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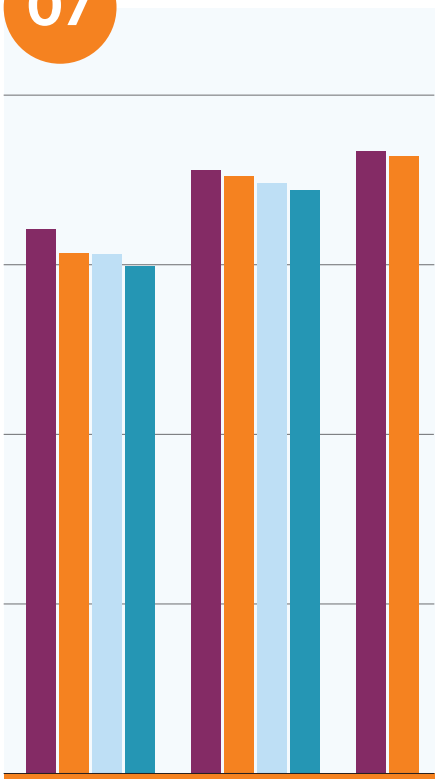
iNNOVATiONS

FROM REGULATORS TO THE FRONT LINES

PHARMACY COMMUNITY PULLS TOGETHER TO COMBAT COVID-19

NABP
National Association of Boards of Pharmacy

Feature News
From Regulators to the Front Lines: Pharmacy Community Pulls Together to Combat COVID-19



Association News
PCOA Results Show Increase in Pharmacy Students' Knowledge Levels Over Program Years

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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.

NABP
National Association of Boards of Pharmacy

Delaware State Board of Pharmacy

Number of Board Members
6 pharmacist members and 3 public members

Number of Compliance Officers/Inspectors
1

Rules & Regulations Established by
State Board of Pharmacy

Number of Pharmacist Licensees
2,208

Number of Pharmacies
1,096

Number of Wholesale Distributors
809

Michelle McCreary, RPh

Pharmacist Compliance Officer, Delaware State Board of Pharmacy

How long have you been serving as an inspector for the Board? What was your role prior to working for the Board?

I have been a pharmacist compliance officer for the Division of Professional Regulation (DPR) for six years. Prior to DPR, I spent 27 years in the private sector. I started my career in 1987 as a full-time retail pharmacist and also worked part-time in a hospital. In 1995, I began a career in long-term care (LTC), serving in multiple capacities: staff, consultant pharmacist, director of operations, and, ultimately, as general manager. In 2007, I was hired as director of pharmacy in a large behavioral health hospital outside of Philadelphia, PA, and was there for seven years.

In your opinion, what tools or skills are a must-have in a pharmacy inspector's toolkit?

To be successful, a pharmacy inspector's toolkit needs to be a large one! Inspectors should have a good working knowledge of all aspects of pharmacy operations – retail, hospital, LTC, sterile and nonsterile compounding, and all areas they may inspect. A very thorough understanding of all state and federal regulations is a must. Inspectors should build relationships with the pharmacists in the areas they inspect. Feeling comfortable with an inspector – even though inspectors have to hold licensees accountable and to a high standard during inspections – always creates a win-win for both. When pharmacists have a good relationship with an inspector, they will be encouraged to comply with the rules and regulations and be less uncomfortable or difficult during the inspection process.

What are some common issues that you have witnessed and addressed?

Most commonly, I have seen inaccuracies of controlled substance (CS) inventory counts. Most pharmacies complete monthly reconciliation of all Schedule II CS; however, variances occur that need to be reconciled. Some pharmacies still keep manual inventories, which are almost always more accurate.

In Delaware, do inspectors also conduct investigations for other health regulatory boards?

I inspected a pharmacy with Drug Enforcement Administration (DEA) in 2015, shortly after I began my position. Multiple violations were found – from food in the refrigerator to thousands of Schedule II drugs unaccounted for due to no inventories. It was extremely difficult and labor-intensive to determine the actual inventory. Multiple boxes of filled prescription bags that had not been picked up by patients for more than two years were found. I have also conducted inspections with Food and Drug Administration and the Office of Health Facilities Licensing and Certification when called by Centers for Medicare & Medicaid Services to complete a validation survey for The Joint Commission.

What steps or approaches did you take in the investigation? What was the outcome of the case?

A formal complaint was filed and investigated further, resulting in a formal hearing. The hearing officer's recommendations went before the Board and the Controlled Substance Advisory Committee, and the outcome was that the license of the owner was suspended for two years. The pharmacy lost its state Controlled Substances Registration and its DEA license. Therefore, the pharmacy was not permitted to fill any CS; all of the CS was transferred out.

What advice would you give to a new board inspector?

Know the environment and the regulations. If something does not seem right or feel right, it probably is not. Have the instinct to know this requires further questioning and evaluation. Always be prepared for anything when you walk into an inspection. Be kind and helpful as a teacher or coach would be. Even when finding violations, most pharmacists want to do the right thing, so guide them. If it is an egregious offense, and they do not cooperate, then clearly you must handle it appropriately. Lastly, as good or as bad as it gets, always remember to smile!

Real-Time Benefit and Price Transparency Tools Are Poised to Change Prescribing

Michael S. Adelberg, MPP
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As we explored in the January 2020 issue of *Innovations*, politicians have recently been very focused on reducing the costs of prescription drugs. In this issue, we take a deeper dive into specific tools encouraged by the Trump Administration that are meant to increase price transparency in both Medicare Part D and commercial markets. In a proposed regulation issued in February 2020, the Centers for Medicare & Medicaid Services (CMS) proposed to add a new type of real-time benefit tool (RTBT) in the Medicare Part D program. This beneficiary RTBT builds off of the prescriber RTBT, which is required starting in 2021 pursuant to a May 2019 final rule. In the commercial market, a November 2019 proposed rule could, if finalized, give enrollees information about negotiated rates and cost-sharing liability for prescription drugs.

