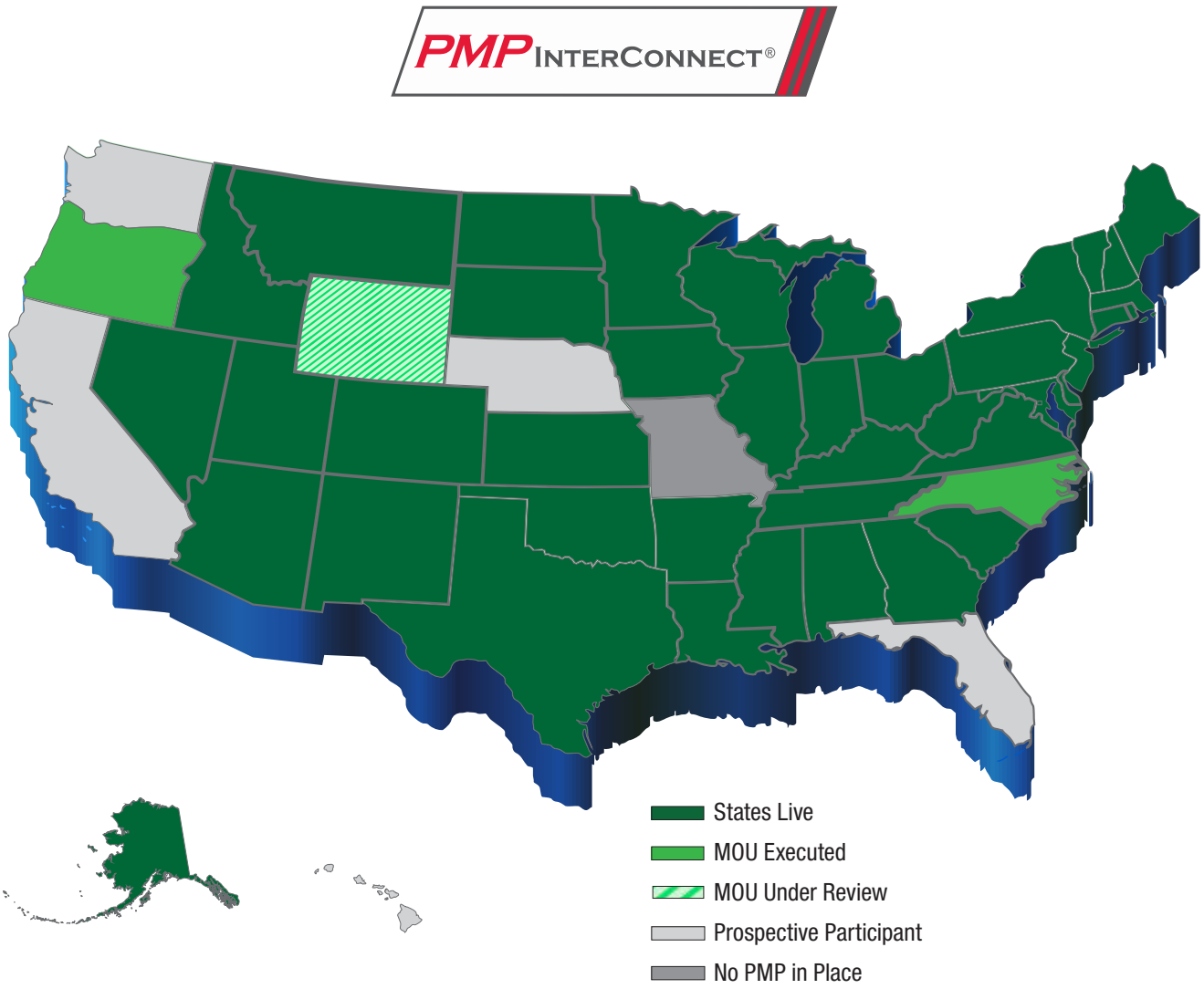
Committee Overview

Composed of representatives of PMPs that have agreed to participate in the PMP InterConnect program, the Steering Committee serves as the governing body of the program. The committee is tasked with discussing and making recommendations related to the operation of the program, including strengthening the network, best practices for state PMPs to facilitate data sharing, integrating PMP data into the health care workflow, and other policy matters. The committee meets at least once per calendar year, in person or by teleconference. The next meeting is scheduled for July 25-26, 2018.

More information about PMP InterConnect, including the most up-to-date information on state participation, is available in the Initiatives section of the NABP website at *www.nabp.pharmacy*. ■

After touring the Association's newly renovated headquarters, attendees were given a brief history and overview of NABP PMP InterConnect by NABP staff.

NABP PMP InterConnect at the Forefront of Data Exchange



Since 2011, NABP PMP InterConnect has been successfully facilitating interstate data sharing between state prescription monitoring programs (PMP). To date, 42 PMPs are connected to the system, which offers participants numerous other benefits:

- Regularly reviewed by PMP experts.
- Highly secure communications exchange platform.
- Ensures that each state's data-access rules are enforced.
- Employs cutting-edge technology that ensures all data is encrypted during transmission and that no data is stored in the system.
- Offers PMPs a more effective means of combating drug diversion and drug abuse nationwide.
- Available to PMPs at no cost, so that states can focus their resources and federal grants to support PMP operations.

Inspectors From Across the Country Earn Certification in Sterile Compounding; 2018 Training Dates Announced

NABP and CriticalPoint, LLC, are pleased to announce two new classes of inspectors who earned the Certification in Sterile Compounding for Inspectors as part of the Sterile Compounding Inspector Training program.

The Association partnered with CriticalPoint to launch this certificate program in 2016, in an effort to assist state boards of pharmacy in credentialing individuals to promote public health and safety through compounded medicines.

