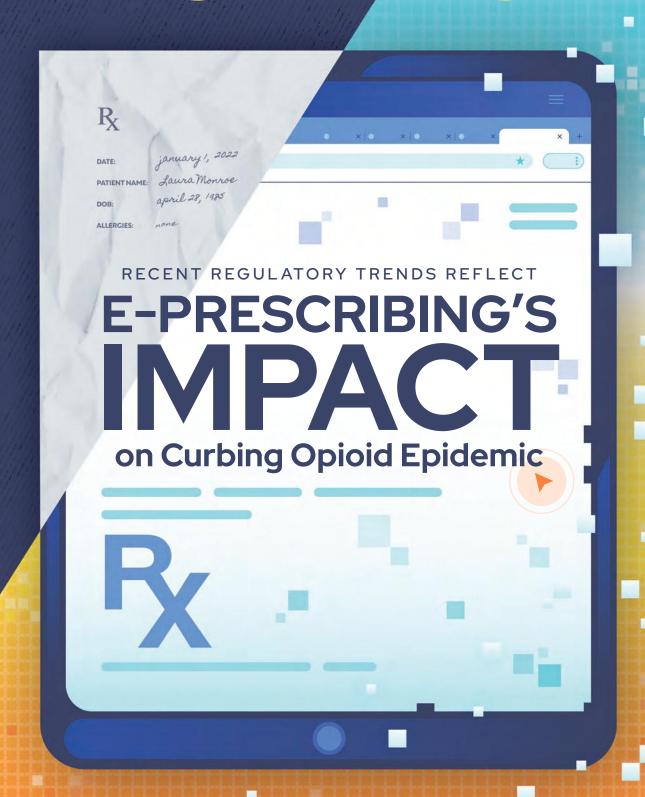
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INNOVATIONS

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NABP Mission Statement

NABP is the independent, international, and impartial Association that assists its member boards in protecting the public health.



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NABP Executive Committee elections are held each year at the Association's Annual Meeting.



Timothy D. Fensky, RPh, DPh, FACA NABP Chairperson

Fellow Members,

Happy New Year! Like many people, I have been using the transition into 2022 as an excuse to reflect on the successes of the previous year and to identify areas of improvement. This helps me set goals for the coming year. This is also true for NABP. We are now closing in on two years since the start of the COVID-19 pandemic. Much has changed since the virus arrived in the United States, but our focus on helping the boards of pharmacy protect public health continues. This has been reflected both in responses to the direct challenges created by COVID-19, as well as renewed efforts in other arenas, many of which were already on our radar long before the pandemic began.

Of course, one of these other arenas is the ongoing opioid crisis. As detailed in the October 2021 issue of Innovations, 2020 saw a new record number of opioid overdose fatalities - nearly a 30% increase from the previous year. While this increase has largely been attributed to complications created by the pandemic, as well as a continued increase in the availability of illegally manufactured synthetic opioids, prescription opioids continue to be one avenue through which many patients develop opioid use disorder (OUD). As has been widely reported elsewhere, many of these patients turn to the black market for illicit opioids when they can no longer get prescription opioids.

While there are limitations to what we can do to prevent this, one thing that we have been able to improve are practices related to the prescribing and dispensing of prescription opioids. By preventing overprescribing, we might be able to reduce the number of people who develop OUD. The data are still out as to whether these efforts make a marked difference in overall abuse, misuse, and diversion of opioids. However, we can point to evidence that shows prescription opioid abuse has remained relatively steady, even during the large increase in overall opioid overdoses over the previous year.

And so, it remains important that we take whatever steps we can to address the crisis.

One major example of this is seen in the efforts of the boards of pharmacy to support electronic prescribing practices. Because electronic prescriptions are considered more secure and easier to track than paper prescriptions, many states now require e-prescribing for at least some controlled substances. At the national level, recent changes to Medicare requirements have also made e-prescribing a requirement for certain types of medications. The cover story for this issue explores the differences among state requirements and what impact they have had so far in improving public health.

This issue also provides an update on the Food and Drug Administration (FDA) memorandum of understanding (MOU) with participating states. This important project focuses on a different area of public health that is also of great importance to the boards of pharmacy - ensuring the safety of compounded medications. There have been several misconceptions about the data sharing project, and my hope is that this article will clarify how the MOU can help boards address patient safety and improve communication between FDA and the boards of pharmacy.

As 2022 begins, I encourage each board and individual member to take advantage of the transition as a time to reflect and set goals. Our profession is always evolving, and it is important that we take the time to think about what we can do to make sure that those changes have the best outcomes in protecting the public health.

Sincerely,

Timothy D. Fensky, RPh, DPh, FACA **NABP** Chairperson

Reverse Distribution: Serving Public Health Under Range of State Rules



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Reverse distribution is an important and often overlooked component of the supply chain system. Reverse distributors are often involved in the disposition or processing of salable or nonsalable products received from an authorized trading partner. These products are then processed for credit or otherwise disposed of and removed from distribution channels. The handling and removal of pharmaceutical products is a substantial public health matter and worth examining from a regulatory

While some states specifically define reverse distributors and what constitutes reverse distribution, many other states either include reverse distributors under the umbrella of wholesale distributors or simply do not address reverse distributors in the statute or regulations. Where there are regulations, they are often vague or inconclusive and require outreach to regulators at the applicable governing body for clarification. Periodically, these regulators interpret and apply their state regulations differently, leading to inconsistent guidance for reverse distributors.

