NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS®

Sharing Compounding Data, Regulators Strive to Increase Patient Safety

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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.

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Joanne M. Trifone, RPh, Director of Pharmacy Investigations, Massachusetts Board of Registration in Pharmacy

Joanne M. Trifone, RPh,
Director of Pharmacy Investigations, Massachusetts Board of Registration in 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 director of pharmacy investigations for the Massachusetts Board of Registration in Pharmacy for almost three and a half years now. Prior to working for the Board, I was a pharmacist for a large retail chain pharmacy and a member of the Massachusetts Board of Registration in Pharmacy for six years.

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

As a pharmacy inspector, some important tools or skills to have in your toolkit include a good command of your state's regulations, the ability to work with licensees to help bring them into compliance, and the focus to be able to follow your board's mission. The Massachusetts Department of Public Health supports ongoing training, particularly in the areas of compounding and regulatory affairs.

What are some common issues that you have witnessed and addressed as an inspector with the Board?

The Board has a strong compliance program in place, with more than 2,000 inspections conducted annually within the Commonwealth. Some of the common issues that have been addressed by our inspection team include noncompliance in the areas of controlled substance record keeping, refrigeration, and drug storage. Specifically, the team finds repeat deficiencies regarding proper reconciliation of the perpetual inventory every 10 days, which often includes findings of expired Schedule II medications not kept on the perpetual inventory count, and findings of noncompliant refrigerators without adequate storage space or consistent temperature monitoring.

In Massachusetts, do inspectors also conduct investigations for the Board of Pharmacy or other health regulatory boards?

Yes, in Massachusetts our pharmacy investigators are trained to conduct inspections as well as investigations for the Board. Some of these investigations can be challenging. For example, one of our cases involved drug diversion by a licensee. The investigation team worked with collaborating agencies and conducted a joint inspection. This investigation was multifaceted, and this collaborative approach built an even stronger evidence-based case. The successful outcome was a voluntary surrender of the license.

What advice would you give to a new board inspector?

We rely on our staff of dedicated inspectors who do their jobs with integrity every single day. They have tremendous expertise when it comes to educating others. One piece of advice for a new board inspector would be to approach inspections as an opportunity to educate the licensee to help bring them into compliance. Ongoing compliance is the goal in protecting and promoting public health.

Massachusetts Board of Registration in Pharmacy

Number of Board Members: 8 pharmacist members, 2 public members, plus 1 physician, 1 nurse, 1 pharmacy technician, 1 representative of the public with experience in health care service delivery, administration or consumer advocacy, and 1 expert in patient safety and quality improvement

Number of Compliance Officers/Inspectors: 1 compliance officer, 12 inspectors

Rules and Regulations Established by: Board of Registration in Pharmacy

Number of Pharmacist Licensees: 13,201

Number of Pharmacies: 1,135 (includes home infusion, mail-order pharmacies, and nuclear pharmacies)

Number of Wholesale Distributors: 40

Health Care Plans of 2020 Presidential Hopefuls Aim to Lower the Cost of Prescription Drugs

Megan S. Herber, MPH
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In Washington, DC, and around the country, the year 2020 has been long anticipated. This month marks the start of a presidential election year. Undoubtedly, this means an increase in political ads and phone calls and a lot of politicians making a lot of promises for the future. However, it is worth taking a minute to understand who is promising what, especially when it comes to health care policy.

As of the writing of this article, the candidate list of Democratic 2020 challengers to President Donald J. Trump remains long – and each of them have a plan for health care.

All of the Democratic candidates have a position on "Medicare for All": Senator Bernie Sanders (VT), Senator Elizabeth Warren (MA), Andrew Yang (NY), Representative Tulsi Gabbard (HI), Senator Cory Booker (NJ), and former Housing and Urban Development Secretary Julián Castro are all strong supporters of the policy. Warren says her plan would cost $52 trillion and require $20.5 trillion in new federal spending over a decade, and Sanders' plan would cost an estimated $33 trillion over that same time span. Mayor Pete Buttigieg (IN), Senator Amy Klobuchar (MN), and Senator Michael Bennet (CO) support expansion of coverage but not full "Medicare for All" – Senator Bennet calls his plan "Medicare X," while Mayor Buttigieg says his is "Medicare for those who want it." Former Vice President Joe Biden would protect and build upon the Affordable Care Act, which is unsurprising given that he was part of the administration that created it. Further, Biden, Bennet, Buttigieg, Sanders, and Yang, during the televised June 2019 Democratic debate, raised their hands when asked if their health care plan would provide coverage for undocumented immigrants. President Trump touts his actions to expand access to association health plans and short-term, limited-duration plans after Congress, in late 2017, passed legislation that repealed the individual mandate requiring individuals to purchase health insurance or otherwise pay a fee.

While the Democratic candidates and President Trump are on opposite ends of the spectrum when it comes to a vision for how Americans obtain health care services overall, they do share three top health policy priorities: reducing prescription drug prices, addressing the opioid epidemic, and improving health care in rural America. Of course, there are different views on the best ways to achieve these goals. While the policy proposals thus far do not directly alter laws and regulations relating to pharmacies or pharmacists, each of those efforts would impact the practice of pharmacy.

Every candidate mentioned here has included a plan as part of his or her campaign for lowering the cost of prescription drugs to increase patient access to needed medications, and many candidates are working toward doing so in their current capacities. While the candidates use varying language and levels of intensity, all have some element of a plan to hold pharmaceutical manufacturers accountable for excessively high drug prices.

This article summarizes the specific proposals of President Trump and the top Democratic candidates, based primarily on their campaign websites as of early November 2019.

Importation Still on the Table

As discussed in the March 2019 issue of *Innovations*, policies to allow the importation of drugs from Canada or other countries are popular on both sides of the aisle, despite safety concerns from NABP and others. In July 2019, President Trump and United States Department of Health and Human Services Secretary Alex M. Azar released a Safe Importation Action Plan outlining regulatory pathways for the Administration to begin importing drugs from Canada. For the Democrats, nearly all would also move toward importation plans ranging from allowing patients to buy drugs directly from other countries to allowing states to experiment with importation.