It is hoped that these tools will speak to the growing problem of drug affordability among the 45 million individuals covered under Part D (ie, seniors and individuals with disabilities), the majority of whom are not protected by a cap on out-of-pocket spending for prescription drugs as commercially insured individuals and Medicaid beneficiaries are. Despite coverage through Medicare Part D, 21% of American seniors, according to the Kaiser Family Foundation, either skip prescriptions, cut pills, or purchase an over-the-counter version of the prescription drug. Eleven percent of seniors reported not telling their physician when a condition worsened because of drug affordability concerns. In contrast, 32% of seniors reported discussing affordability concerns with their pharmacist. While pharmacists are generally willing to help their patients find more affordable options, this places added (and largely avoidable) workload on the pharmacy. The RTBT has the potential to substantially lessen this workload.

What Is an RTBT?

An RTBT, sometimes called a real-time benefits check, is a prescription decision support tool designed to help lower a patient's out-of-pocket drug costs and find more cost-effective therapeutic alternatives. In comparison to consumer-facing discount programs like Blink Health and GoodRx, RTBTs provide individual-specific information tailored to the coverage terms under a person's health plan and associated pharmacy benefits manager (PBM) to give prescribers an understanding of how much a prescription will cost the patient, taking into account whether the patient has met his or her deductible. The RTBT can also integrate information on drug-specific plan requirements for prior authorization, step therapy, or quantity limits – potentially reducing the need for pre-service requests and utilization management checks when clinically equivalent, lower cost alternatives exist.

RTBTs can be most effective when integrated into clinical workflows and electronic health records (EHRs) or e-prescribing systems, such as through an application program interface. In a rule finalized in May 2019, CMS required Part D plan sponsors to include a prescriber-facing RTBT that is integrated in at least one EHR or e-prescribing system. This allows the prescriber to enter prescription information into a tablet or computer in real time via prompts from the relevant system. RTBT information shown to the prescriber in the clinical setting with the patient present can facilitate informed conversations between patient and provider, leading to switches to lower cost alternatives, higher treatment adherence, and fewer prescriptions left at the pharmacy counter. Once the prescription is entered, it is automatically and securely transmitted to the patient's pharmacy of choice.

Increasing drug price transparency at the point-of-sale, by contrast, has been discussed for decades. But since the pharmacist has limited ability to switch prescriptions without prescriber consent and generally cannot advise patients on the full scope of nonprescription drug alternatives, it could be argued that price transparency can be more effective "upstream" during medical appointments.

Recent RTBT Rulemaking for Part D

As referenced previously, in CMS' most recent Part D rule issued in February 2020, a beneficiary RTBT is introduced. This type of RTBT, proposed to be required starting in 2022, would be accessible to beneficiaries **without** the presence of a clinician and, therefore, could be utilized more. By facilitating continuous access to this information, such as through a patient portal or app, CMS hopes to empower beneficiaries and leverage information that will already be required from the prescriber RTBT.

Simply requiring RTBTs will not automatically mean that prescribers and patients will use them. To encourage the use of RTBTs, CMS proposes to allow Part D sponsors to offer nominal rewards such as gift cards for beneficiaries who use the RTBT – up to $15 per use or $75 annually in the aggregate. Sponsors can also place performance incentives, such as splitting RTBT-generated savings, with their network prescribers to encourage RTBT use.

There are two important distinctions between a prescriber RTBT and the proposed beneficiary RTBT. First, the beneficiary RTBT is expected to be presented in a manner that is understandable to the average beneficiary and prepare him or her for a more informative conversation with his or her provider. In addition, CMS offers to provide some discretion to a plan sponsor's pharmacy and therapeutics committee to determine whether to omit certain alternative therapies from the information presented in a beneficiary RTBT. CMS concedes such omissions could be appropriate if the only formulary alternatives would have significant negative side effects for most enrollees and the drug would not typically be a practitioner's first choice for treating a given condition due to those side effects, for cases where medications are considered to be "drugs of last resort" (eg, certain antibiotics), and instances in which there would be interactions with other drugs already used by the beneficiary that would contraindicate prescribing a given drug.

Moving Toward RTBT Implementation

A number of RTBTs are already in use and continue to be refined and enhanced. In 2019, CMS estimated that between 30-90% of Part D sponsors were already supporting an RTBT tool by some measure. Soon after CMS finalized the prescriber RTBT requirement, Humana announced that it had integrated an RTBT, IntelligentRx, into Epic's e-prescribing workflow. Cigna-Express Scripts announced it had developed an app for physicians without EHR RTBT functionality.

Given that an industry standard has yet to emerge, prescribers and plans may incur costs associated with integrating multiple RTBTs into their systems. With respect to a prescriber RTBT, a Part D plan sponsor need not implement widespread adoption; under the regulation, it is sufficient to integrate the RTBT with just one prescriber's system. However, plans with a single health system network partner could be at an advantage to implement a prescriber RTBT across its network. Although we cannot know how many patients are having their prescriptions managed through RTBTs today, it is assumed that a national requirement from Medicare Part D will dramatically expand their use in other market segments, including the commercial market.

Commercial Market Price Transparency Tools

Another proposal could also change the way in which pharmacists interact with patients regarding drug costs. In November 2019, a long-awaited "Transparency in Coverage" proposed rule applicable to non-grandfathered individual and group markets – which collectively cover almost 194 million enrollees – would require greater member-facing price transparency for health services and items, including prescription drugs. Among the seven elements that a health plan must disclose are the out-of-pocket cost-sharing liability that an individual would be responsible for paying under the plan's specific deductible, coinsurance, and co-pay structure. In addition, the rule would require disclosure of a covered item or service's "negotiated rate," which is the amount paid by the plan to an in-network provider (including a pharmacy or mail-order service) for a covered item or service. The Administration, led by the United States Departments of Health and Human Services, Labor, and Treasury, specifically solicited comments on whether this negotiated rate disclosure requirement should be adapted in some way for prescription drugs, given the dynamic nature of prescription drug costs, which are affected by undiscounted list prices for prescription drugs, drug rebates, discounts, or dispensing fees, and proprietary contract terms with PBMs.