The following inspectors earned their certification on June 6-9, 2017:

- Melissa Martin, Kansas State Board of Pharmacy
- Paul Daniels, Kentucky Board of Pharmacy
- Shannon Garrett, Kentucky Board of Pharmacy
- Rhonda Hamilton, Kentucky Board of Pharmacy
- Amanda Harding, Kentucky Board of Pharmacy
- Jessica Williams, Kentucky Board of Pharmacy
- Sarah Favour, Minnesota Board of Pharmacy
- Gerald Pugh, Mississippi Board of Pharmacy
- Sidney Seal, Mississippi Board of Pharmacy
- Megan "Chase" Bissell, North Carolina Board of Pharmacy
- Christie Cutbush, North Carolina Board of Pharmacy
- Maria Fabiano, North Carolina Board of Pharmacy
- Josh Kohler, North Carolina Board of Pharmacy
- Lisa Mendez, North Carolina Board of Pharmacy
- Cindy Parham, North Carolina Board of Pharmacy
- Kim Sims, North Carolina Board of Pharmacy
- Krystal Stefanyk, North Carolina Board of Pharmacy
- Ellen Vick, North Carolina Board of Pharmacy
- Daniel Lari, Washington State Pharmacy Quality Assurance Commission
- Shelley Schuerman, Washington State Pharmacy Quality Assurance Commission

The following inspectors earned their certification on July 18-21, 2017:

- Todd Brooks, Alabama State Board of Pharmacy
- William Craig Jeffers, California State Board of Pharmacy
- Linda Panofsky, California State Board of Pharmacy
- Kathy Hunter, College of Pharmacists of Manitoba
- Gillian Staikos, Florida Department of Health
- Kayla Jones, Kansas State Board of Pharmacy
- Katie Busroe, Kentucky Board of Pharmacy
- Cary Aaron, Louisiana Board of Pharmacy
- Nicole Gross, Louisiana Board of Pharmacy
- Tyler Swinehart, Michigan
- Barb Wood, Missouri Board of Pharmacy
- Rich Cieslinski, NABP
- Michael Karnbach, NABP
- Luis Curras, Nevada State Board of Pharmacy
- Jennifer Geisler, New Jersey State Board of Pharmacy
- Holly Price Hunt, North Carolina Board of Pharmacy
- Cheryl Fox, Oregon State Board of Pharmacy
- Alison Gratton, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy
- Paul Schad, State of Ohio Board of Pharmacy
- Scott Denaburg, Tennessee Board of Pharmacy
- Felicia Carrasco, Texas State Board of Pharmacy
- Emily Applegate, Virginia Department of Health Professions
- Thomas Robinette, West Virginia Board of Pharmacy ■

2018 Training Dates

CriticalPoint, LLC, will hold three Sterile Compounding Inspector Training sessions in 2018:

- July 16-19
- October 8-11
- November 5-8

NABP will provide registration information in early 2018. NABP will fund tuition expenses for one person per jurisdiction to attend sessions in 2018. Through a grant administrated by NABP, The Pew Charitable Trusts will also provide opportunities for some inspectors to attend the training as well as opportunities for NABP surveyors to provide on-site training for state inspectors. Please contact governmentaffairs@nabp.pharmacy for more details about the Pew-funded training.

First 11 Member Boards Fulfill Blueprint Program Requirements to Help Ensure Compounding Safety

Member boards of pharmacy in Kentucky, Louisiana, Mississippi, New Jersey, North Dakota, Ohio, South Dakota, Tennessee, Virginia, West Virginia, and Wyoming are the first participants of the Multistate Pharmacy Inspection Blueprint Program. These 11 states have met all the criteria to become a "Blueprint State."

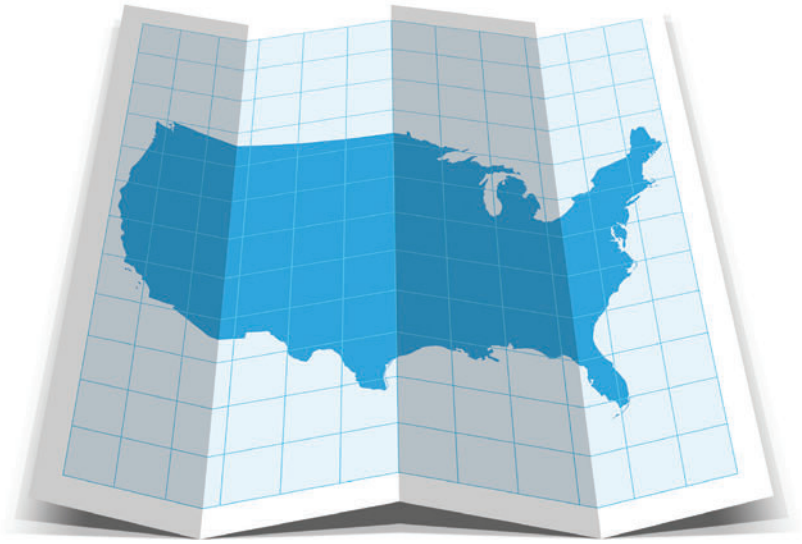
Nine of the 11 participating states will be using the Universal Inspection Form to conduct these inspections of pharmacies that ship sterile compounded products across state lines. The Universal Inspection Form – Sterile Compounding Module is based on the sterile module of the Verified Pharmacy Program® inspection form and includes all United States Pharmacopoeia Chapter <797> standards. Two of the states will use their own inspection forms that have been cross-walked to the Blueprint.

The Multistate Pharmacy Inspection Blueprint Program provides boards of pharmacy with the tools to inspect sterile compounding pharmacies that ship across state lines. The program was developed to create robust state-based inspection processes for conducting inspections and to protect public health. In addition, the Blueprint Program enables participating states to easily identify which resident state inspections meet their requirements.

NABP established the Blueprint Program after working with the member boards of pharmacy to develop the Multistate Pharmacy Inspection Blueprint, a living document that provides a minimum set of inspection criteria for pharmacy inspections. The Blueprint will be regularly reviewed to ensure it stays current with evolving pharmacy regulation and practices.

To reach the shared goal of safe sterile compounded products for patients throughout the United States, NABP is committed to working with states to identify barriers and develop solutions. For additional information about participation in the Blueprint Program, contact governmentaffairs@nabp.pharmacy. Visit Inspection Tools and Services in the Member Services section of the NABP website at *www.nabp.pharmacy* to learn more about the Blueprint Program. ■

Multistate Pharmacy Inspection Blueprint Requirements



To be deemed a Blueprint State and remain an active participant, states must agree to adhere to the program's requirements for conducting inspections of sterile compounding pharmacies that ship across state lines, including:

1. Selecting whether they want to utilize the Universal Inspection Form – Sterile Compounding Module or have their state's inspection form cross-walked with the relevant sections of the Multistate Pharmacy Inspection Blueprint (in this case, United States Pharmacopeia Chapter <797>).
2. Attesting that inspectors/compliance officers who conduct these sterile compounding inspections will have initial training, such as CriticalPoint's Sterile Compounding Boot Camp™, NABP and CriticalPoint Sterile Compounding Inspector Training, or NABP in-state training. Other inspection training may be submitted to NABP for review.
3. Attesting that their compliance officers will participate in annual webinar training to be offered at no cost by NABP.
4. Attesting that their inspection frequency for these sterile compounding pharmacies is no less than once every 18 months.
5. Sharing their inspection reports with other states through the NABP e-Profile Connect unless prohibited by law or board policy. ■

NABP Calls for Nominations for 2018 Awards; Recipients Will Be Announced at the 114th Annual Meeting in Denver

NABP is accepting nominations for its 2018 Awards, which recognize individuals or boards of pharmacy that represent the Association's mission to protect the public health. Nominations are being accepted for the 2018 Lester E. Hosto Distinguished Service Award, 2018 NABP Honorary President, 2018 Fred T. Mahaffey Award, and 2018 John F. Atkinson Service Award. The awards will be presented during the 114th Annual Meeting, to be held May 5-8, 2018, at the Hyatt Regency Denver at Colorado Convention Center in Denver, CO.