Reverse Distribution Process and Regulatory Common Ground

Oftentimes, a reverse distributor receives unwanted, unusable, or outdated pharmaceuticals from a pharmacy or other facility that ships the product(s) directly to the reverse distributor. In other cases, the reverse distributor will pick up and transport, or arrange for the pickup and transport, of the unwanted pharmaceutical products from the customer. In these situations, the reverse distributor will either physically transport the pharmaceutical products itself or ship the products to its destruction facility via the United States Postal Service (USPS) or a common carrier. During this process, the reverse distributor typically takes title and possession of the pharmaceutical products when the products are picked up from the customer. Even if the reverse distributor

uses USPS or a common carrier to ship the product to its destruction facility, the reverse distributor will generally maintain title to such products even though possession has been transferred to the shipping agent. This practice is important because state licensure requirements often, but not always, depend on where in the distribution chain a reverse distributor takes title and/or possession of the pharmaceutical product.

Generally speaking, if an out-of-state reverse distributor picks up a pharmaceutical product from a customer (and thus takes title and possession of the pharmaceutical product) to transport the product to its destruction facility, most states have determined that a nonresident license in that nonresident state is required. However, if the customer (eg, a retail pharmacy), rather than the reverse distributor, ships or transports the pharmaceutical product to the reverse distributor's destruction facility and the reverse distributor does not actually take possession of the product, then the reverse distributor will generally not be required to hold a nonresident license in the customer's state.

If reverse distribution services are interrupted, this can lead to major disruption for retail and hospital pharmacy customers who must remove the pharmaceutical product from their premises. Given the diversion risks when handling waste that involves controlled substances (CS) and public health concerns when handling pharmaceutial waste, it is important that pharmacies utilize specialized, credible reverse distribution vendors to remove and dispose of the waste in a timely and compliant manner.

Reverse Distributor Regulations Vary Among States

For the vast majority of states, reverse distributors are regulated by the state board of pharmacy. In a handful of states, however, regulatory agencies other than the state board of pharmacy exercise regulatory authority over reverse distributors. For example, reverse distributors are overseen by the Department of Health in the District of Columbia and Washington State; by the Department of Consumer Protection in Connecticut; by the Department of State in Delaware; by the Board of Drug and Device Distributors in Louisiana; by the Department of Agriculture & Consumer Services in North Carolina; and by the Department of State Health Services in Texas.

The Landscape of State **Licensing Requirements**

A significant concern of regulators and reverse distributors is the ambiguity surrounding whether a reverse distributor is required to be licensed in a particular state. Not all states license reverse distributors. For example, the Alaska Board of Pharmacy does not require a reverse distributor to hold a license in Alaska so long as the reverse distributor does not resell the collected product. This appears to apply to both resident and nonresident reverse distributors.

Other states have taken a narrower approach and do not require reverse distributors to hold a nonresident license in certain circumstances. For instance, Idaho and Hawaii have indicated that they do not require nonresident reverse distributors to hold a license to conduct business in their respective states. Other states have taken a different approach and tie nonresident licensure to other criteria. For example, a reverse distributor not physically located in Pennsylvania, but performing reverse distribution services in Pennsylvania, is only required to hold a nonresident license if either (i) it has sales representatives physically working or operating in Pennsylvania, or (ii) the reverse distributor is shipping or receiving product containing a list I chemical from a facility located in Pennsylvania.

In some states, guidance on reverse distributor licensure may be provided in documents or policy other than the applicable statute and regulations, especially if they are silent regarding reverse distributors. For instance, some state boards of pharmacy have published frequently asked questions or other guidance documents regarding licensure of reverse distributors. While in other states, a board's meeting minutes or wholesale distributor license application may include insights to help determine whether a reverse distributor is required to hold a license in a specific state.

Once it is determined that a reverse distributor should hold a license in a particular state, there are oftentimes additional considerations - one of which is Drug Distributor Accreditation from NABP. Drug Distributor Accreditation indicates whether a particular wholesaler meets certain minimum compliance standards established by NABP. Drug Distributor Accreditation is a requirement for licensure in Indiana, Iowa, North Dakota, and Wyoming.

Adding Complexity: Reverse Distribution of Controlled Substances

If a reverse distributor will be engaging in the reverse distribution of CS, there are additional considerations to keep in mind. In addition to holding the requisite CS registration certificate from Drug Enforcement Administration, the applicable state CS laws must also be reviewed. Some states will issue a separate state-level CS registration (CSR). Other states will simply indicate on the reverse distributor's underlying state license whether such entity is permitted to handle CS.

Another consideration regarding CS is to understand which state agency is responsible for issuing the CSR. For example, the Iowa Board of Pharmacy and Michigan Board of Pharmacy are responsible for issuing both a distributor license and a separate CSR to reverse distributors handling CS in their applicable jurisdiction. However, there are several states that have separate agencies governing CSR licensure requirements. For instance, the South Dakota State Board of Pharmacy is the agency responsible for issuing a distributor permit to a reverse distributor, but it is the South Dakota Department of Health that is responsible for issuing a CSR to a reverse distributor.

Some states do not require a reverse distributor to hold a distributor license to perform reverse distribution activities generally, but do require the reverse distributor to hold a CSR in order to handle CS. In these situations, the reverse distributor is typically required to first obtain its state distributor license before it can apply for and obtain its CSR. For example, the Hawaii State Board of Pharmacy does not license nonresident reverse distributors; however, the State of Hawaii Department of Public Safety, Narcotics Enforcement Division has indicated that a nonresident reverse distributor collecting CS within Hawaii is required to hold a CSR even though the Board of Pharmacy has indicated that its laws and regulations do not address reverse distributors. Similarly, a nonresident reverse distributor would not be required to hold a license from the New York State Board of Pharmacy if it only sends product out of New York. But New York's Bureau of Narcotic Enforcement requires a reverse distributor to hold a CSR to distribute or handle CS within New York. In both examples, the reverse distributor does not need to hold a distributor license from the board of pharmacy but may need to obtain one nonetheless in order to receive a CSR to handle or distribute CS in those states.

