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iNNOVATiONS

When Crises Converge:

COVID-19 Pandemic Intensifies Opioid Epidemic

NABP
National Association of Boards of Pharmacy

CONTENTS

Feature News
When Crises Converge: COVID-19 Pandemic Intensifies Opioid Epidemic

Association News
Do You Know a Leader in the Pharmacy Profession? Nominate Them for a 2021 NABP Award!

iNNOVATiONS

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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

Cheri M. Atwood, RPh

Director of Compliance, Mississippi Board of Pharmacy

Mississippi Board of Pharmacy

Number of Board Members
7 pharmacist members

Number of Compliance Officers/Inspectors
5

Rules & Regulations Established by
Board of Pharmacy and Mississippi Occupational Licensing Review Commission

Number of Pharmacist Licensees
6,378

Number of Pharmacies
1,602

Number of Wholesale Distributors
584

How long have you served as a compliance agent for the Board? What was your prior role?

I began as a compliance agent with the Board in August 2001. Prior to that, I was a community pharmacist for 18 years in Mississippi. I have been director of compliance since November 2010.

What tools or skills are a must-have in a pharmacy inspector's toolkit?

Knowledge of pharmacy practice, communication skills, and good observational skills are must-haves. Compliance agents should also be level-headed and use good judgment.

What are some common issues that you have witnessed and addressed as a Board inspector?

We have a fair amount of technician and pharmacist diversion. The majority of our technicians divert for sale. There are a few, every now and then, who are impaired and use drugs themselves. Pharmacist diversion is just the opposite. It is mostly for personal use, but we have had a few cases where the pharmacists were selling as well.

We also have had several compounding issues and are trying to develop regulations. Our state was involved in the compounding pharmacy health care fraud scheme investigated by the Federal Bureau of Investigation (FBI) in 2017. As such, the FBI raided pharmacies in a few states, and we accompanied the agents for assistance and to answer any questions they had about pharmacy. Some pharmacists will be convicted of felonies; some have pled guilty; and one is already in jail.

Is there an inspection experience that you found particularly interesting, egregious, or unusual?

A few years ago, a Board member who owned a pharmacy informed us that his mother had called her physician's office, which was located in a clinic, to get a refill on her medication. She wanted to have the prescription sent to her son's pharmacy but was told that she would have to use the pharmacy in the clinic. The Board member could not understand why his mother could not use his pharmacy. We decided to look into the complaint. We searched our database to try to find a pharmacy at that location but could not find one. We talked with the Board of Medical Licensure and one of its investigators went with our compliance agent to the clinic. When they arrived, they asked the administrator to show them the pharmacy. There was a pharmacy technician at the location, but no pharmacist. The technician would fill the prescriptions and ask a nurse to double check them. The administrator hired a company that sets up and supervises pharmacies for physicians' offices. When interviewed, the physicians all thought the pharmacy was legitimate and permitted properly.

What advice would you give to a new board inspector?

Have a working understanding of the regulations because that is what you are basing your inspections on. Never be afraid to ask questions. To me, there is no such thing as a dumb question. Be willing to educate those who you inspect. You have all this knowledge, so please do not keep it to yourself. Do not act as though you know everything when going into a facility to inspect it. Always keep an open mind and be willing to learn new things. ●

Drugmaker Cost-Sharing Assistance Comes Under Increasing Scrutiny With New Federal Rules on Plan Accumulator Programs

Consumers are increasingly being exposed to the rising costs of prescription drugs. While we will not debate every cause of that phenomenon here, we will discuss one method to make drugs more affordable – a method contested among drug manufacturers, pharmacy benefits managers (PBMs) and plans, and patient groups – and how the federal government has recently gotten more involved. Pharmacists and pharmacies should be increasingly vigilant regarding co-pay accumulator programs and be prepared to counsel patients about them.

Manufacturer cost-sharing support like co-pay coupons can greatly affect whether a patient can afford a prescription at the pharmacy counter and stay adherent to a therapy. Co-pay accumulator programs, developed by plans in response to such support, can have the effect of reducing affordability and adherence over the course of the year, therefore impacting interactions between pharmacists and patients. This article will help state boards understand how these programs interact and learn more about federal and state changes that will affect pharmacies and pharmacists.

Co-pay Coupons and Co-pay Accumulators

Direct manufacturer cost-sharing assistance, most often provided in the form of a **co-pay coupon**, has been a popular way to reduce sticker shock at the pharmacy counter. Co-pay coupons have been available in employment-based group health plans or plans purchased on the individual health insurance market.[1] Government health programs like Medicare and Medicaid do not permit manufacturer cost-sharing assistance under long-standing fraud, waste, and abuse laws.

Here is a simple example of how such assistance works: A drug with a $500 out-of-pocket cost (whether resulting from the enrollee being in the plan's deductible phase, or owing coinsurance, or, less commonly, a co-payment) is reduced to $300 by applying a $200 coupon.