Medicare Negotiation

The policy with the most contrast between the parties is allowing Medicare to negotiate drug prices, which is endorsed by every Democratic candidate. President Trump has hinted at supporting negotiation in his Blueprint to Lower Drug Prices and on the 2016 campaign trail. Most Democrats also want to expand Medicare to non-elderly populations, in which case reducing costs to the federal government via the Medicare program specifically would be even more necessary. While lowering costs for Medicare beneficiaries is supported by both sides of the aisle, there is disagreement about whether allowing the government to negotiate Medicare drug prices would be the best option to accomplish this goal, and the nonpartisan Congressional Budget Office has indicated that this policy would produce "negligible" savings.

Pressuring or Requiring Manufacturers to Reduce Drug Prices

The next set of policies on the table would either pressure or require manufacturers to reduce drug prices by setting up penalties, changing how drugs are reimbursed, or revoking patent privileges.

Many candidates favor some version of international reference pricing where drug prices are compared to those in other countries. This includes the president, who often speaks about the need to tie US drug prices to lower prices overseas. The Trump Administration argues for a focus on Medicare Part B drugs because limited competitive forces play a huge role in determining what Medicare pays for these drugs. Some Democratic candidates would levy penalties or taxes on pharmaceutical companies that are above the reference price, while others would rescind patents or otherwise intervene.

Some proposed plans would penalize manufacturers when drug prices rise faster than the rate of inflation, while others would encourage or require that manufacturers and payers work out agreements to pay for drugs on the basis of their value. Lastly, some plans would have the federal government intervene and actually rescind a manufacturer's patent under conditions like an excessively high drug price. This idea stems from "march-in" rights originally granted by the Bayh-Dole Act of 1980, which allows the federal government to march-in on patents for inventions arising from government-funded research (in this case, usually the National Institutes of Health), although no federal agency has ever exercised this power.

Encouraging Generics

All of the candidates also seem to agree that bringing generic drugs to market faster would increase competition and thereby reduce the cost of medications. A few policies intended to do so include:

- requiring brand manufacturers to sell samples to would-be generic manufacturers, also known as ending abuse of the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies program, which manufacturers have used to deny access to their drugs by generic companies;
- ending "pay for delay," in which brand manufacturers pay would-be generic manufacturers to delay entrance into the market in order to maintain their monopoly longer; and
- opening up public – government-run or -sponsored – manufacturing facilities to manufacture generics. Some proposals would also allow for public manufacturing of drugs in shortage or otherwise excessively high-priced drugs.

Meanwhile, President Trump has been working to increase the number of generic approvals by FDA during his administration, with 80 and 99 approvals in 2017 and 2018, respectively, and 85 as of October 2019.

Other Ideas

Most proposals focus on bringing down the cost of the drug to both the patient and the government or private payer. A couple of proposals, however, promise to lower the out-of-pocket costs for prescription or other drugs, such as cancer drugs administered in a facility, for Medicare beneficiaries. This, of course, does not necessarily lower the overall cost of the drug, but would certainly reduce the impact for the patient.

Another policy that does not directly lower prescription drug costs would be taxing pharmaceutical manufacturers. Proposals listed above would tax the manufacturers as a penalty if drug prices rose too high, but three candidates would tax every manufacturer with the idea that their profits are too high and revenue from the tax could be used to subsidize or otherwise lower drug prices.

Finally, two presidential hopefuls would ensure that direct-to-consumer advertising of medications is not tax-free. President Trump has also targeted direct-to-consumer advertising by working to require that drug prices be included in TV ads for drugs.

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NABP Foundation Offering 10 Grants to Attend APhA Institute on Substance Use Disorders

The NABP Foundation® is accepting grant applications from qualified board of pharmacy members or staff who would like to attend the American Pharmacists Association (APhA) Institute on Substance Use Disorders in Salt Lake City, UT, on May 27-31, 2020. This year, NABP will award 10 grants to assist with some of the costs associated with attending. The APhA Institute sessions provide educational programs for attendees on substance use disorders and how to effectively support pharmacists who are impaired or in recovery. More information about the APhA Institute is available at *https://aphainstitute.pharmacist.com*.

To apply for a grant, contact ExecOffice@nabp.pharmacy by February 7, 2020. Grants will be assigned on a first-come, first-served basis. Due to limited space available, those interested in applying for the grant must be prepared to register for the APhA Institute by March 1, 2020. ■

APhA Institute Highlights:

- Four days of education, networking, and personal development
- Help increase awareness of the health and social problems related to substance use disorders
- Gain information and instruction for providing programs to support pharmacists in recovery
- Earn continuing pharmacy education

Policy Perspectives

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This month kicks off the true 2020 campaign season and anything could happen, but one thing is for certain: whoever wins in November 2020 will be looking to keep promises to American patients about lowering the costs of prescription drugs. Policies that will be pursued will vary and their level of success is uncertain, but we will undoubtedly experience the effects of these efforts at the pharmacy counter.

This article was written by Megan S. Herber, MPH, and Sarah-Lloyd Stevenson, both with Faegre Baker Daniels LLP. Please note, the opinions and views expressed by Faegre Baker Daniels do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated. ■

Third Quarter 2019 NABP Clearinghouse Totals Announced

During the third quarter of 2019, a total of 1,607 disciplinary records were submitted by the state boards of pharmacy on 1,392 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 1,607 disciplinary records, there were 2,031 actions reported to the NABP Clearinghouse. Of the 2,031 actions, the three most reported actions in the third quarter were publicly available fine/monetary penalty (754 or 37.1% of all actions); other actions not classified (323 or 15.9% of all actions); and revocation of license or certification (132 or 6.5% of all actions).