Lester E. Hosto DSA

Originally known as the Distinguished Service Award (DSA), the Lester E. Hosto DSA is the highest honor bestowed by the Association. NABP renamed the award to serve as a memorial to the 1990-1991 NABP President Lester E. Hosto, whose motivating presence in the practice of pharmacy was recognized by practitioners of his state, Arkansas, as well as by pharmacy leaders across the nation, and former United States President Bill Clinton.

The Lester E. Hosto DSA recognizes those individuals whose efforts to protect the public health greatly furthered the goals and objectives of NABP. Any individual who meets these criteria may be nominated for the DSA, regardless of his or her member affiliation with NABP.

Honorary President

To be considered for the position of honorary president, nominees must meet the following criteria:

- service on at least one NABP committee or task force;
- participation in NABP/American Association of Colleges of Pharmacy District Meetings and NABP Annual Meetings;
- exemplary services for, or on behalf of, NABP;
- strong commitment to NABP, the mission of the Association to protect the public health, and the practice of pharmacy; and
- affiliation (either current or past) as a board member or as an administrative officer of an active or associate member board.

Individuals submitting nominations for honorary president must be from an active or associate member board.

Fred T. Mahaffey Award

This award is named after the late NABP Executive Director Emeritus Fred T. Mahaffey, who held the executive director position from 1962 to 1987. His leadership and contributions to NABP, state boards of pharmacy, and the protection of the public health were significant and established NABP as one of the leading pharmacy organizations. The award recognizes boards of pharmacy that have made substantial contributions to the regulation of the practice of pharmacy over the past year. Boards considered for this award must have contributed to protecting the public health and welfare through the enforcement of state and federal laws and regulations and to the advancement of NABP goals and objectives as specified in the Association's Constitution and Bylaws.

John F. Atkinson Service Award

Recipients of the John F. Atkinson Service Award are individuals who have provided NABP with exemplary service in protecting the public health, and have shown significant involvement with the Association related to pharmacy law and compliance. This award is named in honor of former NABP General Counsel John F. Atkinson, who served the Association for over 40 years.

Submitting Nominations

To submit a nomination for any of the aforementioned awards, individuals are asked to complete a nomination form, which may be accessed by visiting the Meetings section of the NABP website. Instructions for electronic and hard copy submission of the fillable pdf are provided on the online form. Nominations must be received no later than **December 31, 2017**. The NABP Executive Committee will review the nominations and select the honorary president and award recipients.

For more information, please contact the NABP Executive Office via email at ExecOffice@nabp.pharmacy.

Henry Cade Memorial Award

In addition to the Lester E. Hosto DSA, NABP Honorary President, Fred T. Mahaffey Award, and John F. Atkinson Service Award, NABP will also present the 2018 Henry Cade Memorial Award during the Annual Meeting. The NABP Executive Committee selects recipients for this award who have supported the goals and objectives of the Association and the state boards of pharmacy to protect the public health and advanced the need to maintain the safety and integrity of the distribution and dispensing of medications. **Nominations are not accepted for this award**.

The Henry Cade Memorial Award is named in honor of the late Henry Cade, who served as NABP president from 1987 to 1988. Tireless in his efforts on behalf of NABP and the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy, Cade was also a long-time pharmacy practitioner.

Boards Report More Than 1,600 Disciplinary Actions to NABP Clearinghouse Second Quarter 2017

During the second quarter of 2017, the state boards of pharmacy reported a total of 1,637 disciplinary actions to the NABP Clearinghouse, including actions taken against pharmacists, pharmacies, pharmacy technicians, pharmacy interns, wholesalers, manufacturers, and other licensees. Of the 1,637 actions taken the second quarter of 2017:

- **763 (46.6%) were on pharmacists;**
- **410 (25%) were on pharmacies;**
- **389 (23.8%) were on pharmacy technicians;**
- **29 (1.8%) were on wholesalers and manufacturers;**
- **16 (1%) were on controlled substance licensees;**
- **10 (0.6%) were on pharmacy interns;**
- **8 (0.5%) were on other licensees; and**
- **3 (0.2%) were on mail-order pharmacies.**

For a full breakdown of the actions taken and the bases for actions taken during the second quarter of 2017, see Figure A below and Figure B on page 20.