However, plans and PBMs would argue that coupons undermine pharmacy benefit strategies like formulary design and deter lower-cost generic substitutions. In other words, reducing patient responsibility for a more expensive drug only encourages the utilization of more expensive drugs.

Some states, including California and Massachusetts, discourage brand drug co-pay coupons if lower-cost alternatives are available.[2] Indeed, one white paper found that 90 brand drugs in the top 200 drugs by spending in 2014 had an available coupon; nearly half had generic equivalents or a close generic substitute available at lower cost.[3]

When manufacturer cost-sharing support was first offered, plans and PBMs could not detect it; in the above example, the plan's adjudication system only saw a $500 patient out-of-pocket payment and applied that entire $500 payment to the relevant deductible and out-of-pocket spending maximum accruals. In recent years, however, plans and PBMs have become adept at detecting the presence of a manufacturer payment and distinguishing it from the patient spending. Furthermore, plans and PBMs have developed two main strategies in response: an accumulator program and a maximizer program.[4] We focus on the former here because it is more common and federal regulations do not address the latter.

A **co-pay accumulator program**, as referred to throughout this article, only counts a patient's **actual** out-of-pocket liability when determining patient accruals toward the deductible and out-of-pocket maximum. The patient will, therefore, take longer to reach the phase when the plan pays 100% for covered prescription drugs. In the example above, only $300 accrues to the deductible and out-of-pocket spending maximum under an accumulator program.

Tricia A. Beckmann, JD
Faegre Drinker Biddle & Reath LLP

According to one estimate, almost 60% of enrollees covered by commercial plans in 2018 were potentially subject to either an accumulator program, maximizer program, or both.[5] One pharmaceutical company-funded study found that 10 months after an accumulator program began, patients enrolled in a high-deductible health plan had 233 fewer autoimmune drug refills per 1,000 patients, 20 percentage points higher treatment discontinuation, and 12 percentage points lower proportion of days covered with a positive drug supply when compared to a similar cohort of patients.[6]

Federal Regulations Cemented Accumulator Programs' Existence

Accumulator programs have received little attention from federal regulators until recently. On May 14, 2020, the Centers for Medicare & Medicaid Services (CMS) published the Plan Year 2021 Notice of Benefit and Payment Parameters (NBPP) final rule, which generally permits private plans to operate accumulator programs provided that doing so is consistent with applicable state law (for insured plans).[7]

The final rule effectively rolled back a prior interpretation permitting accumulator programs only when a generic equivalent was available. Stated another way, plans are now permitted, but clearly

not required, to apply toward the annual deductible and out-of-pocket maximum amounts and any form of direct support offered by drug manufacturers to enrollees to reduce their cost-sharing obligations for specific prescription drugs. Direct support offered by manufacturers broadly includes any form of direct support by the manufacturer to make payments on the enrollee's behalf for their coinsurance or deductible obligations, but does not include other third-party payment assistance like payments sourced through crowdfunding, durable medical equipment support, and waived medical debt.

CMS states it does not expect "significant increases" in patient costs given the policy merely confirms the legality of an existing practice. However, CMS indicates that it will be monitoring accumulator programs, particularly in two respects:

- **Discrimination:** CMS reminds issuers and plans that decisions to exclude manufacturer support from accruing toward the annual deductible and out-of-pocket maximum must be applied in a uniform, nondiscriminatory manner, pursuant to other federal regulations.
- **Transparency:** CMS encourages issuers and plans to be "clear and transparent" with consumers regarding whether direct drug manufacturer support will count toward the enrollee's deductible and out-of-pocket maximum. CMS does not explicitly address how prominent this information must be at the time a consumer is choosing a plan nor does it require a special disclosure document highlighting this information. Given that many consumers do not understand the difference between a deductible, out-of-pocket limit, and coinsurance, clearly explaining the nature of an accumulator program, as well as offering solutions like less costly alternatives, will be a daunting task.

What's Next?

It is likely that manufacturers that have generated revenue gains from greater uptake of their products due to direct support will take countermeasures to maintain market share. Patient groups generally see direct support by manufacturers as an imperfect response to high list prices and selective formulary design. Nonetheless, these groups have also campaigned in recent years to prohibit accumulator programs for state-regulated insured plans in at least four states – Arizona, Illinois, Virginia, and West Virginia – as of this writing.[8] The new final rule will likely spur similar state legislative efforts. In a time of economic recession and shrinking state budgets, a ban on accumulator programs may be unpopular if doing so is perceived to lead to higher premiums and total drug spending, particularly for state-subsidized government employee health plans (despite any longer-term savings in reduced hospitalizations and adverse events from greater adherence).

Pharmacists and Accumulator Program Patient Counseling

Never has there been a more important time for patients to improve their health and health insurance literacy. Furthermore, pharmacists' primary concern is ensuring that patients can access the medications that they need. This ensures that pharmacists can assist patients by being proficient in common but complex insurance features like accumulator programs.