Simply requiring RTBTs will not automatically mean that prescribers and patients will use them.

Under the Transparency in Coverage proposed rule, plans would be required to disclose cost-sharing estimates both in real time through a website and in paper form at the request of an enrollee. It is likely that the information would be readily available through a plan's call center and built into member portals already in place in the vast majority of commercial plans today. The Administration proposed to require public release of negotiated rates for in-network providers (including pharmacists) and will likely face fierce legal challenges by insurers if this proposal is finalized. ●

This article was written by Michael S. Adelberg, MPP, and Tricia A. Beckmann, JD, with Faegre Drinker Biddle & Reath LLP. *Please note, the opinions and views expressed by Faegre Drinker Biddle & Reath do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated.*

FROM REGULATORS TO THE FRONT LINES

PHARMACY COMMUNITY PULLS TOGETHER TO COMBAT COVID-19

Challenging government and civil society at all levels, the coronavirus disease 2019 (COVID-19) pandemic has tested the ability of public officials, local and federal agencies, health care entities, and numerous other stakeholders to act quickly and effectively in a public health crisis.

The novel coronavirus SARS-CoV-2 first emerged in China in November 2019, and by mid-March 2020, the World Health Organization declared it a pandemic.

In the United States, the first confirmed COVID-19 case was reported on January 21, 2020; nearly two months later, there were at least 5,800 confirmed cases in all 50 states and the District of Columbia and more than 100 deaths. At press time, those numbers have escalated to more than 1 million confirmed cases with more than 65,000 fatalities in the US alone. Worldwide, confirmed cases have reached over 3.4 million and more than 238,000 deaths. In addition, in April 2020, approximately 90% of Americans – 297 million Americans in 38 states, 21 cities, the District of Columbia, Puerto Rico, and one territory – were under orders to stay at home, except for certain activities, or to work at essential businesses, such as grocery stores. Seven states followed partial lockdowns.

Given the rapid spread of the disease and the absence of a vaccine or effective antiviral medications, health care systems in the US were in danger of becoming overwhelmed unless significant mitigating strategies were implemented. Shelter-in-place orders from states and social distancing practices were initiated to help slow the spread, so that the health care system can help as many patients as possible. By mid-April, it seemed those efforts have "flattened the curve," but many hurdles still remain in ensuring the spread of the virus is slowed to a rate that the health care system can handle. While the development and testing of treatments and vaccines have been fast-tracked by pharmaceutical companies and Food and Drug Administration, safety and efficacy trials, by necessity, will still take months to complete.

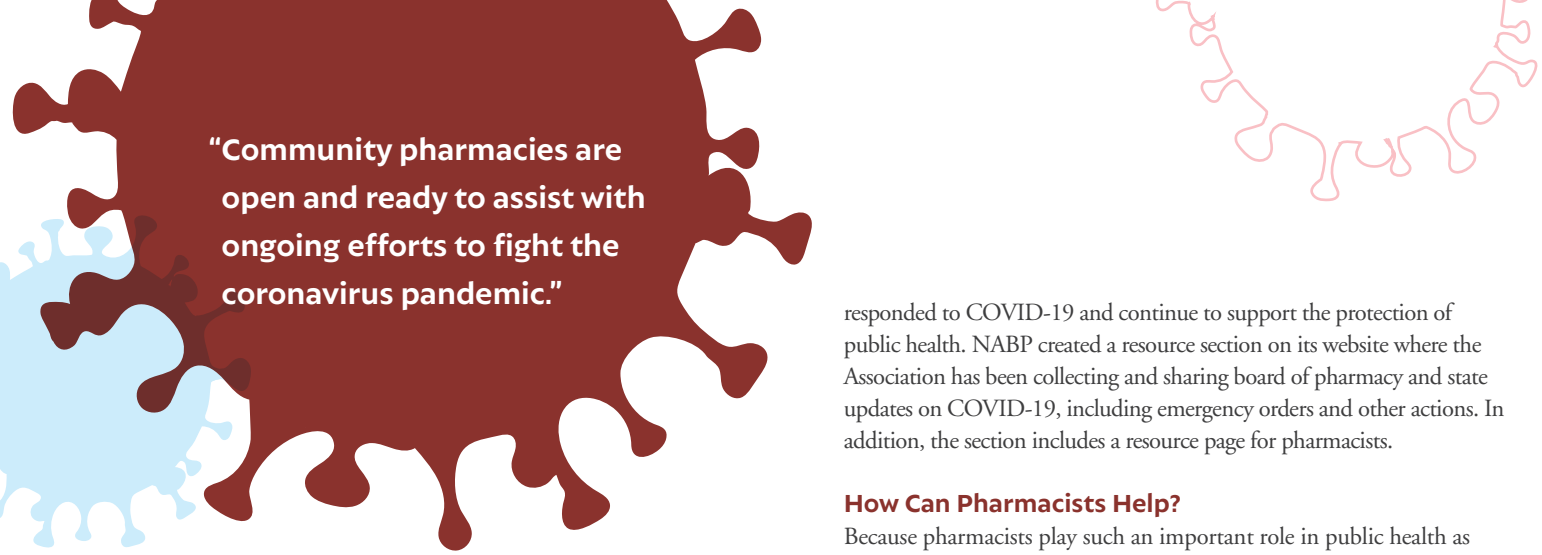
For the boards of pharmacy, previously established emergency preparedness plans have aided their ability to respond rapidly and support pharmacists' and pharmacies' ability to help as many patients as possible during the pandemic. Additional efforts by pharmacists and pharmacies include administering vaccinations and providing medication counseling for the prevention and management of illness and disease other than COVID-19 to lessen pressure on the health care system; coordinating the administration of COVID-19 testing at pharmacies; and dispensing to patients in other states, such as through mail-order pharmacies, to address the increased demand. Boards of pharmacy emergency regulations and several other actions, many coordinated and supported by NABP, have helped pharmacists in their efforts to meet such demands.