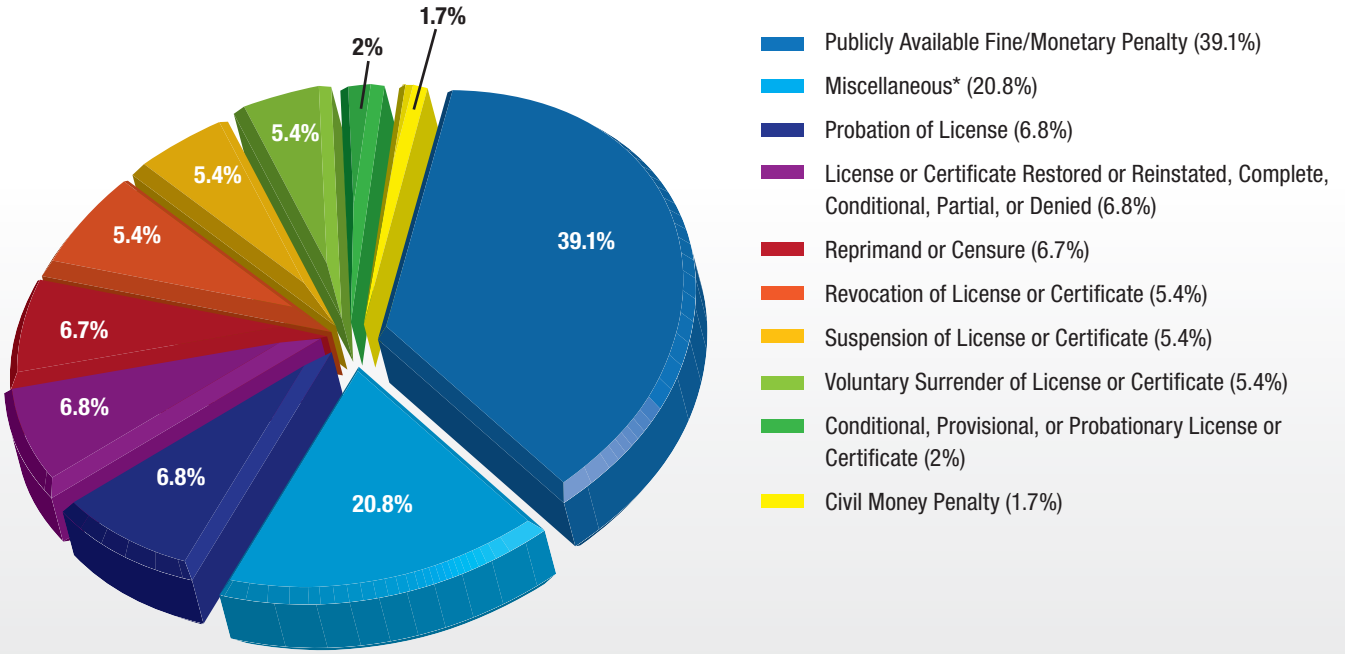
Ensuring Compliance for the Boards

As stated in the NABP Constitution and Bylaws, participation in the NABP Clearinghouse is required as part of a board of pharmacy's membership in the Association. Timely reporting to the NABP Clearinghouse is essential to maintaining the integrity of the licensure transfer program.

In addition, NABP encourages all boards to designate NABP as their reporting agent to the National Practitioner Data Bank (NPDB). By doing so, boards are able to free up valuable resources and staff time to focus on other board matters. With Utah recently joining, 33 boards of pharmacy have designated NABP as a reporting agent to date, allowing the Association to transmit all required records to NPDB, provide feedback on NPDB rejected or accepted data, and assist the boards during compliance audits. In addition, monthly Clearinghouse reports are available for the boards in NABP e-Profile Connect.

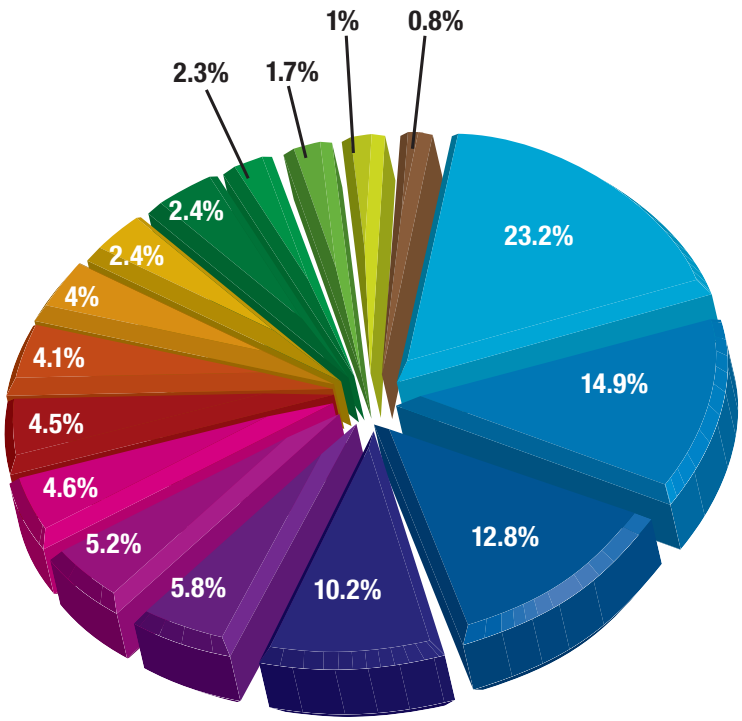
Additional information about the NABP Clearinghouse, including how to designate NABP as a reporting agent for NPDB, is available under the Member Services section on the NABP website at *www.nabp.pharmacy*.

Figure A: Disciplinary Actions Reported During Second Quarter 2017



*The miscellaneous category includes cease and desist; denial of initial license or certificate; denial of license or certificate renewal; directed plan of correction; extension of previous licensure action; interim action – agreement to refrain from practice during investigation; modification of previous licensure action; on-site monitoring; other licensure action – not classified; publicly available negative action or finding; reduction of previous licensure action; restrictions on admissions or services; summary or emergency limitation or restriction on license; summary or emergency action; summary or emergency suspension of license; and voluntary limitation or restriction on license.

Figure B: Bases for Disciplinary Actions Reported During Second Quarter 2017



- Violation of Federal or State Statutes, Regulations, or Rules (23.2%)
- Miscellaneous* (14.9%)
- Failure to Comply With Continuing Education or Competency Requirements (12.8%)
- Diversion of Controlled Substance (10.2%)
- Unable to Practice Safely by Reason of Alcohol or Other Substance Abuse (5.8%)
- License Revocation, Suspension, or Other Disciplinary Action (5.2%)
- Practicing or Operating Without a License or Permit, With an Expired License, or on a Lapsed License (4.6%)
- Fraud (4.5%)
- Error in Prescribing, Dispensing, or Administering Medication (4.1%)
- Criminal Conviction (4%)
- Allowing or Aiding Unlicensed Practice (2.4%)
- Unauthorized Prescribing, Dispensing, or Administering of Medication (2.4%)
- Failure to Maintain Records (2.3%)
- Narcotics Violation or Other Violation of Drug Statutes (1.7%)
- Violation of Federal or State Tax Code (1%)
- Failure to Meet Licensing Board Reporting Requirements (0.8%)

*The miscellaneous category includes breach of confidentiality; conduct evidencing ethical unfitness; conduct evidencing moral unfitness; default on health education loan or scholarship obligations; deferred adjudication; diverted conviction; drug screening violation; expired drugs in inventory; failure to comply with patient consultation requirements; failure to cooperate with board investigation; failure to meet the initial requirements of a license; failure to pay child support/delinquent child support; immediate threat to health or safety; improper or abusive billing practices; improper or inadequate supervision or delegation; inadequate or improper infection control practices; inadequate security for controlled substances; incompetence; lack of appropriately qualified professionals; misappropriation of patient property or other property; misbranding drug labels/lack of required labeling on drugs; negligence; nolo contendere plea; operating beyond scope of license; other disciplinary action – not classified; other unprofessional conduct; practicing beyond scope of practice; sexual misconduct; substandard or inadequate care; substandard or inadequate skill level; unable to practice safely; unable to practice safely by reason of physical illness or impairment; unable to practice safely due to psychological impairment or mental disorder; and violation of or failure to comply with licensing board order.