When patients fill their prescriptions at the pharmacy counter or through mail order, they can continue to use direct cost-sharing support by manufacturers, and pharmacies can continue to accept these payments to reduce patients' out-of-pocket costs. However, as manufacturer support is not accrued toward the patient's deductible and out-of-pocket maximum, a patient may find it more difficult to afford the same medication over time and may put off refilling a prescription or engage in "pill-splitting."

Pharmacists can be proactive by monitoring these potential patient safety concerns, understanding whether a patient's policy or plan contains an accumulator program, educating patients about these features, and reviewing the details of any program along with the patient. If patients believe their medication is too expensive, they can speak to a pharmacist about less costly alternatives to discuss with their health care provider. Price comparison shopping through drug discount card programs and other forms of assistance like patient assistance programs may also reap lower annual net spending for patients, so pharmacists familiar with these programs could point to resources available in the patient's area. ●

This article was written by 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.

Hyperlinks to footnoted references are available in the October 2020 *Innovations* pdf on *www.nabp.pharmacy*.

[1] By contrast, in federal health care programs like Medicare Part D or Medicaid, manufacturers are barred from offering cost-sharing assistance to consumers enrolled due to the beneficiary inducement prohibition under the federal Civil Monetary Penalties Law and Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b), 42 U.S.C. § 1320a-7a(a)(5) (2010).

[2] Cal Health and Safety Code - HSC § 132000—132008; Mass Gen Laws c.175H § 3 (currently effective until January 1, 2021).

[3] Van Nuys K, Joyce G, Ribero R, Goldman D. A Perspective on Prescription Drug Copayment Coupon. *(https://healthpolicy.usc.edu/research/prescription-drug-copayment-coupon-landscape/)*.

[4] The key distinguishing feature of a maximizer program is the amount of the manufacturer's support that is used to set the patient's cost-sharing obligations and is exhausted before the patient is ultimately responsible for paying cost-sharing for the drug.

[5] Zitter Health Insights. The Managed Care Biologics & Injectables Index and Oncology Index: Copay Accumulator Programs. August 2018. *(http://drugchannelsinstitute.com/files/Zitter_Copay%20Accumulator%20and%20Maximizer_09.17.2018.pdf)*.

[6] Sherman BW, et al. Impact of a Co-Pay Accumulator Adjustment Program on Specialty Drug Adherence. Am J Manag Care. 2019; 25(7): 335-340.

[7] 85 Fed. Reg. 29164 (May 14, 2020). The agency's NBPP for 2020 set up a conflict with IRS guidance related to health savings account-qualified high-deductible health plans. See IRS Notice 2004-50 and FAQs About Affordable Care Act Implementation Part 40. August 26, 2019. *(https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf)*.

[8] AIMED Alliance. *(https://aimedalliance.org/copay-accumulators-enacted-laws/)*.

When Crises Converge:

COVID-19 Pandemic Intensifies Opioid Epidemic

In less than a year, the unprecedented coronavirus disease 2019 (COVID-19) pandemic has spread throughout the world, killing over 931,000 people, sickening millions of others, and disrupting everyday life wherever it appears. In the United States alone, the death toll reached over 195,000 people, with 6.5 million confirmed cases by mid-September 2020. To help prevent the spread of the disease, many Americans have been forced for months to stay home and be socially distant. These precautions, along with growing unemployment, have created a perfect storm for individuals battling opioid addiction. Throughout the country, states and counties are seeing opioid-related deaths on the rise, with some reporting death tolls that have doubled in the first six months of 2020 compared to the same time period in 2019.

Before the COVID-19 Pandemic

After years of bleak news about the US opioid epidemic, the Centers for Disease Control and Prevention (CDC) reported in March 2020 that overall drug overdose death rates in the US decreased by 4.1% from 2017 to 2018. Deaths involving all opioids, prescription opioids, and heroin decreased 2%, 13.5%, and 4.1%, respectively. The findings, which come from an in-depth CDC analysis of the latest available drug overdose death data, were published in CDC's March 20, 2020 *Morbidity and Mortality Weekly Report*.

Decreases in all opioid-related death rates were largely driven by decreases in death rates involving prescription opioids, according to the report. Increased efforts to reduce high-dose opioid prescribing have contributed to decreases in prescription opioid-related deaths.

Factors cited in the report that might be contributing to the decrease in heroin-related deaths include fewer people initiating heroin use, increased treatment for people using heroin, more access to naloxone, and shifts from a heroin-based market to a fentanyl-based market.

While shifts to a fentanyl-based market may have contributed to decreases in prescription opioid-related deaths from 2017-2018, deaths involving illegal synthetic opioids such as fentanyl jumped 10% during the same period. Synthetic opioids were involved in nearly half of all drug overdose deaths in 2018, with illegal fentanyl likely spurring the increase in deaths involving synthetic opioids (excluding methadone) during this time. (For more information about the impact of illegal fentanyl and fentanyl-related substances on the US opioid epidemic, read "Fentanyl Supply Increase Brings 'Third Wave' to Evolving Opioid Epidemic" in the October 2019 issue of *Innovations*.)