Of the 1,821 bases for actions cited in third quarter 2019, violation of federal or state statutes, regulations and rules, or health and safety requirements (503 bases or 27.6%); failure to comply with continuing education or competency requirements (287 bases or 15.8%); and other bases not classified (190 bases or 10.4%) 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 to 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. ■

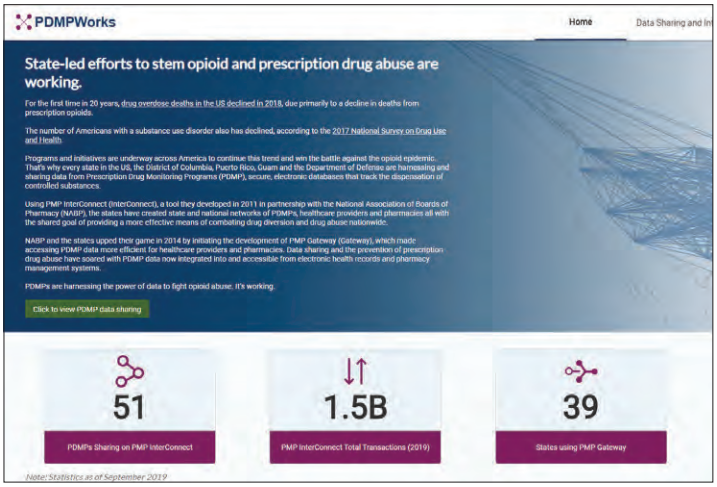
Informational Website for PDMPs Now Available

Sharing accomplishments in interoperability and integration with stakeholders and the public will be easier for state prescription drug monitoring programs (PDMPs) participating in the NABP PMP InterConnect® program with the new *PDMPWorks.org* website. Launched in October 2019, the website features accurate, up-to-date information about PMP InterConnect as well as PMP Gateway, a third-party managed service that works with PMP InterConnect to deliver PDMP data, analytics, insights, and resources to health care systems, pharmacy management systems, and health information exchanges. In addition, the website includes information about how states and their PDMPs are positively impacting the opioid problem.

PDMPWorks.org's home page features information, statistics, and quick facts about PMP InterConnect and PMP Gateway.

On the Data Sharing and Integration page, visitors will find:

- interactive maps showing PMP InterConnect transactions and the growth of PMP Gateway facilities across the United States by state, month, and year;
- information about PDMP data sharing via PMP InterConnect, including interstate data sharing facts and security highlights; and
- information about PDMP data integration via PMP Gateway, including clinical workflow integration facts and security highlights.



The Resources page offers visitors an About Us section and contact information for the website.

In addition, frequently asked questions and answers about PDMPs, PMP InterConnect, and PMP Gateway are included.

Since 2011, PDMPs have been building and enhancing a robust national data-sharing network using PMP InterConnect and PMP Gateway. More than 90% of PDMPs in the US participate. Currently, PMP InterConnect connects 51 of the 54 PDMPs in the US, facilitating more than 58 million interstate PDMP data requests and 178 million responses each month. In addition, more than 550,000 prescribers and pharmacists at over 85,000 facilities are using PMP Gateway service in more than 56 million patient encounters per month.

New NABP Accreditations

The following entities were recently granted NABP accreditation through the select programs noted below. Full listings of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) facilities and Verified-Accredited Wholesale Distributors® (VAWD®) facilities can be found in the Programs section at *www.nabp.pharmacy*.

Accredited DMEPOS Facilities

AdventHealth Pharmacy Sebring
Sebring, FL

S&L Medical Center Pharmacy Inc, dba S&J Medical Center Pharmacy
Decatur, TX

S&L Pharmacy Terrell Inc, dba Bass Rutledge Drug
Terrell, TX

Salfiti Canton Pharmacy Inc, dba Peace Pharmacy
Canton, TX

Salfiti Wichita Falls Pharmacy Inc, dba Franklin Pharmacy
Wichita Falls, TX

Accredited VAWD Facilities

Brooks Life Sciences
Indianapolis, IN (two locations)

Cardinal Health 200, LLC, dba Cardinal Health
Omaha, NE

Edge Pharma, LLC
Colchester, VT

Eversana Life Science Services, LLC, dba EVERSANA Life Science Services
Memphis, TN

McKesson Medical-Surgical Inc
Bethlehem, PA

Oak Drugs, Inc
Chestnut Ridge, NY

Real Value Products Corp, dba Hospital Pharmaceutical Consulting
San Antonio, TX

Republic Pharmaceuticals LLC
Ann Arbor, MI

Spectrum Pharmacy Products, Spectrum Chemicals and Laboratory Products, Spectrum Bulk Chemicals, Spectrum Chemical Mfg Corp, Spectrum
Gardena, CA

Sharing Compounding Data, Regulators Strive to Increase Patient Safety

Pharmaceutical compounding has long posed challenges to those tasked with protecting the public health. While compounded drugs fill a crucial role, helping patients whose clinical needs cannot be met through commercial products already approved by Food and Drug Administration (FDA), these substances require the consideration of applicable standards. A concern voiced by some regulators is that compounded products have not undergone FDA's formal approval process for safety, effectiveness, and quality. Others maintain that knowledgeable compounding pharmacists provide products that are not available to patients and are critical to their care. In recent decades, increases in outsourced sterile compounding and compounded medications shipped between states have complicated oversight efforts and have made that oversight more urgent.

> **"In recent decades, increases in outsourced sterile compounding and compounded medications shipped between states have complicated oversight efforts and have made that oversight more urgent."**

The regulatory landscape of drug compounding has changed markedly from the jurisdictional and regulatory confusion that formed the backdrop of the 2012 deadly fungal meningitis outbreak stemming from one compounding pharmacy's contaminated injectables. Since that time, the 2013 Drug Quality and Security Act (DQSA) placed non-patient-specific compounding, in the form of outsourcing facilities, under FDA oversight, while the states regulate patient-specific compounding. In the slow-moving world of legislative deliberation and regulatory rule-making, change has been comparatively rapid. FDA has issued guidance and final rules on numerous aspects of compounding; state legislatures and regulatory boards, including boards of pharmacy, have rewritten laws and regulations to incorporate best practices and accommodate federal changes; NABP developed programs to help the boards of pharmacy fulfill their oversight responsibilities despite limited resources. Nonetheless, the work to provide adequate safeguards in this area is far from complete.

Closing Loopholes

Since the DQSA's passage, FDA has issued numerous draft and final policy documents to implement the law. Initially, these largely dealt with the establishment of outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). These facilities were defined as entities engaged in non-patient-specific sterile compounding and the guidance stipulated that they follow current Good Manufacturing Practice requirements, report adverse events to FDA, and undergo FDA inspections on a risk-based

schedule, among other requirements. By 2016, FDA was providing final guidance on patient-specific pharmacy compounding under section 503A of the FD&C Act, reiterating the states' responsibilities to oversee and regulate compounding, and including such requirements as the need for the drug to be compounded based on a valid prescription order, in compliance with United States Pharmacopeia (USP) Chapters <795> and <797>, and using approved bulk drug substances. Since then, FDA has continued to offer interim and final notices, guidance, and rules as it works to fully implement the DQSA and offer policy clarifications intended to reduce public health risks related to compounding.