NABP Transitions NAPLEX to New Assembly Platform

New Technology Maintains Quality, Integrity of Exams

NABP has successfully transitioned another examination – the North American Pharmacist Licensure Examination® (NAPLEX®) – to the new pallet assembly model, already in use for the Pre-NAPLEX®, the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), the Pre-FPGEE®, and the Pharmacy Curriculum Outcomes Assessment® (PCOA®). The Association is utilizing this proprietary technology to improve the quality of exams (eg, using more test questions from the item pool and shortening an item's life cycle) and position the Association to bring additional tasks in-house (eg, scoring exams and generating score reports).

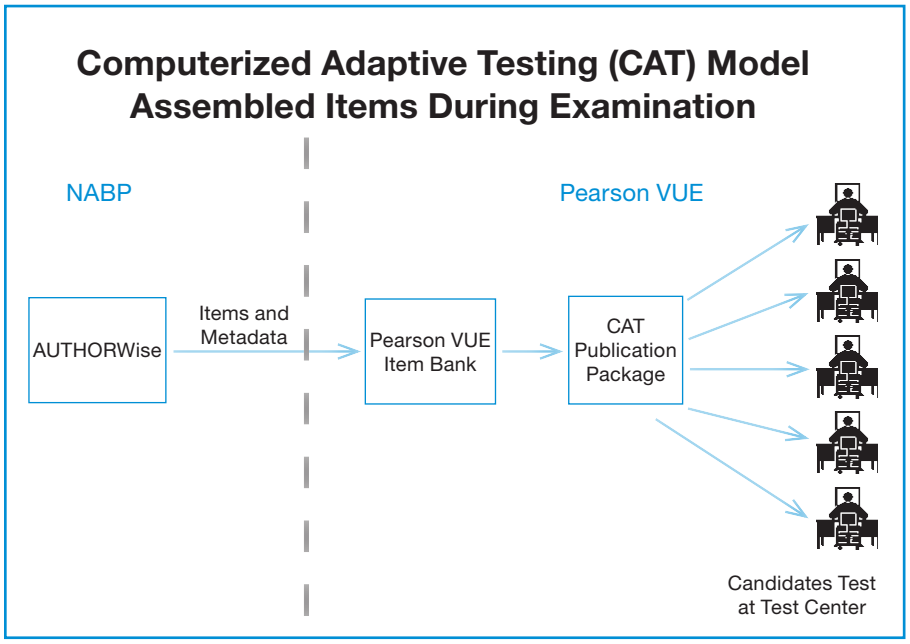
Changes to Exam Model

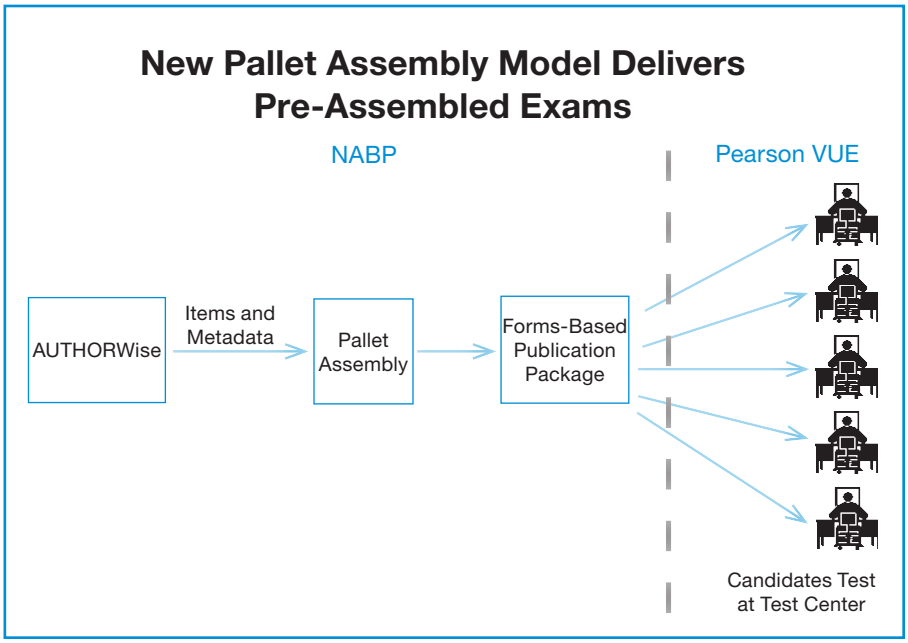
NABP has been utilizing variations of the new forms assembly model since 2014, with the NAPLEX transitioning to the new format in November 2016. In contrast to the previous computer adaptive model where the test was assembled as a candidate was taking the exam, the new linear form exam is pre-assembled. This allows NABP to improve its item pool management and prevent over-exposure of testing items. By handling the exam publication, NABP is able to incorporate new items for the exams on pre-determined schedules or when needed, as in the case to promptly replace items if a medication is discontinued from the market or there are changes in drug therapy. Over the next few years, NABP aims to increase item production across all of the examination programs.

Benefits of New Format

In addition to the infrastructure changes, NABP has brought the scoring of some of the exams in-house, whereas previously, scoring was performed by its outside vendor Pearson VUE. Since the NAPLEX was updated in November 2016, NABP reports seeing continuity in performance when compared to the previous computer-adaptive model of assembly. More about the NAPLEX modifications is available in the September 2016 issue of *Innovations*.

Through regular data analysis, pharmacy practice and curriculum analysis, and with the guidance of the Advisory Committee on Examinations, the Association continues to ensure that its examination programs meet industry standards and best practices for high-stakes examination development, administration, integrity, and security. In addition, NABP remains on the cutting edge of examination technology, holding a patent for its outlier detection tool as well as having successfully deployed the new pallet assembly technology. ■





Volunteer to Serve on ACE!

Be part of the Advisory Committee on Examinations (ACE) – a long-standing committee that safeguards the integrity and validity of NABP examinations. Each ACE appointment is a three-year term. ACE convenes two to three times a year to do the following:

- Oversee the development and administration of NABP examination and certification programs
- Evaluate long-range planning strategies
- Consider policy matters
- Recommend actions to the NABP Executive Committee

Interested?

To be considered for ACE, an individual must hold an active, unrestricted pharmacist license in a state or territory of the United States and meet at least one of the following requirements:

- Be a member or administrative officer of an active member board of pharmacy,
- Have served within the last five years as a member or administrative officer of an active member board of pharmacy,
- Be a practicing pharmacist, or
- Serve as pharmacy school faculty.