Just as the opioid epidemic has continued to evolve, so have responses to the crisis by the White House, Congress, state governments, and the health care community. In 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. The Act's many provisions include increased addiction medicine education, standardization of the delivery of addiction medicine, training for first responders to administer opioid overdose reversal drugs, and authorization of a grant program to establish opioid recovery centers. Increasing naloxone availability to reduce overdose deaths and improving access to medication-assisted treatment (MAT) are other measures to which attention is being paid. (For more information about MAT, read "Breaking MAT Barriers: Boards, NABP Continue Promoting Pharmacists as Key Providers in Addressing Opioid Crisis" in the August 2020 issue of *Innovations*.)

In addition, state and federal governments are continuing to work to reduce the supply of prescription opioids and prevent misuse. Prescription monitoring programs (PMPs), professional education, and stricter limits on opioid prescriptions are some of the approaches being used.

COVID-19's Impact

The first case of COVID-19 in the US was confirmed in January 2020. As the disease spread from state to state and community to community, the number of confirmed cases quickly grew.

In March, some states began issuing shelter-in-place orders and allowing only essential businesses, such as grocery stores and pharmacies, to remain open. Overwhelmed with patients and short on beds, personal protective equipment, and other essential supplies, hospitals and health care providers in affected communities stopped performing non-life-threatening and elective surgeries. Other health care providers closed their facilities, including substance use disorder (SUD) treatment centers, and, when feasible, met with patients online.

By summer, states with previously low incidences of COVID-19 (for instance, Florida, Georgia, and Wisconsin) saw jumps in confirmed cases and deaths, prompting some to adopt a few of the preventive measures (social distancing, masks, and testing) taken by states first impacted by the disease.

For people undergoing SUD treatment, the COVID-19 pandemic has presented more problems – aside from the isolation and economic disruptions faced by millions of Americans – that are causing drug overdoses to spike nationwide. Data from Overdose Detection Mapping Application Program (ODMAP), published in a *Washington Post* article in July 2020, revealed that the number of suspected overdoses (not all fatal) increased 18% in March, 29% in April, and 42% in May compared to the same months in 2019. ODMAP is a federal initiative that collects drug-related data from ambulance teams, hospitals, and police nationwide.

According to *The Washington Post* article, because traditional drug supply lines have been disrupted as borders close and cities shut down, people have been seeking out new suppliers and substances with which they are less familiar. Synthetic opioids, such as fentanyl and other drugs, are increasingly showing up in autopsies and toxicology reports. Social distancing may also be causing people to be more likely to take drugs alone, making it less likely that someone will be there to call for help or to administer emergency treatment if something goes wrong.

NABP Continues to Educate Consumers on Opioid Disposal

NABP launched its 2020 consumer education campaign in May with a focus on the safe disposal of opioids. This year's campaign includes television and radio public service announcements (PSAs) about safely disposing of medications, as well as in-app mobile ads, banner display ads, and video ads, targeted to specific consumers based on their keyword and topic searches in order to reach individuals with a need for information about medication disposal. In addition, NABP President Timothy D. Fensky, RPh, DPh, FACA, and NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, will provide expert advice to consumers via a satellite media tour on October 7. The various campaign components all direct consumers to the Association's *safe.pharmacy* website, where they can find information about safe, proper disposal of unused, unwanted, and expired medications; and the Drug Disposal Locator Tool to search for permanent drug disposal boxes.

Safe medication disposal is a vital topic during the coronavirus disease 2019 (COVID-19) pandemic, as many areas across the country are experiencing increases in opioid overdoses, which may be attributed to substance use disorders and the opioid epidemic being exacerbated by efforts to prevent the spread of COVID-19. Boards of pharmacy interested in sharing the message are encouraged to use the sample social media posts, images, and PSAs available at *https://safe.pharmacy/social-kit*.

"NABP is committed to helping its member boards of pharmacy address the opioid epidemic in their states and on a national level by continuing to work with federal and state agency stakeholders throughout the COVID-19 pandemic and beyond."

In addition, the COVID-19 pandemic is making it difficult for some SUD patients to continue their drug treatment because they cannot see their health care provider or attend a treatment program, due to factors such as shelter-in-place orders, loss of health insurance, the unavailability of treatment drugs, or the closure of treatment facilities.

In April 2020, the National Council for Behavioral Health and ndp | analytics conducted an online survey of 880 community behavioral health care organizations nationwide that treat mental health and opioid use disorder (OUD) patients about the financial challenges they are facing due to the COVID-19 pandemic. Nearly all (92.6%) of the organizations said they had reduced their operations, and almost half said they had cut positions. In addition, the organizations reported that they had canceled, rescheduled, or turned away 31% of patients, and nearly 62% had closed at least one program. The Council has requested $38.5 billion in emergency funding from Congress to prevent the collapse of behavioral health organizations nationwide.

Federal Responses

Recognizing the devastating effect of the COVID-19 pandemic on the opioid epidemic, earlier this year the federal government began to expand existing efforts and introduce new ways to help health care providers treat OUD patients and decelerate the worsening opioid epidemic.