Federal policies as spelled out in FDA's documents have been crucial to the DQSA's implementation, but the development process has at times met with criticism and controversy from different sides. The creation of bulk drug substances lists has been a case in point. For 503B outsourcing facilities, active pharmaceutical ingredients that can be used in compounding are limited to either those substances used to compound drugs that are in shortage, or those substances that have been deemed clinically necessary and appear on an FDA-developed 503B bulks list. Section 503A, meanwhile, requires that the active ingredients used for pharmacy compounding must either comply with the standards of an applicable USP or National Formulary monograph, or, if no monograph exists, be a component of an FDA-approved drug; or, if the substance does not satisfy either of these requirements, it must appear on a 503A bulks list of drug substances evaluated and approved by FDA. Creating these lists has generated pushback from patient safety advocates who wished for more stringent regulation during their development, and also from stakeholders who wanted more lenient evaluation criteria for included substances. Some critics argued that the interim policy had loopholes that, in some cases, could allow compounders to use bulk drug substances that might eventually be deemed unacceptable for that purpose, creating a safety hazard and risking patient harm. They also worried that these loopholes could, in other cases, allow compounders to produce medications already available on the market, but without the regulatory safeguards provided by an FDA-approved product. A different set of critics, however, has taken issue with the restricted number of substances FDA included on the lists and has criticized FDA's evaluation criteria and process for considering substances for inclusion. For example, some have taken issue with FDA's approach and methodology, and have argued that the amount of clinical evidence and usage data required for substance nominations is "unreasonable and burdensome." In the first court case of its kind since the DQSA's passage, however, FDA's evaluation process received a boost last August, when a US District Court judge issued a decision upholding FDA's interpretation of "clinical need" for bulk substances approved for use by 503B outsourcing facilities; the case had been brought following FDA's decision to exclude vasopressin from the 503B bulks list.

Beyond issuing guidance to implement the DQSA, FDA also has been carrying out its role of enforcing compliance with federal regulations. Spurred by the discovery during a 2018 outsourcing facility inspection of more than 4,200 unreported adverse events over a five-year period, FDA has been working to increase compounding safety by such measures as seeking to improve adverse event reporting and helping improve information sharing between states. In a September 2019 statement, FDA Center for Drug Evaluation and Research Director Janet Woodcock, MD, reported that FDA would be taking steps to improve adverse event reporting and would be working with outsourcing facilities to improve mechanisms for obtaining these reports. FDA is also aiming to improve compounding oversight via improved adverse event reporting for 503A compounders as well as outsourcing facilities, by collaborating with the states. Woodcock's September statement reiterated FDA's coordination with state regulators to finalize a standard memorandum of understanding (MOU) under which states would agree to "investigate complaints of adverse events associated with certain compounded drugs from pharmacies operating under section 503A and report serious adverse events and serious product quality issues to the agency." At press time, FDA expected to finalize this MOU toward the end of 2019.

Last October, FDA took an additional step to collaborate with state regulators to improve 503A compounding pharmacy oversight: The agency awarded grant funding to NABP to create a data system that would enable the collection, management, and sharing of interstate compounding pharmacy information. Leveraging NABP's expertise in developing and maintaining interjurisdictional data sharing, the new data system will give the boards of pharmacy a tool with which to report interstate compounding pharmacy information, including significant compliance issues. This information should better enable the boards to make informed oversight determinations and prioritize resources, allowing them to identify and focus on higher-risk compounding pharmacies.

State Boards' Progress

Just as the federal government has substantially increased compounding oversight over outsourcing facilities in the past few years, the state boards of pharmacy have strengthened oversight of 503A compounding pharmacies. The Pew Charitable Trusts published reports in 2015 and 2018 on state oversight of compounding, and found that just within that period of time, the states had made "significant progress" on the issue. By 2018, for example, Pew found that more than 80% of the state boards of pharmacy were holding compounders to strict quality

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Sharing Compounding Data

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standards: 32 boards were requiring sterile compounders to adhere to the quality standards of USP Chapter <797>, with an additional 10 boards reporting having standards "equivalent to or stricter than" the Chapter <797> standards, and four more with pending legislation to bring their requirements in line with Chapter <797>. In 2015, albeit using slightly different research methodology, only 26 states had reported mandating that compounding pharmacies adhere to USP Chapter <797> or equivalent quality standards.

The Pew report found that states likewise had made significant progress on aligning state law with federal law: prohibiting pharmacies from compounding drugs in the absence of a prescription, and recognizing and defining outsourcing facilities. By 2018, 40 boards of pharmacy prohibited traditional pharmacies from doing sterile compounding without a prescription (for example, for office stock); and while an additional 11 boards allowed some compounding for office stock, the laws placed limitations upon the practice. By comparison, in 2015, nearly two-thirds of responding boards indicated that they allowed non-patient-specific compounding to occur to at least some extent. Most states have likewise followed FDA

> "... while a more rigorous inspection schedule might be desirable from an oversight perspective, boards of pharmacy face a number of challenges in execution ..."

recommendations to license 503B compounding facilities; the most common method for doing so is to license or register them in their own category as outsourcing facilities, although approaches differ, such as licensing them as manufacturers or wholesalers.

Annual state inspections of compounders was the one area that had not progressed since 2015. In 2018, Pew found that 23 boards of pharmacy were inspecting in-state 503A sterile compounding pharmacies at least annually, down from 26 in 2015. Health safety advocates have emphasized the importance of inspections both to ensure that safety regulations are being adhered to, and to confirm that compounders claiming to qualify for 503A exemptions are in fact conducting their compounding within the 503A restrictions and do not need to register as an outsourcing facility instead. But while a more rigorous inspection schedule might be desirable from an oversight perspective, boards of pharmacy face a number of challenges in execution; indeed, the Pew report noted various challenges, including scarce resources and, in regard to out-of-state compounders, lack of harmonization in inspection forms and procedures among states.