The regulation of reverse distribution of pharmaceuticals is complex and varied across the states. When developing regulation or policies, or statutory language, boards of pharmacy may want to consider several questions. Is "reverse distributor" defined in the state's law, or does the definition need to be included in regulatory language or board guidance documents? What reverse distributor business activities need to be accounted for? Are resident and nonresident state licensure requirements clear? Do the regulations address the proper handling of CS to prevent diversion? Do the regulations address hazardous waste disposal and compliance with Environmental Protection Agency requirements? •

This article was written by Libby Baney, JD; Jay A. Warmuth, JD; and Jonathan A. Keller, PharmD, JD, RPh, 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.



Wyoming State Board of Pharmacy



Number of Board Memhers

5 pharmacist members, 1 public member, 1 physician, 1 dentist or veterinarian, and 1 pharmacy technician



Number of Compliance Officers/Inspectors



Rules & Regulations Established by State Board of Pharmacy



Number of **Pharmacist Licensees**



Number of **Pharmacies**



Number of Wholesale Distributors

Keith R. Bennett, PharmD, RPh

Chief Inspector/Compliance Officer, Wyoming State **Board of Pharmacy**

How long have you been an inspector for the Board?

I have been serving as an inspector for the Wyoming State Board of Pharmacy since September 2019. Prior to joining the Board, I worked as a contract pharmacist for the Civilian Health and Medical Program of the Department of Veterans Affairs. Before pursuing pharmacy as a career, I served on active duty in the United States Air Force, and I continue to serve in the Wyoming Air National Guard.

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

The Wyoming Pharmacy Act Rules and Regulations, and other applicable federal and state laws that govern the practice of pharmacy are the most important "tools" I have as an inspector. Because policies, procedures, and processes can vary from pharmacy to pharmacy, a thorough understanding of pharmacy law is necessary to ensure accurate and consistent observations across inspections.

Effective verbal and written communication are also essential. When used effectively, these skills foster positive relationships with licensees based on mutual respect as well as allow an inspector to apply knowledge of pharmacy law in a constructive manner. These skills also promote an increased state of compliance over time and an overall positive perception of the Board.

Attention to detail is another important skill. An inspector can be presented with various distractions and interruptions throughout the inspection process. This can lead to a pattern of inconsistent observations over time, thereby reducing the effectiveness of the inspection program.

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

When I first started as an inspector, the 2019 version of US Pharmacopeia (USP) General Chapter <797> was incorporated by reference in the Board's rules. At that time, it was anticipated that the 2019 version of USP <797> and General Chapter <800> would become official and eventually take its place. Many sterile compounders in the state were either planning or undergoing a remodel to come into compliance with the new chapters. The Board had also been in the process of educating licensees on USP <800> standards in preparation of the new chapters becoming official. Within my first seven months, the new chapters were remanded and USP <800> became informational. As a result, the Board approved an emergency rule adopting the 2008 version of USP <797> by reference. In May 2021, the Board approved new rules for sterile compounding, and I have been addressing issues and confusion to help bring sterile compounders into compliance.

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

The most egregious case I investigated involved a veterinary wholesaler that was repackaging and relabeling prescription drugs for use in ornamental fish, and then distributing those products in other states without the appropriate licenses and/or registrations. This case required thorough research and understanding of federal law as well as other states' laws requiring licensure to engage in wholesale distribution. The Board concluded that the distributor violated the Wyoming Pharmacy Act by selling adulterated drugs, selling misbranded drugs, failing to maintain records, and engaging in unlicensed practice. The owner and company were prohibited from renewing, reinstating, or obtaining any license from the Board for 10 years and will have to pay an administrative penalty of \$500,000 for any future attempt to renew, reinstate, or obtain any license through the Board.



efore Drug Enforcement Administration (DEA) published an interim final rule in 2010, which gave practitioners the option to write prescriptions for controlled substances (CS) electronically, e-prescribing for CS was prohibited in many states. Now, 11 years later, the regulatory and technological landscape has shifted significantly.

As part of the larger effort to curb the opioid crisis, many states are now (or will soon be) mandating e-prescriptions for certain CS. This shift in the general perception of e-prescribing – from vulnerability to asset in the opioid crisis – means that even jurisdictions that are not currently requiring e-prescribing for certain types of CS may be considering such legislation in the near future.

E-Prescribing Has Become Widely Utilized

E-prescribing is the practice of using digital methods to transmit prescription information between a prescriber and the dispensing pharmacy. The more traditional handwritten prescriptions continue to be utilized but have started to be seen as less secure and more prone to potential abuse, in part, because abusers and

drug traffickers have grown more sophisticated in their use of technology that makes it easier to defeat watermarks and other security measures used with paper prescriptions. Meanwhile, security protocols and procedures for e-prescribing have improved and are often integrated directly into providers' electronic health record systems, making this a more secure option.

From a regulatory standpoint, e-prescribing has two major benefits that are often cited. First, the records and security protocols that accompany e-prescribing generally make it harder for those who abuse prescription opioids to receive them. This vigilance to protect the prescription drug supply during the ongoing opioid crisis remains important, particularly given the recent increase in overall opioid overdoses (see the October 2021 issue of *Innovations* for more details).