Previous Emergency Preparedness Efforts

Because effective emergency response depends on advance planning, over the last 15 years NABP, the boards of pharmacy, and professional pharmacy associations have paid increased attention to emergency preparedness. In the early 2000s, the SARS and MERS epidemics, Hurricane Katrina, the H1N1 swine flu pandemic, H5NI avian flu threats, and the Ebola crisis, among other events, reinforced the need to have plans in place to deal with emergencies, including the need to establish enabling legislation, memoranda of understanding, and other legal mechanisms that facilitate nimble responses. As part of NABP's assistance to the boards of pharmacy in planning for public health emergencies, the Association's 2006 Task Force on Emergency Preparedness, Response, and the US Drug Distribution System created an emergency planning guide for distribution to the boards, drafted "Model Rules for Public Health Emergencies" for inclusion in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, and recommended additional language for existing sections of the *Model Act*. Adoption of language addressing emergencies has varied by state. A scholarly survey published in 2016 found that, perhaps not surprisingly, those states with the most declared emergencies at that time were the most likely to have incorporated recommended rules addressing public health emergencies into their state pharmacy acts.

Boards Expedite Emergency Licensure via NABP Passport

NABP's long-standing Electronic Licensure Transfer Program® has also extended itself to supporting and responding to the pandemic. In late



March 2020, the Association launched a new companion program, the NABP Passport, to support state boards of pharmacy in processing requests for temporary and emergency licensure for nonresident pharmacists, pharmacy technicians, interns, and pharmacy businesses. Available at no cost to individuals and boards of pharmacy, the NABP Passport allows nonresident pharmacists, pharmacy technicians, pharmacy interns, and pharmacy businesses seeking temporary or emergency licensure to apply for a state-specific NABP Passport through a one-page form in their NABP e-Profile. NABP screens the applicant for license verification and a disciplinary history review. When approved, applicants will have a temporary "COVID-19 authorization" NABP Passport certificate that documents their request to work in another state under an emergency declaration. Users will receive a confirmation email and be able to print their NABP Passport as needed. NABP will report each request to the relevant boards of pharmacy securely through NABP e-Profile Connect.

Currently, over 19 states are utilizing or preparing to use the NABP Passport, and the number continues to grow. Boards can utilize the NABP Passport by recognizing it as a temporary authorization to practice in their state, or they may use it as a prerequisite and require other steps from applicants before granting emergency or temporary licensure approval.

Board Responses to COVID-19

By mid-March, 48 state governors had issued declarations of emergency in order to maximize the tools at their states' disposal to combat the spread of COVID-19, and President Donald J. Trump declared a national emergency on March 13. California Governor Gavin Newsom emphasized his state's use of an emergency declaration as a legal mechanism that facilitates state agencies' ability to deal with the crisis. "This proclamation . . . It's about resourcefulness," he said. "It's about our ability to add tools to the toolkit." The California State Board of Pharmacy subsequently reminded licensees that, under the state of emergency, the Board had the authority to waive provisions of the state's pharmacy law or regulations, if in the Board's opinion "the waiver will aid in the protection of public health or the provision of patient care," and directed licensees to email waiver requests to the Board. In some states, emergency declarations loosened rules regarding prescription refills. In North Carolina, for example, the Board reminded pharmacists that they had the authority to issue 30- and 90-day emergency refills under particular circumstances. And as in California, the North Carolina governor's emergency declaration allows the Board to waive aspects of the state's pharmacy practice act "in order to permit the provision of drugs, devices, and professional services to the public."

Since the time of this writing, many more boards of pharmacy have responded to COVID-19 and continue to support the protection of public health. NABP created a resource section on its website where the Association has been collecting and sharing board of pharmacy and state updates on COVID-19, including emergency orders and other actions. In addition, the section includes a resource page for pharmacists.

How Can Pharmacists Help?

Because pharmacists play such an important role in public health as frontline and accessible health care providers, numerous organizations – from Centers for Disease Control and Prevention to boards of pharmacy to professional associations – have provided guidance to them regarding emergency planning. With the COVID-19 outbreak, pharmacists are encouraged to provide information and answer questions regarding the disease and its management as well as provide information on prescriptions, refills, emergency supplies, and more. Pharmacists are also being asked to implement infection control procedures and monitor pharmacy staff wellness, among other measures, even as they manage inventory flow and ensure that patients receive necessary medications and supplies. Expanded scope-of-practice rules have allowed pharmacists to offer important services that assist the health care system overall, such as administering vaccinations. Even though a vaccine is not currently available for COVID-19, pharmacists can help reduce other demands on the system by administering flu or pneumonia vaccines. In the same vein, in March 2020, Florida joined 16 other states in allowing pharmacists to test patients and initiate treatment for influenza and group A *Streptococcus*.

In a published letter to Vice President Mike Pence, the National Community Pharmacists Association (NCPA) highlighted the importance of community pharmacists in combating the COVID-19 pandemic, noting that pharmacists can help prescribe medications via collaborative practice agreements, educate patients, counsel patients regarding how to manage or relieve symptoms, compound hand sanitizer, and provide home delivery services. "Community pharmacies are open and ready to assist with ongoing efforts to fight the coronavirus pandemic," said NCPA Chief Executive Officer B. Douglas Hoey, MBA, RPh. "Unleashing our capabilities and utilizing our relationships with patients are the best ways to communicate and engage with rural and underserved communities in particular, as independent community pharmacists are trusted, well-established health care providers."