Open positions on ACE are determined by the current composition of the committee and in accordance with NABP policy. Each ACE appointment is for a three-year term, beginning June 1, 2018.

Interested individuals are asked to submit a written statement of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Drive, Mount Prospect, IL 60056, or via email to ExecOffice@nabp.pharmacy no later than December 31, 2017.

Please contact the NABP Competency Assessment department at CompAssess@nabp.pharmacy with any questions regarding ACE. ■

Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

Centre Care Pharmacy
New York, NY

Family Choice Pharmacy Corp
New York, NY

Family Discount Drugs
Owingsville, KY

A full listing of nearly 450 accredited DMEPOS companies representing almost 28,500 facilities is available on the NABP website at *www.nabp.pharmacy.*

2017-2018 ACE Members Convened in August 2017

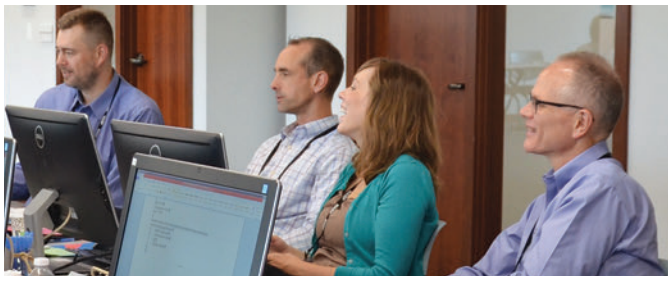
Members of the 2017-2018 Advisory Committee on Examinations (ACE) convened at NABP Headquarters in August to oversee the development and administration of the Association's examination and certification programs. Pictured are (front row, left to right) Debra Glass, BPharm, RPh, member, Florida Board of Pharmacy; David Chikao Young, PharmD, RPh, Salt Lake City, UT; Anita Young, EdD, RPh, Northeastern University Bouvé College of Health Sciences; Theresa M. Talbott, BSPharm, RPh, member, Pennsylvania State Board of Pharmacy; (back row, left to right) Reginald "Reggie" Dilliard, DPh, NABP Executive Committee liaison; Bruce Waldrop, PhD, Samford University McWhorter School of Pharmacy (ex officio member, Foreign Pharmacy Graduate Equivalency Examination®/Pharmacy Curriculum Outcomes Assessment® program); Neal F. Walker, RPh, Hill City, MN; Benjamin L. Prewitt, PharmD, RPh, Lebanon, OH (ex officio member, North American Pharmacist Licensure Examination® program); Mark T. Conradi, JD, RPh, Clanton, AL (ex officio member, Multistate Pharmacy Jurisprudence Examination® program); Michael A. Burleson, BSPharm, RPh, former executive director, Kentucky Board of Pharmacy; and Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Roseman University of Health Sciences.

FPGEE and PCOA Review Committee Members Convene

In August 2017, members of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and Pharmacy Curriculum Outcomes Assessment® (PCOA®) Review Committee met at NABP Headquarters to review and approve examination forms and new exam questions.

(Right) Pictured are (left to right) Brian M. Hodges, PharmD, RPh, BCPS, BCNSP, West Virginia University School of Pharmacy; Brian Hemstreet, PharmD, RPh, FCCP, BCPS, Regis University School of Pharmacy; Lynn Kassel, PharmD, RPh, Drake University College of Pharmacy & Health Sciences; and Sheldon G. Holstad, PharmD, RPh, American College of Clinical Pharmacy.

(Left) Pictured are (clockwise, from left) Matthias Lu, PhD, Professor Emeritus, University of Illinois at Chicago College of Pharmacy; Carolyn Friel, PhD, RPh, Massachusetts College of Pharmacy and Health Sciences; Philip Proteau, PhD, Oregon State University College of Pharmacy; Dale Eric Wurster, Jr, PhD, University of Iowa College of Pharmacy; William Kolling, PhD, RPh, Southern Illinois University Edwardsville School of Pharmacy; Karen Nagel-Edwards, PhD, RPh, Midwestern University Chicago College of Pharmacy; and Bruce Waldrop, PhD, Samford University McWhorter School of Pharmacy.



NABP Report Addresses Danger of 'Canadian' Pharmacies

In August, NABP released the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: August 2017* that discusses how rogue online pharmacies exploit the American perception that Canadian pharmacies provide safe medication at a lower cost.

In a recent study, NABP reviewed more than 100 pharmacy websites that used "Canada" or "Canadian" in their name or URL, or posted a Canadian contact address, and found that 74% source drugs from countries outside of Canada. None of the 108 websites included in the study required a valid prescription, which can pose a serious health risk for patients.

Half of the so-called "Canadian" websites source drugs from India or a combination of countries where counterfeit products are known to originate. Another 20% dispense drugs from unspecified foreign locations.

Sourcing medications from countries without stringent regulation and oversight exposes patients to medications that are not approved by Food and Drug Administration or Health Canada. The risk that these imported drugs are counterfeit, contaminated, or subpotent is high; and quality assurance is a major concern.

The report was released amidst discussions on proposed legislation that would allow United States consumers to legally import prescription medications from Canadian pharmacy sites. Without a tightly regulated international supply chain in place, it will be difficult to shield consumers from the risks associated with this type of policy.

Canada would continue to be an intermediate shipment point for unapproved medications. Neither Canada nor the US are in a position to set up the appropriate inspection programs, as stated in the report.