While acknowledging these real-world impediments to more comprehensive oversight, the Pew report recognized as an interim solution NABP's numerous programs to help the boards of pharmacy maximize their resources and best protect the public health. The Verified Pharmacy Program®, for example, provides the boards with a participating pharmacy's verified data and a uniform inspection, giving the boards the background needed to make informed licensing decisions on nonresident pharmacies seeking licensure in their states. Compounding pharmacies often become verified to demonstrate their compliance with USP standards. Another tool is NABP's Multistate Pharmacy Inspection Blueprint Program, in which participating states agree to a set of requirements for conducting inspections in their state. The blueprint – which is regularly updated – provides a minimum set of inspection criteria so states can tell when an inspection that has taken place in a fellow Blueprint state meets their requirements, eliminating the need for duplicate inspections without sacrificing safety. Currently, nearly 20 states have signed on to participate in the program. Finally, NABP also offers training programs to assist the boards to develop and maintain high-quality inspection programs.

Throughout the evolving landscape, NABP will continue to support the boards of pharmacy as they carry out their duties protecting the public health. ■

Online Registration Available Soon on the Annual Meeting Website

Join your regulatory colleagues at the 116th NABP Annual Meeting for important Association business sessions, education, and networking opportunities. Specifically, the Annual Meeting allocates time for board delegates to elect new Executive Committee officers and members, discuss proposed amendments to the NABP Constitution and Bylaws, and vote on proposed Association resolutions. In addition, ample sessions and events provide attendees the opportunity to participate in continuing pharmacy education activities and to network with peers. Online registration will be available at *www.NABPAnnualMeeting.pharmacy.*

Travel Grant Available to Active Member Boards of Pharmacy

The NABP Foundation® is once again offering active member state boards of pharmacy travel grant opportunities to attend the 116th NABP Annual Meeting. One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board's administrative officer, and will provide reimbursement for travel expenses, including travel, hotel rooms, meals, taxis, parking, and tips.

Eligible individuals can receive up to $1,500 in grant monies to attend. The grant does not include registration fees. All applicants will be informed of whether they have qualified for the grant.

The grant was established to assist boards in sending voting delegates to the Annual Meeting, so they may participate in important business, including discussing and voting upon resolutions and amendments to the NABP Constitution and Bylaws, electing NABP Executive Committee officers and members, and attending educational sessions regarding current issues facing pharmacy regulators.

Last year, 40 state boards of pharmacy applied and were approved for the 115th NABP Annual Meeting Travel Grant. For more information on the Annual Meeting Travel Grant, contact the NABP Executive Office at ExecOffice@nabp.pharmacy.

How to Apply for the Travel Grant

- Executive officers of the state boards of pharmacy may request grant applications directly from NABP and submit completed applications by email to ExecOffice@nabp.pharmacy or via mail to NABP Headquarters.
- Applications should be submitted prior to the Annual Meeting.
- To receive reimbursement, boards must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions.

Explore the Birthplace of the National Anthem During the 116th NABP Annual Meeting in Baltimore

Photo courtesy of Visit Baltimore

NABP invites its members and other pharmacy stakeholders to "Charm City" for the Association's 116th Annual Meeting in Baltimore, MD. Attendees will have the opportunity to explore unique sights and experience the multicultural history of Baltimore after participating in important business and continuing pharmacy education sessions. Themed "When Members Unite, Ideas Ignite," the Annual Meeting will be held May 14-16, 2020, at the Renaissance Baltimore Harborplace Hotel.

Photo courtesy of Visit Baltimore

The Charm City

The city of Baltimore was established in 1729 and is located in the Inner Harbor area, which connects the city to the Chesapeake Bay. The city's Inner Harbor was once the second leading port of entry for immigrants to the United States and is the second-largest seaport in the Mid-Atlantic. The city was named for the Irish Barony of Baltimore, which is an anglicization of the Irish name Baile an Tí Mhóir, meaning "town of the big house." It was created as a port for shipping grain and tobacco, and soon after, local waterways were being harnessed for flour milling.

In the mid to late 1700s, Baltimore's population grew exponentially, nearly quadrupling in size by 1800. As the city developed from a small town to a small city, Baltimore made a major historical mark, playing a crucial role in the War of 1812, when soldiers stationed at Fort McHenry successfully defeated the British. As the battle at Fort McHenry raged on, an American lawyer, Francis Scott Key, found himself detained on a British ship within sight of the fort. His view of the American flag as it soared high above the fort inspired Key to write "The Star-Spangled Banner," the poem that later became the lyrics to the National Anthem.

The name "Charm City" dates back to 1975. The name grew from the city's lead advertising executives and creative directors who had been tasked – by then Mayor William Donald Schaefer – to find a way to promote the city. Full-page advertisements ran in the *Baltimore Sun* and the *Evening Sun* featuring Baltimore's unique charms: steamed crabs, Mount Vernon, museums, Babe Ruth, and the city's neighborhood streets.

Historically, Baltimore was known as a working-class port town whose main focus was steel processing, shipping, auto manufacturing and transportation. Now, Baltimore's modern service economy is led by high-tech, biotech, and medicine, and attracts over 26.2 million visitors each year.

Local Sights and Cultural Attractions

Baltimore has a diverse range of activities and attractions for visitors of all interests, from history buffs to sports enthusiasts. The Inner Harbor is one of the biggest tourist stops where you can find distinctive restaurants, bars, shops, and businesses throughout the harbor.

Not only is Baltimore known for its historic sites and quaint neighborhoods, Baltimore's restaurants are well known for crab. However, Chesapeake Bay cuisine offers an assortment of international and ethnic cuisine, catering to all taste buds.

Other key attractions of the city include the USS Constellation, the last sail-only warship designed and built by the US Navy in 1854; and the home of one of the greatest baseball players in history – George Herman "Babe" Ruth, Jr – just a few blocks from the Inner Harbor. The Top of the World Observation Level, located on the 27th floor of the Baltimore World Trade Center, offers breathtaking views of Maryland's urban center. This is the world's tallest pentagonal building.

Located on the plaza between Pratt Street and the Baltimore World Trade Center, lays a 22-foot-long steel beam artifact from the Twin Towers in New York. The steel beams represent the heroism, commitment, and sacrifice of the September 11, 2001 victims, rescuers, first responders, and their families. The memorial also has limestone artifacts from the Pentagon and a large, black granite monolith, representing those lost in the Shanksville, PA, Flight 93 crash.