Given COVID-19's rapid spread and devastating impact on public health, quick responses by the government at every level – and by all stakeholders – are central to efforts to stem the disease's advance. Pharmacists remain a crucial piece of the frontline health care response to the pandemic, and boards of pharmacy are playing a major role in ensuring the continued safe provision of pharmacy services during the crisis. NABP remains committed to assisting the boards of pharmacy as they do so. ●

Visit the NABP COVID-19 resource section for more information on the NABP Passport, board of pharmacy updates, and general updates for pharmacists at *www.nabp.pharmacy/coronavirus-updates.*

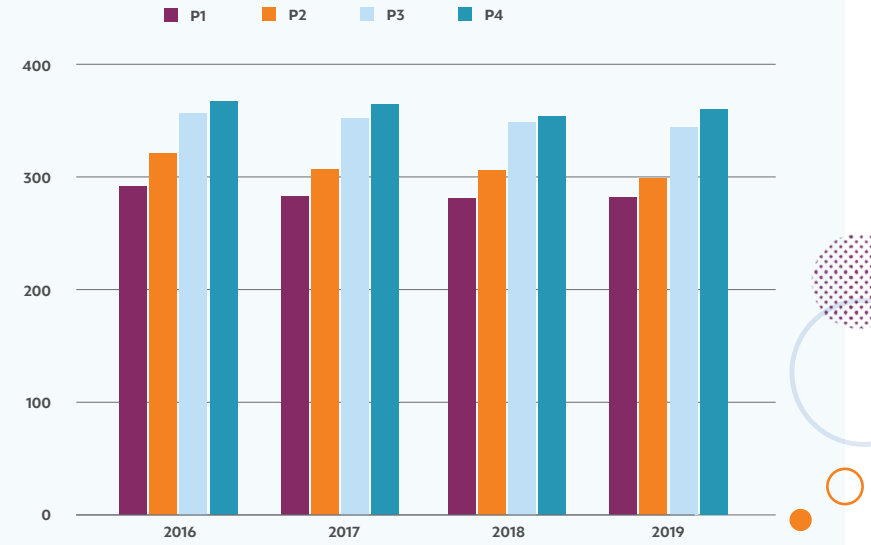
PCOA Results Show Increase in Pharmacy Students' Knowledge Levels Over Program Years

Pharmacy Curriculum Outcomes Assessment® (PCOA®) results continue to show how students build knowledge as they advance through pharmacy school. PCOA score results provide valuable information about students' knowledge in subject matter representative of United States doctor of pharmacy program curricula. The PCOA is the only independent, objective, and national assessment that enables schools and colleges of pharmacy to measure their students' knowledge in pharmacy curricula and compare their results to previous years and other peer programs throughout the US.

Scores Increase as Students Advance

PCOA results show that scores generally increase gradually as students advance from the first year through the final year of their professional didactic curriculum. This progression is evidence that PCOA results measure the expected increase in students' knowledge in US pharmacy school curricula. **Figure A on this page shows the overall mean scaled scores for students testing in 2016-2019.** The development and retention of student knowledge is also observed over the four content areas of the assessment: basic biomedical sciences, pharmaceutical sciences, social/behavioral/administrative pharmacy sciences, and clinical sciences. For example, PCOA data show that P1 students score higher in basic biomedical sciences than in clinical sciences. This result is attributed to the fact that many pharmacy students have previously studied basic biomedical sciences, which are common prerequisites for entering pharmacy school, while many students do not gain clinical science experience until they begin their doctor of pharmacy program. This is evidenced in PCOA results, which show that P3 and P4 students score higher in the more specialized content areas, such as clinical sciences and social/behavioral/administrative pharmacy sciences. **Figure B on page 8 illustrates the progression and retention of student knowledge over the four content areas.** NABP surveys the schools and colleges of pharmacy after each testing