Another benefit of e-prescribing is a reduction in medication errors. With handwritten prescriptions, there is more room for error from both the dispenser and the prescriber. For example, handwriting can more easily be misinterpreted by a pharmacist as compared to type. Also, studies have shown that a prescriber is more likely to make a mistake when handwriting a prescription in the first place. E-prescribing software can prevent some of these mistakes and also removes several of the steps involved in filling a prescription.

In fact, some of these regulatory changes have already occurred at the federal level. In 2018, Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Among the law's provisions is a requirement for Medicare Part D or Medicare Advantage prescription drug plans to begin requiring e-prescribing for Schedule II-V CS. As of press time, Centers for Medicare & Medicaid Services (CMS) has set the enforcement start date for these requirements for January 1, 2023. Food and Drug Administration (FDA) has also delayed the start date for compliance action for Part D prescriptions written for beneficiaries in long-term care facilities to January 1, 2025.

Majority of States Now Mandate E-Prescribing for at Least Some Medications

At the state level, the trend has been dramatically shifting toward e-prescribing requirements in recent years. According

... when factoring in states with "pending legislation," at least 37 states will mandate e-prescribing in some form within the next few years.

... security protocols and procedures for e-prescribing have improved and are often integrated directly into providers' electronic health record systems, making this a more secure option.

to the NABP 2022 Survey of Pharmacy Law, at least 22 states and jurisdictions require e-prescribing for certain drugs. More information gathered by MDToolbox, a company that offers e-prescribing software, indicates that, when factoring in states with "pending legislation," at least 37 states will mandate e-prescribing in some form within the next few years.

These laws have significant variations in their approach to enforcement methods, waivers, and exemptions, and which medications require e-prescribing.

Regarding which drugs are required to be prescribed electronically, there appear to be three major categories of law. The first is comprised of laws that require all prescription medications to be submitted electronically. For example, in Florida, House Bill 831 requires prescribers to generate and transmit all prescriptions electronically, except under certain conditions, such as conflict with FDA restrictions on e-prescribing or prescriptions issued to individuals receiving hospice care or who are in an assisted living facility. A waiver process is available to prescribers who meet certain conditions.

According to the MDToolbox data, 18 states' e-prescribing requirements are limited to CS. An additional eight states have more specific requirements under which drugs are required to be electronically prescribed. Some states, such as Maine and Virginia, are applying their e-prescribing mandates only to medications that contain opioids. Others are limiting the requirement to apply only to certain schedules of CS. For example, Arizona's laws require Schedule II CS to be electronically prescribed, while Colorado's law includes Schedule II-IV CS.

It should be noted that during the coronavirus disease 2019 pandemic, some states waived or postponed implementation of their e-prescribing requirements to make it easier for health care providers to provide phone-in and written prescriptions when needed.

State Overview of E-Prescribing Requirements



States mandating e-prescribing for all prescriptions (9):

CA NV
FL NY
IA PA
MI WV
MN



States mandating e-prescribing for all controlled substances (18):

NM IL OK IN RI KY SC MΑ TN MO TX UT NE NH WA WY NI



States with more limited requirements (8):

AR (Schedule II-VI CS)

AZ (Schedule II CS)

CO (Schedule II-IV CS)

KS (all CS containing opioids)

ME (all CS containing opioids)

MD (Schedule II)

NC (certain Schedule II and Schedule III CS)

VA (all prescriptions containing opioids)

NABP Resolutions on E-Prescribing

NABP has been closely watching e-prescribing laws and regulations for some time. Recent action related to the practice has been the subject of two Annual Meeting resolutions from 2018 and 2019.

- Resolution 114-3-18 acknowledges evidence that mandating
 e-prescribing provides multiple advantages and resolves that
 NABP collaborate with appropriate stakeholders, including DEA,
 CMS, and e-prescribing experts, to examine the feasibility of
 mandating that all prescriptions be transmitted electronically.
- Resolution 115-1-19 resolves that NABP should engage stakeholders to encourage prescribers and pharmacists to use e-prescribing transactions to avoid duplicative or inappropriate prescribing and medication therapy.

E-prescribing is just one of many tools that health care providers and regulators are utilizing in their efforts to curb prescription drug misuse and abuse. NABP will continue to monitor changes in e-prescribing regulations and their effect on pharmacy practice and regulation. Further updates will be provided in future communications. •

FDA Delays Enforcement Date for Statutory Compounding Limit. Extends Deadline for States' MOU Decisions



In summer 2021, Food and Drug Administration (FDA) announced that states would receive an additional 12 months to decide whether to sign its Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) before the agency would enforce its statutory 5% limit on out-of-state distribution. This announcement came following a request from some states and NABP for additional time to determine the legal and logistical ramifications of signing the MOU. Per the announcement, enforcement of the statutory limit will now begin on October 27, 2022. At that time, the 5% limit will only apply to pharmacies in states that have not signed the MOU.

As of press time, FDA is evaluating a September 2021 court order that remanded the MOU to FDA to either certify that it

will not have a significant economic effect on small businesses or prepare a regulatory flexibility analysis.

The FDA Compounding MOU Project was established through a partnership between NABP and FDA and aims to improve data sharing related to compounding pharmacies. As part of the project, NABP developed the information sharing network to help state boards of pharmacy collect, manage, and share data related to compounding pharmacies with FDA in order to meet the obligations of the MOU. FDA worked with NABP to develop a standard MOU for use by the state boards of pharmacy to aid their compliance with section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act. States that sign the MOU must identify pharmacies that are compounding human drug products and distributing inordinate amounts of

such products interstate and report those pharmacies to FDA. Boards can use the information sharing network, accessible via NABP e-Profile Connect, to meet the obligations outlined in the MOU. While boards are not required to enter data into the network, they are encouraged to do so to create a uniform and streamlined reporting process with FDA.