In February 2020, Drug Enforcement Administration (DEA) announced improved access to MAT, especially in rural areas, where people with OUD often have limited treatment options. Under the proposal, narcotic treatment program registrants authorized to dispense narcotic drugs approved to treat opioid dependence would be authorized to implement a mobile component to their registration, eliminating the need for a separate DEA registration. The streamlined registration process will make it easier for providers to offer needed services in remote or underserved areas, according to DEA.

DEA announced in March 2020 that it had partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA) to ensure that authorized practitioners may admit and treat new patients with OUD during the pandemic. DEA previously announced that practitioners may prescribe controlled substances (CS) to patients using telemedicine without first conducting an in-person evaluation. As a result, practitioners now have more flexibility to prescribe buprenorphine to new and existing OUD patients via telephone by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine.

In April 2020, DEA announced that it had issued a final order to increase the 2020 aggregate production quotas (APQs) available to pharmaceutical manufacturers by 15% for certain CS needed to treat COVID-19, including fentanyl, morphine, hydromorphone, codeine, ephedrine, pseudoephedrine, and certain CS intermediates. The agency also increased the APQ for methadone to ensure that opioid treatment programs have sufficient supplies to treat patients suffering from OUD.

Nineteen US senators signed a letter in May 2020 urging congressional leadership to support increased funding to address SUDs as the pandemic continues and worsens. The letter requested an additional $2 billion in funding, which would be allocated to states and local officials through SAMHSA's Substance Abuse Prevention and Treatment block grants and State Opioid Response grants. The grants would allow the funds to be directed toward areas with the most significant needs.

NABP Initiatives

NABP is committed to helping its member boards of pharmacy address the opioid epidemic in their states and on a national level by continuing to work with federal and state agency stakeholders throughout the COVID-19 pandemic and beyond.

In a May 2020 report to NABP membership, NABP President Timothy D. Fensky, RPh, DPh, FACA, outlined his initiative for 2020-2021, which includes eliminating barriers to patients seeking OUD treatment through MAT programs and expanding the role of the boards of pharmacy in promoting pharmacists as vital members of teams providing MAT services. (To read Fensky's initiative, visit the NABP website at *www.nabp.pharmacy/presidential-initiative*.)

Reiterating the role that pharmacists and state boards of pharmacy play in protecting the public health, NABP sent a letter to congressional leadership in June 2020 urging Congress to continue supporting robust investments in federal programs to combat both the ongoing opioid epidemic and the COVID-19 pandemic. The letter expressed concern about reports that opioid overdoses and abuse may be increasing during the pandemic.

"Early data has demonstrated that the economic downturn, prolonged periods of social distancing, and overall uncertainty of COVID-19 have caused an increase in opioid-related mortality in at least 30 states," stated NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, in the letter. "Congress must continue to consider the damage caused by the opioid epidemic and proactively invest in countermeasures to ensure this crisis is not further exacerbated by the COVID-19 pandemic."

The letter also reviewed some of the Association's efforts to help its member boards respond to the crisis, including expanding pharmacists' access to PMPs across state lines through NABP PMP InterConnect®. NABP also asked Congress to consider NABP as a potential resource when considering legislation and other public health policies impacting the practice of pharmacy.

More information about the impact of the COVID-19 pandemic on the opioid epidemic will be provided in future NABP communications. ●

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 for a three-year term, beginning June 1, 2021. ACE convenes two to three times a year to:

- oversee the development and administration of NABP examination and certification programs;
- evaluate long-range planning strategies;
- consider policy matters; and
- 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 current 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. Currently, there are two open positions on ACE.

Interested individuals are asked to submit a written statement of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Lemrey "Al" Carter at NABP Headquarters, 1600 Feehanville Drive, Mount Prospect, IL 60056, or via email to ExecOffice@nabp.pharmacy no later than December 31, 2020.

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

Second Quarter 2020 NABP Clearinghouse Totals Announced

During the second quarter of 2020, a total of 1,035 disciplinary records were submitted by the state boards of pharmacy on 912 individual and organization e-Profiles. The majority of disciplinary records submitted were for pharmacists, pharmacies, and pharmacy technicians. Please note that a disciplinary record can have multiple "actions" and "bases for actions," which explains why there will always be more actions and bases for actions than records reported.

Contained in the 1,035 disciplinary records were 1,309 actions reported to the NABP Clearinghouse. Of the 1,309 actions, the three most reported actions in the second quarter were publicly available fine/monetary penalty (422 or 32.2% of all actions); other actions not classified (195 or 14.9% of all actions); and revocation of license or certificate (125 or 9.5% of all actions).

Of the 1,221 bases for actions cited in second quarter 2020, violation of federal or state statutes, regulations and rules, or health and safety requirements (323 bases or 26.4%); failure to comply with continuing education or competency requirements (155 bases or 12.7%); and other bases not classified (116 bases or 9.5%) were the top reasons why disciplinary actions were taken during the quarter.