Located in the Inner Harbor are the National Aquarium and the Maryland Science Center. The aquarium holds more than 16,000 creatures, and the science center features three floors of interactive and educational exhibits. For sports enthusiasts, Oriole Park at Camden Yards, built in 1992, led the trend as the first of the downtown retro ballparks. Visitors can experience the stadium tour all year. History buffs will enjoy the unique museums and rich history Baltimore has to offer such as the historic Fort McHenry National Monument and Historic Shrine, the house of Edgar Allan Poe, and the renowned Johns Hopkins Hospital and University.

Getting Around

The Renaissance Baltimore Harborplace Hotel is located downtown within steps of the city's famed Inner Harbor. It is eight miles from the Baltimore/ Washington International Thurgood Marshall Airport and is one and a half miles from Penn Station.

Individuals arriving from the airport may take the SuperShuttle for a cost of $17 per person one way; reservations are required. Fare for the SuperShuttle can be purchased at *www.supershuttle.com* or on the SuperShuttle app. Taxis can also be arranged from the lower level of the airport terminal near doors 5 and 13 and are estimated to cost $30 one way. Guests choosing to rent a vehicle can select from 10 rental agencies located 10 minutes from the airport and accessible via courtesy shuttles from the lower level of the terminal.

The Renaissance Baltimore Harborplace Hotel offers valet parking and on-site parking options. Valet parking at the hotel costs $46 per day, and on-site parking costs $36 per day.

Much of Baltimore can be accessed on foot, but the city also has several alternatives for transportation. A water taxi is a great way to get around to see the sights on the water. Adult one-way tickets are $9 and an all-day adult ticket is $16. Visit the Baltimore Water Taxi website at *www.thewatertaxi.com* for schedules and route maps. The Maryland Transit Administration (MTA) offers many easy and affordable ways to get around. Basic fares for the local bus and light rail are $1.90 one way; $2.50 for the express bus one way; and $4.40 for a day pass. For your convenience, you can purchase a CharmCard for $10, which is a rechargeable public transportation ticket that makes it easy to add extra fares at all MTA ticket vending machines. The Charm City Circulator, complimentary buses that run every 10-15 minutes, offers service to top city attractions. Learn more about the Charm City Circulator routes and times at *www.charmcitycirculator.com.*

More details will soon be available on the 116th Annual Meeting website at *www.NABPAnnualMeeting.pharmacy.*

Explore Baltimore

- **Visit Baltimore**
  https://baltimore.org
- **Top of the World Observation Level**
  www.viewbaltimore.org/about
- **Oriole Park at Camden Yards**
  https://mlb.com/orioles/ballpark
- **Fort McHenry National Monument and Historic Shrine**
  www.nps.gov/fomc/index.htm
- **Baltimore Museum of Art**
  www.artbma.org
- **Historic Ships of Baltimore**
  www.historicships.org
- **Babe Ruth Museum**
  www.baberuthmuseum.org
- **Edgar Allan Poe House**
  www.poeinbaltimore.org
- **9/11 Memorial of Maryland**
  www.msac.org/911-memorial-maryland

NABP Announces 2020-2021 Executive Committee Openings; Elections to Take Place at Annual Meeting

NABP has received the following nominations for the open Executive Committee officer and member positions:

President-elect (one-year term)

- Caroline D. Juran, RPh, DPh, Virginia

Treasurer (one-year term)

- Reginald B. "Reggie" Dilliard, DPh, Tennessee

District 3 (three-year term)

- Jeffrey J. Mesaros, PharmD, JD, RPh, Florida

District 4 (three-year term)

- Lemrey "Al" Carter, MS, PharmD, RPh, Illinois

District 8 (three-year term)

- Kamlesh "Kam" Gandhi, PharmD, RPh, Arizona
- J. David "Dave" Wuest, RPh, Nevada

Updates to the list of nominations will be posted in the About section of the NABP website at www.nabp.pharmacy.

Individuals interested in running for an open officer or member position must submit a letter of intent, including the expiration date for their term on the active member board, and a résumé or curriculum vitae to the NABP executive director/secretary at least 45 days prior (by March 30, 2020) to the Annual Meeting's First Business Session. ■

Executive Committee Nomination and Election Process

NABP/AACP District Meetings

Members are nominated by the district to run for the open Executive Committee member positions for their district.*

Annual Meeting

First Business Session
Candidates for open Executive Committee member and officer positions introduced.

Second Business Session
Candidate and seconding speeches are presented.

Final Business Session
Board of pharmacy delegates vote for new Executive Committee members and officers on behalf of their board. Newly elected officers and members are installed during the Final Business Session.

** Individuals may submit their nomination outside the district process for the open member positions. Only those individuals who have been determined by NABP to meet all qualifications for the open member positions will be placed on the ballot. More information can be found in the NABP Constitution and Bylaws on the NABP website.*

Candidate Qualifications

- must be an affiliated member (administrative officer or board member) of the Association currently serving on a board of pharmacy of an active member state at the time of nomination and election
- must not currently serve as an officer, official, or board or staff member for any national or state pharmacy organization
- must not have a conflict of interest with the purpose, mission statement, and operation of NABP

More information about the procedures for nominating and electing Executive Committee officers and members is available in Article IV, Sections 3(b) and 3(c) of the NABP Constitution and Bylaws. ■

Proposed Resolutions to Be Distributed in February 2020

Important Deadlines

- **February 7, 2020** – Proposed resolutions must be received at NABP Headquarters for preconference distribution to the state boards of pharmacy.
- **February 13, 2020** – Proposed resolutions are distributed electronically to state boards of pharmacy for review.
- **April 24, 2020** – Proposed resolutions must be submitted to be considered at the Annual Meeting.

Any active member board, district, or committee of the Association may submit resolutions to NABP. Questions regarding resolution procedures should be directed to the NABP Executive Office via email at ExecOffice@nabp.pharmacy. ■

> **"Resolutions not submitted at least 20 days prior to the Annual Meeting, but submitted within a time frame that the Executive Committee deems appropriate (prior to the meeting of the Committee on Resolutions), may be presented during the Annual Meeting and will be considered for adoption by the Association upon the affirmative vote of three-fourths (3/4) of those active member boards present and constituting a quorum."**
>
> **— Article IV, Section 6, Part (d)**
> **NABP Constitution and Bylaws**

Now Accepting Proposals for Educational Poster Session

Limited Spots Available; Proposals Due by February 26

NABP is seeking proposals for its annual Educational Poster Session. Proposed posters should reflect the overall theme of "Uniting to Protect the Public Health." Board of pharmacy members and staff, as well as schools and colleges of pharmacy, are invited to submit their proposals as they relate to this year's poster session theme. Poster proposals may be descriptive, scientific, or informational in nature. Possible topics include policy development, public health initiatives, and legislative issues, among others.