Figure A: Overall Mean Scaled Scores for All Students Testing in 2016-2019

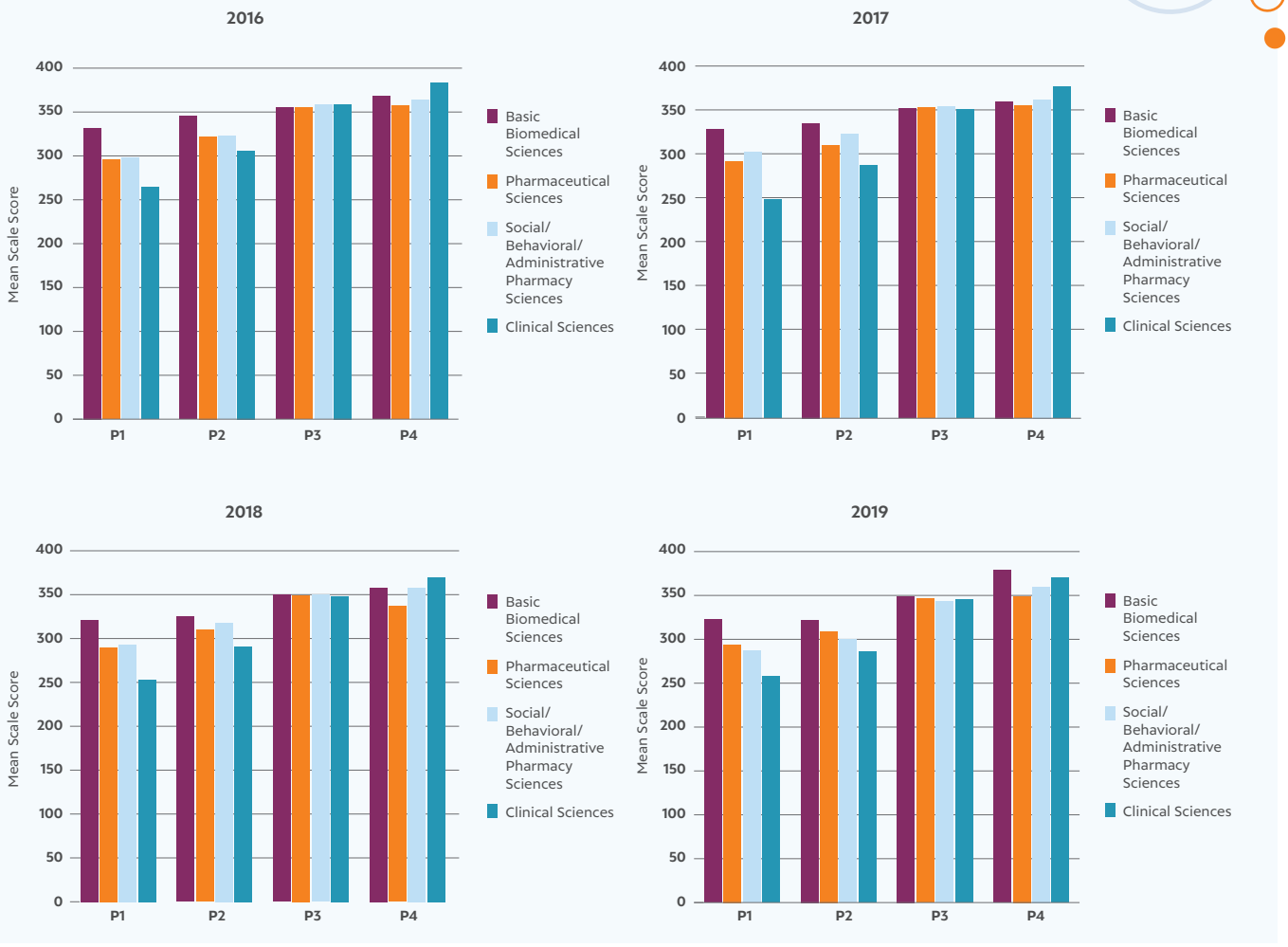


Data from 2016-2019 indicate that there is a progression of student scores from across program years P1 through P4. The average scores of P1-P4 students taking the PCOA each year is shown.

New Report Examines 2019 PCOA Outcomes

NABP has published a report that presents descriptive statistics for Pharmacy Curriculum Outcomes Assessment® (PCOA®) scores from five testing windows during the 2019 administrations. The report, *PCOA School Outcomes for Students Nearing the End of Their Didactic Curriculum: 2019,* reviews results of the 2019 Accreditation Council for Pharmacy Education reporting cohorts, which are comprised of students from more than 140 schools and colleges of pharmacy who have completed their didactic coursework (typically in their third year). The report is available in the Research Briefs and Papers section on NABP's website at *www.nabp.pharmacy.*

Figure B: Progression and Retention of Knowledge From 2016-2019



Data from 2016-2019 demonstrate progression and retention of knowledge in the four core competency areas as students progress through the professional didactic curriculum.

window to gather information regarding their experiences and to create a dialogue regarding program improvement. As part of a school or college of pharmacy's efforts in student and curricular strategies assessment, the PCOA may also be used to:

- evaluate educational objectives;
- measure the overall performance of pharmacy students and compare their scores to a representative national sample;
- evaluate student progress in the curriculum when used with classroom assessment, portfolios, etc;
- track scores from year to year in order to monitor student growth;
- review student performance after curricula have been modified or updated; and
- conduct educational research.

Since 2016, the PCOA has been a requirement for individuals nearing the completion of their didactic curriculum to meet Standard 24: *Assessment Elements of the Accreditation Council for Pharmacy Education (ACPE) Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree.* In 2019, there were 18,940 PCOA exams administered to students enrolled in one of the 140 ACPE-accredited schools and colleges of pharmacy. In 2019, NABP surveyed pharmacy students regarding their demographic information and work and study habits. The Association is using the data to better understand how these factors impact a student's PCOA results. More information on the survey results will be available in future NABP communications.

More information about the PCOA, including the updated PCOA Administration Highlights document that provides additional PCOA data, is available in the Programs section of the NABP website at *www.nabp.pharmacy.*

2020-2021 FPGEE/PCOA Review Committee Members to Contribute Expertise to Exam Programs

NABP is pleased to announce 27 returning members and one new member of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®)/Pharmacy Curriculum Outcomes Assessment® (PCOA®) Review Committee for 2020-2021. This group of dedicated volunteers contributes its time and expertise to review and verify the examination questions and forms and assists with the development of new test questions for the FPGEE and PCOA programs.

The FPGEE/PCOA Review Committee ensures the integrity and validity of the examination programs and acts under the policy and planning guidance of the NABP Advisory Committee on Examinations and the NABP Executive Committee. The FPGEE/PCOA Review Committee is composed of pharmacists and academicians who are representative of the diversity of pharmacy education and are specialists in the areas of clinical sciences, pharmaceutical sciences, and basic biomedical sciences, as well as social, behavioral, and administrative pharmacy sciences. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency statements. The FPGEE/PCOA Review Committee members are appointed to a three-year term.

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Color denotes new member

New York State Board of Pharmacy

Number of Board Members
11 pharmacist members and 2 public members

Number of Compliance Officers/Inspectors
Centralized investigations pool

Rules & Regulations Established by
Board of Regents

Number of Pharmacist Licensees
27,113 (includes foreign addresses)

Number of Pharmacies
6,649 (in-state and out-of-state)

Number of Wholesale Distributors
1,296 (in-state and out-of-state)

John M. Marraffa, Jr, RPh

Chair, New York State Board of Pharmacy

When were you appointed to the Board of Pharmacy? What type of member are you (technician, public member, other)?

I am a pharmacist member. I was appointed to the Board on September 16, 2014 and recently named chair of the Board.

What steps should a board member take to be successful in his or her role?

Board members are advocates for public health and welfare. A new board member must be well versed in pharmacy practice laws and also understand the roles that other agencies and departments play in protecting patients. It is also important to understand the various pharmacy practice areas and how they impact patient care. A critical component of a board member's role is staying up to date on today's profession, paving the way to influencing the profession of tomorrow. A successful member must be a good listener, an avid learner, and always willing to develop new relationships. Members should be authentic, acting in ways that are consistent with their own values, while remaining sensitive to the needs of others.

Has the Board encountered any challenges to developing and/or implementing new policies, legislation, or regulations?

There are many challenges that come with regulating a profession. A small piece of legislation can have a sweeping impact on the entire practice of pharmacy. The legislative process is lengthy, sometimes hindering our ability to quickly pass new laws. Often, we consider whether a need can be addressed through the adoption of new regulations, which have the same legal force as statutes.

What advice would you give to a new board member?