As stated in the NABP Constitution and Bylaws, participation in the Clearinghouse is required as part of a board of pharmacy's membership in the Association. Timely reporting to the Clearinghouse is essential to maintaining the integrity of the licensure transfer program. Boards may access the Clearinghouse using NABP e-Profile Connect. ●

Do You Know a Leader in the Pharmacy Profession? Nominate Them for a 2021 NABP Award!

NABP is accepting nominations for its 2021 awards, which recognize individuals or boards of pharmacy that represent the Association's mission to protect the public health. The awards will be presented during the 117th Annual Meeting, to be held May 13-15, 2021, in Phoenix, AZ. Nominations are being accepted for the following awards:

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.

Carmen A. Catizone 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.

The award was renamed in 2020 to honor former NABP Executive Director/Secretary Carmen A. Catizone, who then served the Association for 35 years. The award honors Catizone's unwavering leadership, commitment, and dedication to NABP and its mission to protect the public health.

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. The award also recognizes exceptional accomplishments related to pharmacy law and compliance. This award is named in honor of the late John F. Atkinson, who served as NABP outside legal counsel for more than 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 submission will be provided on the Annual Meeting page of the NABP website. Nominations must be received no later than December 31, 2020. 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

Nominations are not accepted for the Henry Cade Memorial Award. Instead, 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.

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 longtime pharmacy practitioner.

NABP's *Innovations* and Drug Disposal Awareness Campaign Honored With 2020 EXCEL Awards

NABP received four 2020 EXCEL Awards during Association Media & Publishing's (AM&P's) 40th Annual EXCEL Awards Celebration, held virtually on July 14, 2020. AM&P's prestigious EXCEL Award program recognizes excellence and leadership in nonprofit and for-profit association media, publishing, marketing, and communications.

NABP RECEIVED THE FOLLOWING HONORS:

Innovations May 2019

SILVER
Editorial Excellence – Print Newsletter

AM&P EXCEL SILVER WINNER 2020

Innovations March, April, and May 2019

SILVER
General Excellence – Print Newsletter

AM&P EXCEL SILVER WINNER 2020

Drug Disposal Awareness marketing campaign

SILVER
Promotional Content – Awareness Campaign

AM&P EXCEL SILVER WINNER 2020

Innovations September, October, and November/December 2019

BRONZE
General Excellence – Print Newsletter

AM&P EXCEL BRONZE WINNER 2020

AM&P's 2020 EXCEL Awards program drew 688 entries in seven broad categories ranging from digital publishing and magazines to books and promotional campaigns. Of those, the judges selected 270 entries to receive EXCEL Awards. During the Awards Celebration, AM&P announced the award levels for each of the awards (Gold, Silver, and Bronze). The 2020 EXCEL Award winners will be featured in the August/September issue of AM&P's *Signature* magazine. ●

Bahamas Pharmacy Council

Number of Board Members
4 pharmacist members, 1 medical practitioner, and 2 public members

Number of Compliance Officers/Inspectors
8

Rules & Regulations Established by
Bahamas Pharmacy Council

Number of Pharmacist Licensees
185

Number of Pharmacies
79

Number of Wholesale Distributors
12

Gina A. Archer, MHA, PharmD, RPh

Member, Bahamas Pharmacy Council

When were you appointed to the Bahamas Pharmacy Council? What type of member are you?

I was appointed by the minister of health in July 2018 to serve as chair of the Bahamas Pharmacy Council and have been serving in this position to date. I am a pharmacist by profession and presently employed by the Ministry of Health, where I have the dual role of acting chief pharmacist and director of the Bahamas National Drug Agency.

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

Board members should first make every effort to prepare for and attend all meetings. Members should actively participate and make meaningful contributions at meetings as well as serve on the various committees. It is also important to be familiar with their respective state or country legislation, as I have observed that this is key in decision making and policy creation.

What are some recent policies, legislation, or regulations that the Council has implemented or is currently working on?

The Pharmacy Council is, at present, working on a number of policy and pharmacy regulation reviews. The focus of one of the Council's committees is improving the mechanism for the import and export registration process of drugs within the Bahamas. The Pharmacy Act (2009) gives the Council the authority to approve all drugs imported into and exported out of the country, and this approval is given once set criteria for each drug product is met. In order to streamline the process for the registration of drugs within the Bahamas, the Council realized that the present regulations had to be amended. Some of the proposed amendments include adding relevant definitions to the regulations (parallel import being an example of one of them) and expanding on the current list of required supporting documents.

Another piece of regulation that the Council's finance committee has been working on is the restructuring of the existing fee schedule. As the Council continues to grow, the Pharmacy (Registration and Licensing) Regulations (2010), which contain the various fee schedules for practitioners and facilities, are no longer sufficient to support the activities of the Council. Discussions pertaining to forecasting and developing a new fee table are actively ongoing.

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

The Council has encountered a few challenges, but not many. One of the challenges faced regarding the forward movement of the recommended amendments to the import/export regulations was the delay in getting the document to the Ministry of Health. Due to the recent changes in the makeup of the Council body, these amendments must be reviewed again before they are forwarded to the Ministry of Health and then onward for the Cabinet's approval.