Truths and Misconceptions About the MOU

NABP has identified a few misconceptions that have circulated among boards of pharmacy and stakeholders. These misconceptions can impede the enactment of this measure that the Association believes is vital to the protection of public safety.

The first of these misconceptions is that states can negotiate their own versions of the MOU. Understandably, the standard

MOU is meant to avoid a patchwork of agreements that FDA and pharmacies located in multiple states would need to track and comply with. There is only one MOU that exists, and all states that sign it will be under the same obligations.

Another misconception is that the MOU forces states to scrutinize every compounded prescription. States do not need to evaluate and verify every compounded drug prescription to determine whether a pharmacy has met the inordinate amount threshold. The information sharing network was created specifically to help states more easily determine and report this information. States may also utilize the information sharing network to report complaints of serious adverse drug events and product quality issues for

Boards can use the information sharing network, accessible via NABP e-Profile Connect, to meet the obligations outlined in the MOU.

compounded human drug products shipped out of state by compounding pharmacies.

Finally, another misconception relates to inspections and investigations of compounding physicians' offices. The MOU does not require boards to enter physicians' offices to inspect or investigate compounding activities. It only requires states to report complaints of adverse drug events or product quality issues for compounded human drug products compounded by physicians' offices and shipped out of state, if they become aware of such complaints. In addition, the MOU requires states to report if they become aware that a physician's office is shipping any amount of compounded products interstate.

Greater compounding oversight reduces the chance of another tragedy like the 2012 multistate outbreak of fungal meningitis, which was linked to drug products compounded by the New England Compounding Center (additional information on the latest regulatory responses to the tragedy is available in the November/December 2021 issue of *Innovations*). Increased oversight provided by the MOU also helps ensure greater patient confidence that regulators are closely watching the facilities that produce compounded drugs that improve and save lives. •

By signing the MOU and participating in the project, boards of pharmacy are obligated to report the following to FDA:

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate, as well as certain compounding data.
- Complaints of serious adverse experiences or quality issues relating to human drug products compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to human drug products compounded by a physician and distributed interstate.
- Information relating to the interstate distribution of any amount of human drug products compounded by physicians.

Volunteer to Serve on a Committee or Task Force

NABP is seeking volunteers from its active member boards of pharmacy to serve on its 2022-2023 committees and task forces. 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 online by **Friday**, **June 3**, **2022**. The form is available in the

Members section of the NABP website under Board Resources.

All materials will be forwarded to NABP President-elect Reginald B. "Reggie" Dilliard, DPh, who will make the appointments following the 118th NABP Annual Meeting.

NABP Clearinghouse 2021



Over 1,400 Disciplinary Actions Recorded

The Association's data results for the third quarter of 2021 showed that a total of 1,425 disciplinary records were submitted to the **NABP Clearinghouse by state boards** of pharmacy on 1,236 individual and business NABP e-Profiles.

Of the 1,425 actions reported in third quarter 2021:

- 514 (36%) were on pharmacists;
- 475 (33%) were on pharmacies;
- 326 (23%) were on pharmacy technicians;
- 38 (3%) were on wholesalers, manufacturers, and distributors;
- 32 (2.2%) were on other individuals;
- 20 (1.4%) were on pharmacy interns;
- 12 (0.8%) were on other licensees;
- 4 (0.3%) were on Drug Enforcement Administration and Food and Drug Administration registrations; and
- 4 (0.3%) were on controlled substance licenses.

Third Quarter 2021 Action Code Categories INDIVIDUALS

	COUNT	%		COUNT	%
Publicly Available Fine/ Monetary Penalty	256	23.1%	License/Certificate Restored or Reinstated, Complete, Conditional, Partial, or Denied	82	7.4%
Probation of License	137	12.3%			
Other Licensure Actions - Not Classified	122	11%	Reduction, Modification, or Extension of Previous Licensure Action	44	4%
Revocation of License/ Certificate	100	9%	Summary or Emergency Action, Limitation, Suspension, or Restriction	34	3.1%
Suspension of License/ Certificate	100	9%	on License		
			License	17	1.5%
Voluntary Surrender of License/Certificate	100	9%	Denial of Initial License or Renewal License/Certificate	14	1.3%
Reprimand or Censure	96	8.6%	Miscellaneous	8	0.7%

TOTAL 1,110

Third Quarter 2021 Bases for Action Code Categories INDIVIDUALS

	COUNT	%		COUNT	%
Noncompliance With Requirements	462	45.1%	Fraud, Deception, or Misrepresentation	39	3.8%
Improper Prescribing, Dispensing, Administering Medication/Drug Violation	196	19.1%	Improper Supervision or Allowing Unlicensed Practice	31	3%
Other Licensure Actions - Not Classified	121	11.8%	Misconduct or Abuse	18	1.8%
Criminal Conviction or Adjudication	87	8.5%			
Unsafe Practice or Substandard Care	66	6.4%	Confidentiality, Consent, or Disclosure Violation	5	0.5%