When you commit to a board of pharmacy, you must contribute with your strongest effort. Get involved. Expand your learning opportunities by joining task forces and committees addressing topics with which you are unfamiliar. Always be willing to seek out new opportunities to network in a way that furthers your voice. To fully understand the expectations of a board member, identify a mentor who can help you grow. I have been very fortunate to have some inspiring leaders and mentors who have seen my potential, stood by me, and motivated me. It is through true collaboration that you build leadership.

When you commit to a board of pharmacy, you must contribute your strongest effort. Get involved.

Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings?

I served on the Task Force on the Regulation of Pharmacist Care Services in 2015, the Task Force on the Pharmacist Integrated Communication Skills Examination in 2016, and the Committee on Constitution and Bylaws in 2018. I have attended a few district meetings and all but one NABP Annual Meeting since being appointed to the Board. Opening the doors to communication is the first step in affecting change. Pharmacy is evolving, and meetings like these provide a platform to learn how other states are adapting to this evolution. They are great forums for sharing ideas, exploring legislation, and brainstorming ways to positively impact our communities. Through these relationships and conversations, I am able to advocate for the advances that will improve public health and patient care. ●

Executive Officer Changes

- **Jessica Sapp** has been named executive director of the Florida Board of Pharmacy, replacing Jennifer Wenhold, MSW. She is also executive director of the Florida Department of Health and the Florida Board of Dentistry. Sapp holds a certified public manager certification from Florida State University.
- **Laura Turner, JD,** has been named director of the Indiana Board of Pharmacy, succeeding Darren J. Covington, JD. Prior to this appointment, Turner was deputy general counsel with the Indiana Criminal Justice Institute. Other past positions include agency counsel for the Indiana Department of Transportation and deputy attorney general for the Office of Indiana Attorney General. Turner earned her juris doctor degree from Indiana University Robert H. McKinney School of Law.
- **Dina Jazrawi, PharmD, RPh,** has been named executive secretary of the New York State Board of Pharmacy. Most recently, she served as a clinical implementation pharmacist. Other past positions include pharmacy manager, pharmacy district manager, and licensed district leader in large pharmacy organizations.

Board Member Appointments

- **Seung Oh, PharmD, RPh,** has been appointed a member of the California State Board of Pharmacy. Oh's appointment will expire in 2023.
- **Jignesh "Jig" Patel, RPh,** has been appointed a member of the California State Board of Pharmacy. Patel's appointment will expire in 2023.
- **Kristopher Rusinko, MBA, MEd, PharmD, RPh,** has been appointed a member of the Maryland Board of Pharmacy. Rusinko's appointment will expire April 30, 2022.
- **Surinder Kumar Singal, RPh,** has been appointed a member of the Maryland Board of Pharmacy. Singal's appointment will expire April 30, 2022.
- **Courtney Bahny, CPhT,** has been appointed a member of the Montana Board of Pharmacy. Bahny's appointment will expire July 1, 2023.
- **Krystal Freitas, MSW, PharmD, RPh,** has been appointed a member of the Nevada State Board of Pharmacy. Freitas' appointment will expire October 31, 2022.
- **John Colaizzi, Jr, PharmD, RPh,** has been appointed a member of the New Jersey State Board of Pharmacy. Colaizzi's appointment will expire May 31, 2023.
- **Michael Ortynsky, RPh,** has been appointed a member of the College of Pharmacists of British Columbia. Ortynsky's appointment will expire November 15, 2022.
- **Jennifer Godsell** has been appointed a member of the Newfoundland and Labrador Pharmacy Board. Godsell's appointment will expire in May 2022.
- **Jason Ryan** has been appointed a member of the Newfoundland and Labrador Pharmacy Board. Ryan's appointment will expire in May 2022.

116th NABP Annual Meeting Changes to Virtual Format in Response to COVID-19

As communicated to its readership in the April 2020 issue of *Innovations*, in response to the coronavirus disease 2019 (COVID-19) pandemic, NABP changed the Association's Annual Meeting from the traditional in-person format to a virtual meeting delivered in a condensed format and focused on the business sessions. The virtual 116th NABP Annual Meeting will be held Thursday, May 14, 2020, and will include the opportunity for member boards to:

- elect candidates to fill the open officer and member positions on the NABP Executive Committee;
- vote on proposed resolutions; and
- discuss/vote on proposed amendments to the NABP Constitution and Bylaws.

The meeting is open to all board of pharmacy members and staff as well as other interested stakeholders. Those interested in attending can confirm their attendance by registering on the NABP Annual Meeting website at *www.NABPAnnualMeeting.pharmacy*. An email will be sent to registered attendees closer to the meeting with instructions for accessing the livestream meeting.

Boards of pharmacy voting delegates will be sent separate instructions for registering for the meeting, along with other meeting details.

For more information about the meeting, including a schedule of events and future continuing pharmacy education opportunities, visit the Annual Meeting website at *www.NABPAnnualMeeting.pharmacy*. The outcomes from the 116th NABP Annual Meeting will be provided via future NABP communications, including *Innovations*.

Alabama Requires Technicians to Complete Training

The Alabama State Board of Pharmacy now requires all newly registered technicians to complete a Board-approved training program within the first six months of their registration. This training requirement, outlined in Board Rule 680-X-2-.14, The Role of Technicians in Pharmacies in Alabama, will ensure a minimum level of competence for all practicing technicians registered by the state. More information is available in the Board's February 2020 *Newsletter*.

Ohio Requires Pharmacists to Report Certain Types of Conduct

Per Board Rule 4729:1-4-02, the State of Ohio Board of Pharmacy now requires licensed pharmacists to report certain types of conduct of which they have knowledge to the Board, along with self-reporting requirements. Specifically, the rule requires pharmacists to report the following to the Board:

- Conduct indicating an individual licensed or registered by the Board is addicted to or is suspected to be abusing alcohol, drugs, or other chemical substances; or is impaired physically or mentally to render the individual unfit to carry out his or her professional duties
- Violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Ohio Revised Code (ORC) Chapters 4729 (Pharmacy Practice Act), 4752 (Home Medical Services), 3715 (Pure Food and Drug Law), 3719 (Controlled Substances), 3796 (Medical Marijuana Control Program), 2925 (Drug Offenses), and 2913 (Theft and Fraud), or any rule adopted by the Board under those provisions by an individual or entity licensed or registered by the Board
- Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern, or pharmacist that constitutes unprofessional conduct or dishonesty

A pharmacist is not required to report a dispensing or prescription error except when the error is the result of reckless behavior or unprofessional conduct and meets any of the following per the National Coordinating Council for Medication Error Reporting and Prevention's *Index for Categorizing Medication Errors*. Per section 4729.23 of the ORC, the identity of the pharmacist making a report in accordance with this rule will remain confidential.