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

During my two years as chair of the Bahamas Pharmacy Council, I had the great opportunity to attend the Interactive Compliance Officer and Legal Counsel Forum in December 2019 and the Interactive Member Forum in January 2020. These forums were tremendously beneficial and highly insightful. It was a valuable experience to learn what other boards were doing to ensure patient safety as pharmacy practice evolves, whether it be in the form of telepharmacy or the Canadian competency assessment of pharmacists. I was able to interact with other board members and take back new information to my Council. ●

Executive Officer Change

- **Eric Lacefield, MBA**, has been named executive director of the Georgia Board of Pharmacy, replacing Tanja Battle. He is also executive director of the Georgia Board of Dentistry. Prior to assuming this position, Lacefield was deputy executive director of both boards for seven years. His previous positions include director of the Registrations Division for the Georgia Secretary of State; director of Clayton County Community Development in Clayton County, GA; and deputy city manager of the City of Villa Rica, GA. Lacefield received a master of business administration in finance from Clark Atlanta University.

Board Member Appointments

- **David A. Darce, RPh**, has been appointed a member of the Louisiana Board of Pharmacy. Darce's appointment will expire June 30, 2026.
- **Anthony G. "Merc" Mercante, RPh**, has been appointed a member of the Louisiana Board of Pharmacy. Mercante's appointment will expire June 30, 2026.
- **Trina Buettner, RPh**, has been appointed a member of the State of Ohio Board of Pharmacy. Buettner's appointment will expire on June 30, 2023.
- **Tosha Williamson, RPT**, has been appointed a member of the Wyoming State Board of Pharmacy. Williamson's appointment will expire March 1, 2025.

INTERACTIVE MEMBER FORUM

January 27, 2021 | Virtual Meeting

The NABP Interactive Member Forum will return this winter as a virtual meeting offering a variety of opportunities for dialogue on shared challenges faced by board of pharmacy members. Invitations and details for the forum will be sent to members, as designated by Board executive officers, in October 2020.

Minnesota Allows Independent Prescribing by Pharmacists for Certain Medications

Pharmacists will be able to independently prescribe self-administered contraceptives, nicotine replacement medications, and opioid antagonists, provided that they:

- follow a protocol developed by the Minnesota Board of Pharmacy in consultation with the Minnesota Board of Medical Practice; the Minnesota Board of Nursing; the commissioner of health; professional pharmacy associations; and professional associations of physicians, physician assistants, and advanced practice registered nurses.
- complete appropriate training programs and continuing education.
- provide appropriate counseling to patients.

The Board will provide additional information to pharmacists once the protocols have been developed.

Virginia Pharmacists May Initiate Certain Drugs and Devices to Adults

House Bill 1506, signed by Governor Ralph Northam on April 6, 2020, went into effect on July 1, 2020. It allows pharmacists to initiate treatment, dispense, and administer certain drugs and devices to persons 18 years of age or older in accordance with statewide protocols to be developed by the Virginia Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board to establish such protocols by November 1, 2020, and promulgate regulations to implement the provisions to be effective within 280 days of its enactment. A meeting of representatives from the Board, Board of Medicine, and Department of Health convened this summer to provide recommendations regarding the development of the protocols and regulations.

As authorized in the bill, the statewide protocols will specifically address pharmacist initiation, dispensing, and administration of the following to persons 18 years of age or older:

- epinephrine,
- injectable or self-administered hormonal contraceptives,
- prescription prenatal vitamins,
- dietary fluoride supplements,
- naloxone or other opioid antagonists, and
- medications covered by the patient's insurance carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase the over-the-counter (OTC) equivalent of the same medication.

The bill also requires a work group consisting of representatives of the Board of Pharmacy, Board of Medicine, Department of Health, schools of medicine and pharmacy located in the commonwealth, and other stakeholders to provide recommendations regarding the development of protocols for pharmacist initiation of treatment, dispensing, and administration to persons 18 years of age or older of:

- vaccines;
- drugs for tobacco cessation, including nicotine replacement therapy;
- tuberculin purified protein derivative for tuberculosis testing;
- drugs or devices for the treatment of conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria;
- drugs for the prevention of human immunodeficiency virus, including drugs for pre-exposure and post-exposure prophylaxis; and
- drugs sold OTC for which the patient's health insurance provider requires a prescription.

It is anticipated that this larger work group will also meet in early fall to develop its findings and recommendations, which must be reported to the governor and the chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

Washington Bill Allows Pharmacies' Licenses to Extend to Remote Dispensing for Opioid Use Disorder Medications

To increase access to medications for vulnerable populations with opioid use disorder, Washington's 66th Legislature passed Substitute Senate Bill (SSB) 6086, allowing pharmacies to extend their pharmacy licenses to include remote dispensing sites. Under this new legislation, pharmacies may register a remote dispensing site with the Washington State Pharmacy Quality Assurance Commission. Once registered, the pharmacy's license is extended to include the remote dispensing site. SSB 6086 states a remote dispensing site is "where technology is used to dispense medications approved by Food and Drug Administration for the treatment of opioid use disorder." SSB 6086 requires the Commission to adopt rules establishing minimum standards for registered remote dispensing sites. While the Commission engaged in rulemaking specific to registered remote dispensing sites, the Commission put out a policy statement to clarify regulatory standards and made the registration available for remote dispensing sites on July 1, 2020. ●

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.