TOTAL 1,025

Third Quarter 2021 Action Code Categories BUSINESSES

	COUNT	%		COUNT	%
Publicly Available Fine/ Monetary Penalty	407	54%	License/Certificate Restored or Reinstated, Complete, Conditional, Partial, or Denied	4	0.5%
Reprimand or Censure	241	32%			
Probation of License	34	4.5%	Monitoring, Closure, or Other Operational Business	4	0.5%
Voluntary Surrender of License/Certificate	21	2.8%	Modification		
Revocation of License/			Reduction, Modification, or Extension of Previous	1	0.1%
Certificate	19		Licensure Action		
Other Licensure Actions - Not Classified	16	2.1%	Suspension of License/ Certificate	7	0.9%

TOTAL 754

Third Quarter 2021 Bases for Action Code Categories BUSINESSES

	COUNT	%		COUNT	%
Noncompliance With Requirements	491	63.4%	Fraud, Deception, or Misrepresentation	22	2.8%
Improper Supervision or Allowing Unlicensed Practice	202	26.1%	Other Actions - Not Classified	13	1.7%
			Confidentiality, Consent, or Disclosure Violations	6	0.8%
Improper Prescribing, Dispensing, Administering Medication/Drug Violation	38	4.9%	Criminal Conviction or Adjudication	2	0.3%

TOTAL 774

Join Fellow NABP Members in the Valley of the Sun for the 118th Annual Meeting

NABP invites its members and other pharmacy stakeholders to Phoenix, AZ, for the Association's 118th Annual Meeting. Themed "Expanding Our Vision to Advance Public Health Protection," the Annual Meeting will be held May 19-21, 2022, at the Sheraton Grand at Wild Horse Pass. Join your regulatory colleagues 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 with the opportunity to participate in continuing pharmacy education activities and to network with peers.



Online Registration Will Soon Be Available on the **Annual Meeting Website**

In February 2022, check out the Annual Meeting website for the latest information about the 118th Annual Meeting. Online registration, hotel and transportation details, and more will soon be available at NABPAnnualMeeting.pharmacy



Travel Grant Available to Attend 118th **NABP Annual Meeting in Phoenix**

The NABP Foundation is once again offering travel grant opportunities for individuals planning to attend the 118th NABP Annual Meeting in Phoenix, AZ. Eligible individuals may receive up to \$1,500 to cover the cost of travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include registration fees. All applicants will be informed of whether they have qualified for the grant.

- 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.
- Active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

To obtain a grant application, board administrative officers may contact ExecOffice@nabp.pharmacy.



Proposed Resolutions Will Be Distributed in February

Proposed resolutions received at NABP Headquarters by Friday, February 11, 2022, will be distributed electronically to state boards of pharmacy on the following Thursday, February 17, 2022, for review prior to the 118th NABP Annual Meeting. This mailing will constitute the only preconference distribution of proposed resolutions. All resolutions – those distributed for early review as well as those received after February 11 – will be presented to the voting delegates during the Second Business Session of the Annual Meeting by the chair of the Committee on Resolutions and subsequently voted on during the Final Business Session.

Any active member board, district, or committee of the Association may submit resolutions to NABP. To be considered during the Annual Meeting, resolutions must

be received by Friday, April 29, 2022, in accordance with Article IV, Section 6, Part (d) of the NABP Constitution and Bylaws. 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.

Questions regarding resolution procedures should be directed to the NABP Executive Office via email at ExecOffice@nabp.pharmacy.

Important Deadlines

- February 11, 2022
 Proposed resolutions
 must be received at
 NABP Headquarters for
 preconference distribution to
 the state boards of pharmacy.
- February 17, 2022
 Proposed resolutions are distributed electronically to state boards of pharmacy for review.
- April 29, 2022
 Proposed resolutions must be submitted to be considered at the Annual Meeting.



Submit Your Poster Proposal by February 23

Limited Spots Available – Don't Delay!

NABP is seeking proposals for its annual Educational Poster Session. 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 of "Sharing Our Vision to Advance Public Health Protection." Poster proposals may be descriptive, scientific, or informational in nature. Possible topics include policy development, public health initiatives, and legislative issues, among others.

The Poster Session will be held the morning of Saturday, May 21, 2022, at the 118th NABP Annual Meeting in Phoenix, AZ. To be considered for the Poster Session, individuals must be able to attend the in-person meeting on May 21. Selected poster presenters must also 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 \$75 to take the Pre-NAPLEX*, a practice examination for students

preparing for the North American Pharmacist Licensure Examination.

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.

Interested in submitting a proposal? Contact NABP Professional Affairs staff via email at Prof-Affairs@ nabp.pharmacy for detailed instructions. Proposals must be submitted by Wednesday, February 23, 2022.



NABP Announces 2022-2023 Executive Committee Openings; Elections to Take Place During Annual Meeting

As of press time, NABP has received the following nominations for the open Executive Committee officer and member positions:

President-elect (one-year term) Lenora S. Newsome, PD, Arkansas

Treasurer (one-year term)Jeffrey J. Mesaros, PharmD, JD, RPh, Florida

District 1 (three-year term)Bradley S. Hamilton, BSPharm,
RPh, Maine

District 2 (three-year term) Janet Getzey Hart, RPh, Pennsylvania **District 3 (one-year term)** Traci Collier, PharmD, RPh, South Carolina

District 5 (three-year term) Shane R. Wendel, PharmD, RPh, North Dakota

Updates to the list of nominations will be posted on the Annual Meeting page in the About section of 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 prior (by April 4, 2022) 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

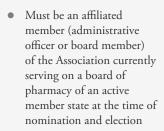
Candidate and seconding speeches are presented.



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, which can be accessed in the About section of the NABP website.

Candidate Qualifications



- 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.