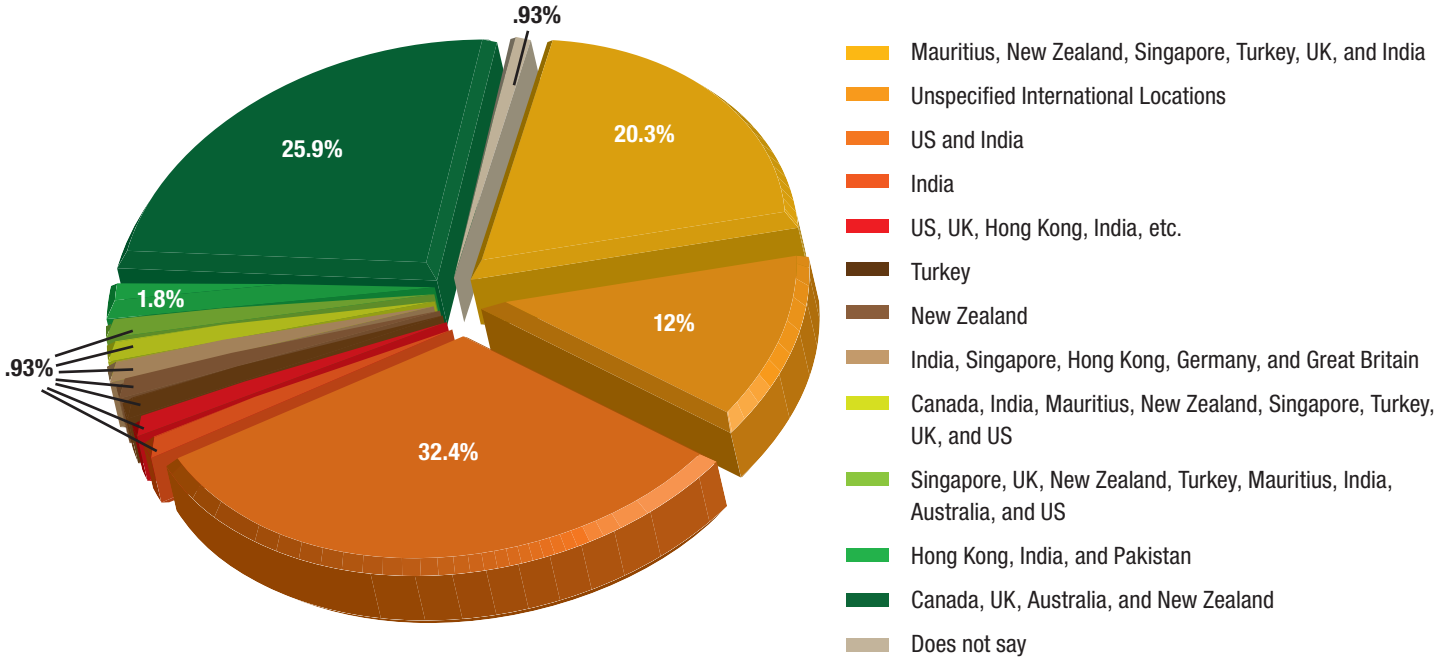
In 2016, NABP partnered with Canada's National Association of Pharmacy Regulatory Authorities to verify online pharmacies located or doing business in Canada. The agreement was formed as part of the .Pharmacy Verified Websites Program, which exists to help consumers identify safe and lawful internet pharmacies.

The "Canadian" websites in this study are among the nearly 11,700 websites selling prescription medicines that NABP has reviewed in the last nine years. Of those websites, 96% were found to be operating illegally. A list of safe online pharmacies can be found on the Buying Safely page of *www.safe.pharmacy*.

The full report is available on the Program and Committee Reports page in the Publications and Reports section of *www.nabp.pharmacy*.

From Where Do So-Called Canadian Internet Pharmacies Source Their Drugs?

Of the 108 so-called Canadian pharmacy websites reviewed by NABP, 74% source the medications they sell from outside of Canada. Half (54) of the sites source the drugs they sell from India or India and some combination of other countries; 20% (22) source them from unspecified foreign locations.



Around the Association

Executive Officer Changes

- **Chelsea Church, PharmD, DPh, BCPS,** has been named executive director of the Oklahoma State Board of Pharmacy, replacing Interim Executive Director Cindy Fain, DPh. Church joined the Oklahoma State Board of Pharmacy in 2012 as a pharmacist compliance officer, covering central/southwestern Oklahoma, and completed the state's Council on Law Enforcement Education and Training – certified training for peace officers in 2014. Church previously was an associate professor at Southwestern Oklahoma State University College of Pharmacy, specializing in internal medicine for 13 years. She received both the Health-System Pharmacist of the Year Award and the Continuing Excellence Award from the Oklahoma Society of Health-System Pharmacists. Church graduated from the University of Oklahoma College of Pharmacy in 1998 and completed a primary care pharmacy practice residency in Tuscaloosa, AL, in 1999.

- **Carrie Phillips, MS, PharmD, DPh, BCPS,** has been named executive director of the Vermont Board of Pharmacy. Phillips most recently was director of pharmacy at Copley Hospital in Morrisville, VT, overseeing comprehensive pharmacy services and operations at the critical-access hospital as well as managing a 10-person staff. Previously, Phillips served as director of pharmacy for the implementation of pharmacy services at Green Mountain Psychiatric Care Center in Morrisville, VT; as project manager for the implementation of pharmacy services at the Vermont Psychiatric Care Hospital in Berlin, VT; and in various roles at St Peter's Health Care in Albany, NY.

- **Michael L. Goff** has been named acting executive director of the West Virginia Board of Pharmacy, replacing David E. Potters.

Board Member Appointments

- **Brenda Denson, PharmD, RPh,** has been appointed a member of the Alabama State Board of Pharmacy. Denson's appointment will expire December 31, 2021.

Board Member Reappointments

- **Richard de Blaquiere, PharmD, RPh,** has been reappointed a member of the Idaho State Board of Pharmacy. De Blaquiere's appointment will expire June 30, 2022.

- **Bessie McGirr, RPh,** has been reappointed a member of the Wyoming State Board of Pharmacy. McGirr's appointment will expire February 28, 2023. ■

Newly Accredited VAWD Facilities

The following facilities were accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

Alvix Laboratories, LLC
Ocean Springs, MS

AmerisourceBergen Drug Corporation
Roanoke, TX

Atlantic Business Organizations Corp, dba ABO Pharmaceuticals
San Diego, CA

Auburn Pharmaceutical Company
Salt Lake City, UT

B&B Pharmaceuticals, Inc
Englewood, CO

BioRidge Pharma, LLC, dba BioRidge Pharma
Florham Park, NJ

Cantrell Drug Company
Little Rock, AR

Discount Drug Mart, Inc
Medina, OH

Fisher Scientific Company, LLC, dba Fisher Scientific and Fisher Healthcare
Denver, CO

Hercules Pharmaceuticals, Inc
Port Washington, NY

Kenco Logistic Services, LLC
Chattanooga, TN

Louisiana Wholesale Drug Co, Inc
Sunset, LA

Medical Specialties Distributors, LLC
Oakwood Village, OH

Medline Industries, Inc, dba Medline Industries
McDonough, GA
Tolleson, AZ

TQM, LLC, dba Two Rivers Medical
Greenville, SC

Walgreen Company
Moreno Valley, CA

A full listing of more than 580 accredited VAWD facilities is available on the NABP website at *www.nabp.pharmacy.*

Minnesota Board Adopts Work Conditions Rule

The Minnesota Board of Pharmacy adopted its proposed work condition rule that went into effect on July 1, 2017. The rule:

- Prohibits pharmacies located within Minnesota from requiring pharmacists, pharmacist-interns, and pharmacy technicians to work more than 12 consecutive hours within a day (24-hour period).
- Requires pharmacies to allow pharmacists, pharmacist-interns, and pharmacy technicians to take a 30-minute, uninterrupted break if they work more than six continuous hours per day.
- Requires pharmacies to allow pharmacists, pharmacist-interns, and pharmacy technicians adequate time during each four-hour work period to use the nearest conveniently located restroom.
- Allows, but does not require, pharmacies to close when a pharmacist is on break and away from the licensed pharmacy space.
- Establishes requirements for the operation of the pharmacy and the dispensing of filled prescriptions if a pharmacy remains open when the pharmacist is on break and away from the pharmacy.
- Creates an exception for bona fide emergencies.