Additional information, including self-reporting requirements, is available in the Board's February 2020 *Newsletter*.

Oregon and Utah Begin Requiring Reporting of Gabapentin to State CS Databases

In 2019, as a result of the Opioid Epidemic Task Force, Oregon Governor Kate Brown signed House Bill 2257 into state law. Among new policy directives, the bill requires Oregon pharmacies to report all gabapentin prescriptions dispensed, the diagnosis code (ICD-10), and the reason for prescription to the state prescription drug monitoring program (PDMP). The program's related administrative rules became effective January 1, 2020, and state that the ICD-10 code and reason for prescription are to be reported when provided by the prescriber with the prescription. If the prescription issued by the prescriber does not include this information, the pharmacist is not responsible for retrieving the missing information. The Oregon PDMP has stated that missing ICD-10 and reason for prescription data will not mean the record is incomplete when submitted, and therefore will not be rejected or returned for completion at this time.

Utah also now requires pharmacies dispensing the prescription gabapentin to report the dispensing and sale transaction to the Controlled Substance Database (CSD). Pharmacies that do not possess a controlled substance license, but dispense gabapentin, will be required to report to the CSD at each dispensing and sale of the prescription.

Additional information about these rule changes is available in each board's February 2020 State *Newsletter*. ●

State Board News articles are selected from the newsletters of state boards that participate in the NABP State Newsletter Program. Five years' worth of issues are posted on the NABP website on each participating state's page.

FDA to Launch New Controlled Substances Program, Opioid Data Warehouse

United States Food and Drug Administration (FDA) will be launching a new Controlled Substances Program (CSP) to advance its response to the opioid crisis and other prescription drug abuse and misuse. The CSP, which will encompass the controlled substances (CS) staff and the CS initiatives, will help to coordinate FDA's Center for Drug Evaluation and Research (CDER) activities and emerging issues related to CS, including prescription opioids, benzodiazepines, and stimulants, according to a report from the Regulatory Affairs Professionals Society. The CSP will also manage an opioid data warehouse to integrate internal and external data sources.

Douglas Throckmorton, MD, deputy center director for regulatory programs, announced the formation of the CSP. Marta Sokolowska, PhD, the current associate director for CS within the CDER, will lead the program. Sokolowska will oversee the current CS staff along with the newly formed CS initiatives team.

"Addressing the opioid crisis remains one of CDER's top public health priorities. While it is encouraging to see that total drug overdose deaths in the US dropped 4.1% from 2017 to 2018 – the first decrease in almost three decades – there is still much work to do as deaths from drug overdoses remain at historically high levels," wrote Throckmorton in an email.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the US during 2018, according to the 2019 National Drug Threat Assessment released by Drug Enforcement Administration (DEA). Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

The National Drug Threat Assessment can be accessed through DEA's website, *www.dea.gov.*

FDA Requests Withdrawal of Weight Loss Drug Lorcaserin Due to Cancer Concerns

Following reports that lorcaserin (Belviq®) may be associated with an increased risk of cancer, FDA is asking Arena Pharmaceuticals, the drug's manufacturer, to withdraw it from the market. In January 2020, FDA announced a review of clinical trial data and publicized the range of cancer types reported during a safety clinical trial, including pancreatic, colorectal, and lung cancers, according to safety information on the FDA website. On February 13, 2020, FDA requested the withdrawal and began recommending patients stop taking the drug.

FDA is also advising health care providers to stop prescribing and dispensing lorcaserin to patients, and to contact patients who are currently taking the drug to inform them of the increased occurrence of cancer seen in the clinical trial.

Adverse events or side effects related to the use of lorcaserin may be reported to FDA's MedWatch Adverse Event Reporting Program.

Removing Medications From Child-Resistant Packaging Increases Chance of Accidental Ingestion by Children

When storing medications, adults should not remove them from child-resistant containers, new research published in the *Journal of Pediatrics* suggests. The research, which was conducted by researchers from the Centers for Disease Control and Prevention (CDC), Emory University School of Medicine, and the Georgia Poison Center, estimates that more than half of medications accidentally ingested by children had already been removed from child-resistant containers.

When storing medications, adults should not remove them from child-resistant containers, new research published in the *Journal of Pediatrics* suggests.

Four common scenarios for why medications were removed from child-safe packaging were identified:

- The medication was removed to help the patient remember to take them.
- The medication was removed for ease of travel or transport.
- The medication was removed for convenience.
- The medication was unintentionally removed (such as when dropped or spilled).

Grandparents' pill organizers were often involved. While children most often were exposed to their parents' medications, more than half of the cases of accidental ingestion were related to medications belonging to grandparents and tended to be drugs that are very harmful to children, even in small amounts. CDC recommends that both grandparents and parents be reminded to keep medications up and away and out of reach and sight of children. More information is available at *www.cdc.gov/media/releases/2020/p0212-dangerous-pills.html.* ●

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UPCOMING EVENTS

116th NABP Annual Meeting
May 14, 2020 | Virtual Meeting

NABP Program Review and Training
June 17, 2020 | Virtual Meeting

NABP/AACP District 3 Meeting
August 9-12, 2020 | Hilton Head, SC

NABP/AACP District 1 and 2 Meeting
September 9-11, 2020 | Annapolis, MD

NABP/AACP District 4 Meeting
October 7-9, 2020 | Columbus, OH

NABP/AACP District 6, 7, and 8 Meeting
October 11-13, 2020 | Carefree, AZ

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