Proposals may only be submitted by individuals who will be available to present the poster in Baltimore, MD, if selected. Selected poster presenters must be available in March and April for correspondence with NABP staff and to submit required materials.

Students are welcome to submit poster proposals. If selected, the student(s) must be accompanied by a credentialed advisor or licensed pharmacist. All participating pharmacy school students will receive a complimentary voucher in their NABP e-Profile valued at $65 to take the Pre-NAPLEX®, a practice examination for students preparing for the North American Pharmacist Licensure Examination®.

The Poster Session will be held the morning of **Friday, May 15, 2020,** at the 116th NABP Annual Meeting.

Poster Session presenters may be eligible to earn Accreditation Council for Pharmacy Education-accredited continuing pharmacy education credit. Details will be provided to individuals who are selected to present posters. Those selected to present a poster will receive a complimentary meeting registration.

Those interested in submitting a proposal should contact NABP Professional Affairs staff via email at Prof-Affairs@nabp.pharmacy for detailed instructions. Proposals must be submitted by **Wednesday, February 26, 2020.** ■

Jordan L. Wulz, PharmD, MPH, BC-ADM, Concordia University Wisconsin School of Pharmacy, was a participant in the 2019 NABP Educational Poster Session.

Christina Lindsay, PharmD, RPh, Member, Missouri Board of Pharmacy

Christina Lindsay, PharmD, RPh

Member, Missouri Board of Pharmacy

When were you appointed to the Board of Pharmacy? Are you a pharmacist, pharmacy technician, public member, or other type of member?

I was appointed to the Board in December 2014. I am a pharmacist.

In your opinion, what steps should a board member take to be successful in their role?

First, if there is a practice setting that a board member feels he or she wants to further educate himself or herself on, then he or she may want to partner with licensees or board members who are subject matter experts in that practice and really immerse himself or herself in the issues, so he or she can be a contributing member when discussing those topics at board meetings. Second, a board member may want to become involved in the different meetings that come up for board members to understand what other states are doing, how they are being challenged, and how they are handling the different concerns that are coming in front of their board.

What are some recent policies, legislation, or regulations your Board has implemented or is currently working on?

One thing that the Board is working on is defining "direct supervision." A lot of the Board's language states that a pharmacist should have "direct supervision" over pharmacy technicians. What does that mean? How do we define that? Direct supervision could be interpreted to mean one-on-one, where the pharmacist is physically present, or it could mean that technology is allowing the pharmacist to be present remotely. Until we define direct supervision, we are not able to insert technology into the practice of pharmacy in our state. We want to make sure that the Board feels comfortable with that definition before pursuing the insertion of technology into the practice.

The other thing the Board is working on is the incorporation of standards-based practice language. We have approached that by building a road map. That road map starts with defining direct supervision and analyzing the various types and utilization of technology, so we can further allow some of these advances within the practice, and then building the framework that allows us to move forward. With the standards-based practice approach, we have to ensure that the language we are writing incorporates what is going on in the practice today as well as where the future of the profession is going to ensure that the Board remains agile to the practice.

Has the Board encountered any challenges to developing and/or implementing these new policies, legislation, or regulations? If so, explain.

I feel the biggest challenge the Board faces is getting all the stakeholders to understand the needs of the other sectors within the practice. The needs of community pharmacies are different from those of hospital pharmacies, ambulatory care or nuclear pharmacies. Each wants something different, but it might oppose the practice or thoughts of another group. How do we get them to understand that each has their own set of challenges, and how do we find a solution that would work for all?

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Missouri Board of Pharmacy

Number of Board Members: 6 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors: 9

Rules and Regulations Established by: Board of Pharmacy

Number of Pharmacist Licensees: 10,770

Number of Pharmacies: 2,728

Number of Wholesale Distributors: 1,541

Around the Association

Executive Officer Changes

- **Zennia Cruz Pecina, MSN, RN,** has been named executive officer of the Guam Board of Examiners for Pharmacy, succeeding Marlene Carbullido, MSN, RN. Pecina is also executive officer for the Guam Board of Nurse Examiners, Guam Board of Medical Examiners, and four other boards.
- **Lauren Lyles-Stolz, PharmD,** has been named executive director of the Washington State Pharmacy Quality Assurance Commission. Most recently, Lyles-Stolz served as a German Chancellor Fellow with Siemens Healthineers AG in Berlin, Germany, researching population health management, primarily in Germany and the United States. After receiving a doctor of pharmacy degree from the University of Mississippi School of Pharmacy, Lyles-Stolz completed her postdoctoral fellowship at Eli Lilly and Company, while also working as a part-time pharmacist at a mail-order pharmacy. After completing the fellowship, she served as manager of pharmacy affairs at the Academy of Managed Care Pharmacy.

Board Member Appointments

- **Brian Jolly, PharmD, RPh,** has been appointed to the Arkansas State Board of Pharmacy. Jolly's appointment will expire June 30, 2025.
- **Michael E. Brinson, PharmD, RPh,** has been appointed to the Georgia State Board of Pharmacy. Brinson's appointment will expire June 30, 2023.
- **Karl Peicker, RPh,** has been appointed to the New Hampshire Board of Pharmacy. Peicker's appointment will expire October 21, 2024.
- **William T. Lee, RPh, MPA, FASCP,** has been appointed to the Virginia Board of Pharmacy. Lee's appointment will expire June 30, 2023. ■

Interview With a Board Member

continued from page 16

What advice would you give to a new board member?

Keep your focus at the forefront of your mind. The purpose of you being on the Board is to protect the public health. As things come before the Board, ask yourself if what the Board is addressing will ensure that the public health is being protected. If it is, then move forward with it. If not, then re-examine whether it is something that should be on your table at that time. Also, make sure that you learn how a rule is made from A to Z. What is the difference between a statute and a rule? Who are the different stakeholders that need to be involved for you to be able to change a rule or a statute? And if you suggest a rule change, how does it impact others? Make sure that you are aware of these things as you work through the legislative process.

Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings? If so, in your experience, what are the benefits of participating in these NABP activities?

I have attended several NABP district meetings and Annual Meetings. When I can, I make those a priority. A lot of states are dealing with the same issues and challenges, but each state is tackling them a little differently. To be able to hear their success stories and learn from things that did not go the way they planned is great information to take back to the Board, and to consider and keep in mind while working through some of those same challenges. ■

NABP Seeks Committee and Task Force Volunteers

NABP is seeking volunteers from its active member boards of pharmacy to serve on committees and task forces during the 2020-2021 period. Executive officers and current board members, including public members, interested in serving on a committee or task force are encouraged to submit an application and an up-to-date résumé or curriculum vitae. Board of pharmacy staff interested in volunteering for NABP task forces are also encouraged to apply.

Please apply on the NABP website by **Friday, June 5, 2020.** The online form is available in the Member Services section of the NABP website under NABP and Boards of Pharmacy.

All materials will be forwarded to NABP President-elect Timothy D. Fensky, RPh, DPh, FACA, who will make the appointments following NABP's 116th Annual Meeting. ■

Arizona Implements Universal Recognition Policy for Licensure

The Arizona State Board of Pharmacy is now accepting applications for licensure via a universal recognition policy. The universal recognition policy allows Arizona residents to use an out-of-state professional or occupational license to qualify for an Arizona license to work. To qualify, an applicant must:

- prove residency in Arizona;
- be currently licensed or certified for at least one year in another state in the United States discipline applied for and at the same level of practice as recognized in Arizona;
- be in good standing in all states where currently or previously licensed or certified;
- meet all applicable education, work, exam, and/or clinical supervision requirements in the other state where originally licensed or certified;
- complete a criminal background check when required by law;
- take and pass any applicable exam on Arizona state law; and
- pay all applicable fees to the Board.

Arizona Passes Senate Bill to Deregulate Nonprescription Retailers

During Arizona's 2019 legislative session, Senate Bill 1170 was passed to deregulate nonprescription retailers. As of August 27, 2019, a nonprescription retailer permit is no longer required to sell over-the-counter drugs and devices to customers.

Minnesota Sets Conditions for CBD Sales

Effective January 1, 2020, certain products containing cannabidiol (CBD) derived from hemp can be legally sold under Minnesota state law only if conditions are met. A list of required conditions is available in the Minnesota Board of Pharmacy's October 2019 *Newsletter*.

Beginning January 1, 2020, all products containing CBD derived from hemp (other than a food product) that does not meet the new requirements will be considered an illegal misbranded and/or adulterated drug.

The area within a business that is licensed by the Board as a pharmacy cannot stock or sell a product containing CBD derived from hemp unless the product meets the required conditions outlined in the Minnesota Board of Pharmacy newsletter. More details are outlined in the Minnesota Board of Pharmacy's October 2019 *Newsletter*.

North Carolina Allows Donation of More Prescription Drugs and Devices

An amendment to North Carolina General Statute 90-85.44, which governs the donation of drugs and devices in North Carolina, was signed into law. As amended, the statute makes a drug eligible for donation if, among other things, the drug has not reached its expiration date at the time of donation. More information is available in a North Carolina Board of Pharmacy's frequently asked questions document at *www.ncbop.org/faqs/Pharmacist/faq_DonatingRXs.htm*.

North Carolina Board Partners With More Powerful NC to Fight Opioid Misuse

The North Carolina Board of Pharmacy and More Powerful NC, a public-private partnership formed to fight the opioid epidemic, have partnered to confront prescription opioid misuse. The Board provided two resources for pharmacists and pharmacies in support of the More Powerful NC campaign.

First, the Board has printed prescription vial auxiliary labels that pharmacists are encouraged to place on pain medication prescriptions. These labels encourage patients to protect children by disposing of medications safely and include the *MorePowerfulNC.org* URL. Labels are available to pharmacies at no cost, while supplies last.

Second, one-sheet "bag stuffer" handouts in several sizes and formats that provide information to pharmacists and patients on the resources available at *MorePowerfulNC.org* are available. The file is also available for any pharmacist, pharmacy, or member of the public to download at *www.ncbop.org/PDF/MorePowerfulNCOpioidBagStufferJuly2019.pdf*.

Newsletters of state boards that participate in the NABP State Newsletter Program are available on the NABP website. Five years' worth of issues are posted on each participating state's page.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulations would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring that the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal also introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repacking and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorneys general and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulation and instructions for providing public comment are available in the October 23, 2019 *Federal Register* announcement.

HHS Guide on Tapering or Discontinuation of Long-Term Opioid Use Now Available

The Department of Health and Human Services (HHS) has published a new guide for clinicians covering important issues to consider when changing a patient's chronic pain therapy. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health, in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA's Safe Use Initiative Director Advises Research to Improve Provider Outcomes

To help health care providers protect patient health, Scott Winiecki, MD, director of Food and Drug Administration's (FDA's) Safe Use Initiative, part of the agency's Center for Drug Evaluation and Research (CDER), recommends using FDA-funded research to better understand which patients are at risk for serious side effects and other harm that can result from use of certain medications. This advice was shared in a recent article, "Safe Use of Medicine Relies on Strong Research," published on the CDER Conversations section of the FDA website. The article provides an overview of FDA's Safe Use Initiative, which seeks to facilitate collaboration in the health care community to reduce preventable harm. The article discusses the kinds of research that can be helpful, who conducts it, and examples of the types of related research FDA funds. Winiecki also shares where individuals and organizations can get more information about applying for FDA funding for their own research. ■

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UPCOMING EVENTS

Committee on Law Enforcement/ Legislation
January 14-15, 2020
NABP Headquarters

NABP Interactive Member Forum
January 28-29, 2020
NABP Headquarters

FPGEE Administration
April 2, 2020

Committee on Constitution and Bylaws
April 6, 2020
Teleconference

116th NABP Annual Meeting
May 14-16, 2020
Baltimore, MD

NEVER MISS A MINUTE. FOLLOW US ON SOCIAL.