The Board further clarifies that pharmacists, technicians, and interns are not required to take breaks. Similarly, the rule does not prohibit pharmacists, interns, and technicians from working shifts that are longer than 12 hours – so, they can volunteer to do so, as long as they are not coerced into volunteering.

A copy of the adopted rule and additional documents related to the rulemaking process can be found on the Board website at *https://mn.gov/boards/pharmacy/statutes/rules.jsp*. In addition, the full text of the rule can be found at *https://www.revisor.mn.gov/rules/?id=6800.2160.*

Washington Passes Opioid, Drug Donation Laws

The 2017 Washington State Legislature passed and signed into law the following bills, which affect the practice of pharmacy:

- Engrossed Substitute House Bill (HB) 1427 requires certain disciplining authorities to update opioid prescribing rules by January 1, 2019, expands access to the prescription monitoring program (PMP), and requires the Washington State Department of Health (DOH) to provide provider and other information at least quarterly to entities who use the PMP for quality improvement and other purposes. This law also requires the DOH to annually report, beginning November 15, 2017, to the governor and legislature on the number of facilities, entities, and provider groups that have integrated their electronic health records with the PMP.
- Substitute HB 1765 allows the donation of prescription drugs under the professional judgment of a pharmacist. With the exception of controlled substances (CS), the law allows all medications to be donated as long as the patient or patient's representative completes and signs a donor form certifying that the drugs have never been opened, used, adulterated, or misbranded. Participation by pharmacists and pharmacies in Washington is voluntary.

North Carolina Requires an NABP e-Profile ID

Under a new North Carolina Board of Pharmacy Rule .1615 (21 North Carolina Administrative Code 46.1615), all pharmacists, technicians, pharmacies, and durable medical equipment (DME) facilities in North Carolina are required to obtain and report an NABP e-Profile ID. This requirement will make it easier for Board staff to access and track information on continuing education fulfillment, pharmacy and DME facility inspections, and out-of-state disciplinary actions.

Arizona Passes Pharmacy-Related Bills

The 2017 Arizona legislative session passed several bills related to pharmacy that became law.

- HB 2308: Pharmacy board; logistics providers; permits; requires a third-party logistics provider (3PL) that engages in the logistics services of prescription or over-the-counter dangerous drugs or devices into, within, or from the state of Arizona to hold a 3PL permit. This bill also outlines storage practices, security requirements, and policies and procedures to be followed by each 3PL and requires a 3PL to have a designated representative at each facility who meets certain requirements, including obtaining a fingerprint clearance card.
- Senate Bill (SB) 1269: Pharmacists; scope of practice; expands a pharmacist's scope of practice in Arizona to include dispensing of emergency refills for certain medications, prescription and dispensing of tobacco cessation drug therapies, and prescription and administration of oral fluoride varnish, if outlined requirements are met.
- SB 1377: Controlled substances; approved medications; allows any compound, mixture, or preparation that contains cannabidiol to be prescribed in Arizona, if certain requirements are met.
- HB 2493: Addresses drug overdose; establishes the Drug Overdose Review Team in the Arizona Department of Health Services and modifies requirements relating to the dispensing and prescribing of an opioid antagonist for emergency purposes.

For additional details on 2017 legislative changes, visit the July 2017 *Arizona State Board of Pharmacy Newsletter*, available in the Boards of Pharmacy section of the NABP website. ■

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Adverse Events Reported on Guardian Pharmacy Services' Compounded Product for Eye Injection

FDA received adverse event reports on April 5 and June 1, 2017, and conducted a follow-up concerning at least 43 patients who were administered intravitreal injections of a drug containing triamcinolone and moxifloxacin that was compounded by Guardian Pharmacy Services in Dallas, TX. The patients were administered Guardian's product at the end of a cataract surgery procedure at the PRG Dallas Ambulatory Surgery Center in Dallas, TX, and at the Park Central Surgical Center in Dallas, TX. Over the course of several months, patients developed various symptoms, including vision impairment, poor night vision, loss of color perception, photophobia, glare, halos, flashing lights, ocular discomfort, pain, loss of balance, headaches, and/or nausea. A number of symptoms were not exhibited until at least one month postoperatively, indicates a safety alert, which is available at *www.fda.gov/Drugs/DrugSafety/ucm569114.htm.*

During follow-up examinations of the Park Central patients, physicians observed that the patients had diminished visual function involving both visual acuity and visual fields. Optical coherence tomography testing initially showed macular edema, which was followed in some cases by retinal degeneration. While the symptoms reportedly improved in some patients over the five-month post-operative period, a number of patients remain with a significant reduction in best-corrected visual acuity and visual fields. FDA encourages health care providers to report adverse events and product quality defects associated with compounded drugs to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015, and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates.

The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment. Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose, and to target interventions with prescribers based on opioid prescribing guidelines.

The July 7, 2017 *Morbidity and Mortality Weekly Report*, "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

Compounder Medistat Prohibited From Manufacturing, Distributing Drugs

Under a consent decree of permanent injunction, Medistat RX, LLC, of Foley, AL, the company's co-owners, and quality manager and pharmacist-in-charge, are prohibited from manufacturing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), in addition to other requirements. Medistat manufactured and distributed purportedly sterile drug products that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act. In addition, Medistat manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Additional information is available in the July 6, 2017, news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm565874.htm.*

INNOVATIONS®

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

UPCOMING EVENTS

NABP/AACP Districts 6, 7, and 8 Meeting
October 8-11, 2017
San Antonio, TX

FPGEE Administration
October 10, 2017

National Prescription Drug Take-Back Day
October 28, 2017

NABP/AACP District 4 Meeting
November 1-3, 2017
Toledo, OH

NABP Interactive Compliance Officer & Legal Counsel Forum
November 29-30, 2017

PARE Administration
December 5-16, 2017