Number of Board Memhers

5 pharmacist members and 2 public members



Number of Compliance Officers/Inspectors



Rules & Regulations Established by

District of Columbia **Board of Pharmacy** and the District of Columbia mayor



Number of **Pharmacist Licensees** 2,036



Number of **Pharmacies**



Number of Wholesale **Distributors**

Ashlee Bow, PharmD, RPh, AAHIVP

Member, District of Columbia Board of Pharmacy

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

I have served as a pharmacist member of the District of Columbia Board of Pharmacy since March 2019. I have been a pharmacist for eight years, working in a community pharmacy, and have worked in the District of Columbia since 2016. I currently serve as chair of the Communications Subcommittee and am a member of the Pharmacy Laws and Regulations Subcommittee.

What steps should a board member take to be successful in their role?

Doing your homework before board meetings is the most important step in being a successful board member. Before each meeting, I go through all of the meeting materials and often research what is happening in other states so that I can fully understand any issues we may discuss. I also find myself constantly using NABPLAW® Online, depending on what we are discussing during our meetings. You can never be too prepared for a meeting.

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

The Board's Laws and Regulations Subcommittee has been working diligently to update regulations. We have been reviewing each chapter of the District of Columbia's Pharmacy Laws and Regulations, which include pharmacist-in-charge requirements, immunizations, 90-day refills, and techcheck-tech. We are also putting together a workplace survey for pharmacists, pharmacy technicians, pharmacy technician trainees, and pharmacy interns in the District.

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

There are always challenges that arise when changes are being made. The coronavirus disease 2019 pandemic has been a major challenge for us, forcing us to put some things on hold while we worked to create emergency regulations. All of our meetings are now virtual, and pharmacists are really busy during this time, so scheduling can also be a challenge.

What advice would you give to a new **Board member?**

New board members should have the confidence to ask questions when they do not understand something or need more clarification. It is important to stay informed and up to date as much as possible on current events in pharmacy and to have a working knowledge of the regulations in your jurisdiction. It is very important that new members understand the commitment it takes to be on a board of pharmacy and the time that they will need to invest.

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 am not currently serving on an NABP task force, but I attended the virtual 117th NABP Annual Meeting in May 2021. It was very refreshing to hear new ideas from other board members, and there were great networking opportunities to meet members from other states. I particularly enjoyed the breakout rooms, as I was able to engage with other attendees on familiar topics in which I had some interest as well as gain exposure to new topics.

Executive Officer Changes

- James R. Skizewski has been named executive officer of the Hawaii State Board of Pharmacy, replacing Lee Ann Teshima. Skizewski also serves as executive officer for the Hawaii Board of Elevator Maintenance and the Certified Nursing Aide and Nursing Home Administrator programs. He graduated from the University of Hawaii at Manoa with a bachelor's degree in governance and sociology.
- Christine M. Horne has been named board administrator III of the New Hampshire Board of Pharmacy, replacing Traci Weber. She has worked for the state of New Hampshire for eight years and is currently board administrator III for nine boards. Horne holds an associate's degree in business management from Hesser College.
- Brad Wojciechowski has been named executive director of the Wisconsin Pharmacy Examining Board, replacing Christine Poleski. Wojciechowski graduated from the University of Wisconsin-Eau Claire with a bachelor's degree in political science.

Board Member Appointments

- Patrick Adams, RPh, has been appointed a member of the Hawaii State Board of Pharmacy. Adams' appointment will expire June 30, 2023.
- Mark Brown, RPh, has been appointed a member of the Hawaii State Board of Pharmacy. Brown's appointment will expire June 30, 2025.
- Catalina Cross, PhD, has been appointed a public member of the Hawaii State Board of Pharmacy. Cross' appointment will expire June 30, 2023.
- Kent Kikuchi, MBA, RPh, has been appointed a member of the Hawaii State Board of Pharmacy. Kikuchi's appointment will expire June 30, 2025.
- Sheri M. Tokumaru, PharmD, BCCCP, has been appointed a member of the Hawaii State Board of Pharmacy. Tokumaru's appointment will expire June 30, 2024.

- Mark Bunton, RPh, has been appointed a member of the Indiana Board of Pharmacy. Bunton's appointment will expire October 1, 2024.
- Jason Jablonski, RPh, has been appointed a member of the Indiana Board of Pharmacy. Jablonski's appointment will expire October 5, 2024.
- James "Jim" Mennen, RPh, has been appointed a member of the Iowa Board of Pharmacy. Mennen's appointment will expire April 30, 2024.
- Lucinda Noches Talbert has been appointed a public member of the Kansas State Board of Pharmacy. Talbert's appointment will expire April 30, 2025.
- Pierre Boutros, RPh, has been appointed a member of the Michigan Board of Pharmacy. Boutros' appointment will expire June 30, 2025.
- Carolyn R. Bodell, RPh, has been appointed a member of the North Dakota State Board of Pharmacy. Bodell's appointment will expire May 8, 2026.
- Ron J. Horner has been appointed a public member of the North Dakota State Board of Pharmacy. Horner's appointment will expire May 8, 2026.
- Jason George, PharmD, RPh, has been appointed a member of the State of Ohio Board of Pharmacy. George's appointment will expire June 30, 2025.
- Tod Joseph "T.J." Grimm, MBA, RPh, has been appointed a member of the State of Ohio Board of Pharmacy. Grimm's appointment will expire June 30, 2024.
- Richard Joyce, CPhT, has been appointed a member of the Oregon State Board of Pharmacy. Joyce's appointment will expire February 29, 2024.
- Edward G. Misto, RPh, has been appointed a member of the Rhode Island Board of Pharmacy. Misto's appointment will expire September 1, 2024.