FIP Releases COVID-19 Guidance for Pharmacists

To support pharmacists through the coronavirus disease 2019 (COVID-19) pandemic, the International Pharmaceutical Federation (FIP) released its latest global guidance in three reports, covering clinical information and treatment guidelines, advice for pharmacy teams, and frequently asked questions (FAQs). Specifically, the guidance includes:

- evidence related to treatments and disease transmission;
- advice on use of masks and rapid point-of-care tests;
- examples of professional services offered globally during the pandemic by pharmacists;
- recommendations for pharmacy practice and operations; and
- answers to FAQs sent by pharmacists around the world.

The new guidance replaces the update FIP provided in March 2020. Additional resources are available in the FIP COVID-19 Information Hub. NABP continues to share information about how boards of pharmacy are responding to COVID-19 in the Coronavirus Updates section of the NABP website. Pharmacists are also encouraged to check their state board(s) of pharmacy websites for jurisdiction-specific information.

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids or Treatment for OUD

Discussing naloxone with patients receiving opioid medications or medications used to treat opioid use disorder (OUD) is crucial for raising awareness about the availability of the drug, says Food and Drug Administration (FDA). The agency recommends that health care providers include these discussions as a routine part of prescribing, and is requiring label changes to these medications to include the recommendation. Specifically, the labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment, as announced in a Drug Safety Communication. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

ASHP Survey Provides Insights Into Current Hospital, Health-System Pharmacy Practice

Formulary management, pharmacogenomics, opioid stewardship, and pharmacist prescribing authority are some of the key areas explored through an annual survey conducted by the American Society of Health-System Pharmacists (ASHP). Pharmacy directors of more than 5,000 United States hospitals responded to the survey, and the results provide key insights on hospital and health-system pharmacy practice. Of the hospitals that participated in the survey:

- 89% give pharmacists the authority to write medication orders; among these, 94% of pharmacists are able to modify or initiate therapy by policy or protocol, whereas 6% are authorized to prescribe medications;
- 5.4% reported their recommendations for scheduling of pharmacogenomics testing for determining drug and dosage; 90% indicated that their pharmacists experience limitations in dispensing products for pharmacogenomics drug therapy management;
- 65% indicated that their pharmacists function as leaders for accountability concerning the hospital's opioid stewardship programs; and
- 85% have been using a prescription drug monitoring database, compared to 63.5% in 2018.

". . . pharmacists continue to assume greater responsibility and are taking a leading role in addressing the opioid crisis . . ."

In all, results from the survey show that pharmacists continue to assume greater responsibility and are taking a leading role in addressing the opioid crisis, advancing compounding pharmacy safety, and leveraging clinical decision support tools to improve prescribing practices. The full results of the survey are published in the July 2020 issue of *American Journal of Health-System Pharmacy*.

PTCB and APhA Develop Immunization Credential Program for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB), in collaboration with the American Pharmacists Association (APhA), has announced a pharmacy technician credential program for immunization delivery. The program is for those certified pharmacy technicians (CPhTs) who complete the APhA/Washington State University Pharmacy-Based Immunization Administration by Pharmacy Technicians program, which provides CPhTs with the knowledge and skills they need to safely administer vaccines.

Additional information about pharmacy technician certification programs offered by PTCB can be found at *ptcb.org/credentials*. More information about how NABP and its member boards are continuing to explore the expansion of CPhT roles in pharmacy practice can be found in the August 2019 issue of *Innovations* (pages 6-8, 10). ●

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National Association of Boards of Pharmacy

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UPCOMING EVENTS

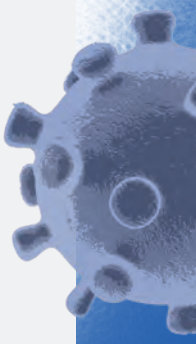
NABP/AACP District 4 Meeting
October 8, 2020 | Virtual Meeting

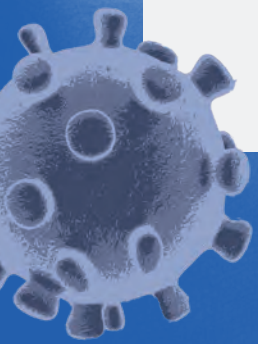
NABP/AACP Districts 6, 7, and 8 Meeting
October 13, 2020 | Virtual Meeting

NABP Task Force on Medication Reuse
October 29, 2020 | Virtual Meeting

NABP Task Force on Medication-Assisted Treatment
November 17, 2020 | Virtual Meeting

NABP Overview Task Force on Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment
December 1, 2020 | Virtual Meeting





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