• Cheryl Lynn "Cheri" Garvin, RPh, has been appointed a member of the Virginia Board of Pharmacy. Garvin's appointment will expire June 30, 2025.

Board Member Reappointments

- Jonathan Brunswig, PharmD, RPh, has been reappointed a member of the Kansas State Board of Pharmacy. Brunswig's appointment will expire April 30, 2025.
- Bill Walden, RPh, has been reappointed a member of the Kansas State Board of Pharmacy. Walden's appointment will expire April 30, 2025.
- Kyle A. McCree has been reappointed a public member of the Michigan Board of Pharmacy. McCree's appointment will expire June 30, 2025.
- Jillian Foster, MBA, PharmD, has been reappointed a member of the Mississippi Board of Pharmacy. Foster's appointment will expire June 30, 2026.
- Ryan Harper, PharmD, RPh, has been reappointed a member of the Mississippi Board of Pharmacy. Harper's appointment will expire June 30, 2026.
- Kenneth Kenyon, PharmD, RPh, BCPS, has been reappointed a member of the Washington State Pharmacy Quality Assurance Commission. Kenyon's appointment will expire January 19, 2025.
- Hoang-Uyen Thorstensen, CPhT, has been reappointed a member of the Washington State Pharmacy Quality Assurance Commission. Thorstensen's appointment will expire January 19, 2025.

Kansas Pharmacist Education Program to Focus on PDMP Utilization

In fall 2021, the Kansas prescription drug monitoring program (PDMP), K-TRACS, began outreach to Kansas pharmacies to gauge interest in peer-to-peer education regarding K-TRACS utilization. Also known as academic detailing, the program is intended to help pharmacists incorporate K-TRACS into their clinical workflows and adopt best practices to prioritize patient safety. The K-TRACS staff pharmacist will meet with peers to identify challenges in their pharmacy related to controlled substance (CS) dispensing and K-TRACS usage. They will then work together to identify and implement noncommercial, evidence-based solutions that promote positive patient outcomes.

More information is available in the Board's September 2021 Newsletter.

New Mexico Approves HIV Post-Exposure Prophylaxis and Point-of-Care Testing

The New Mexico Board of Pharmacy approved pharmacist prescriptive authority for the prescribing of HIV post-exposure prophylaxis therapy in conjunction with point-of-care testing. Pharmacists who wish to obtain this prescriptive authority must go through Board-approved training and adhere to the Board-approved protocol. Portions of this training that are in addition to the required Accreditation Council for Pharmacy Education-accredited training for prescriptive authority are approved as acceptable toward the 30hour continuing pharmacy education requirement outlined in 16.19.4.10 New Mexico Administrative Code.

Tennessee Legislative Updates Address Compounding, Criminal History, and Immunizations

The Tennessee Board of Pharmacy implemented several legislative updates related to the regulation of compounding pharmacies, criminal history background, and immunizations. The following is a summary of these changes that are now in effect.



- Prior to renewing or applying for licensure in Tennessee, an out-of-state pharmacy practice site must submit to the Board its most recent inspection by the regulatory agency of its respective state, conducted within the past year.
- Upon learning that a health care prescriber was indicted of certain criminal offenses (CS violations or sexual offenses), the Tennessee Department of Health's licensing authorities are required to automatically restrict the prescriber's ability to prescribe Schedule II CS until the case reaches a final disposition. The restriction shall be removed upon sufficient proof of acquittal or dismissal/nolle prosequi. Further, licensing authorities are required to automatically revoke the license of a practitioner who is convicted of those same criminal offenses.
- Regulatory changes prohibit Governor Bill Lee from issuing an executive order and a state agency, department, or political subdivision from promulgating, adopting, or enforcing an ordinance or resolution that requires a person to receive an immunization, vaccination, or injection for the SARS-CoV-2 virus or any variant of the SARS-CoV-2 virus. In addition, new regulation deletes the previous override during an epidemic or immediate threat of an epidemic of an objection against vaccination that was made based on religious tenets, and prohibits requiring the coronavirus

disease 2019 vaccine to attend K-12 schools.

More information is available in the Board's September 2021 Newsletter.

Wyoming Implements New Sterile Compounding Inspection Process

A new sterile compounding inspection process will be implemented in Wyoming starting this current fiscal year (July 1, 2021-June 30, 2022). All sterile compounding inspections will now be completed in two phases. The first phase will consist of a virtual pre-inspection, and the second phase will include an unannounced on-site inspection. The virtual pre-inspection will consist of a comprehensive review of policies, records, and documentation. All pharmacists-incharge will be notified of the virtual pre-inspection and provided 30 days to compile and submit all required information. The intent of the virtual pre-inspection is to prevent interruptions in daily operations that typically occur while reviewing such records on site. Once the virtual pre-inspection is complete and reviewed with the designated person, inspectors will follow up with a random, unannounced on-site inspection. This second phase will consist of completing the associated retail or institutional inspection checklists and observation of processes, techniques, and adherence to procedures.



Most articles published in State Board News are selected from the newsletters of state boards that participate in the NABP State Newsletter Program. Issues are posted on the NABP website on each participating state's page.

NABP Joins Other Regulatory Associations in Launching Opioid Regulatory Collaborative

NABP and three other state board associations have launched the Opioid Regulatory Collaborative (ORC). The ORC will bring together senior leaders from NABP, the American Association of Dental Boards, the Federation of State Medical Boards, and the National Council of State Boards of Nursing to share resources and strategies to slow opioid substance use disorder by uniting key health professionals. Like NABP, these organizations each support state boards that regulate the respective health care providers that practice in the United States.

More information can be found through the News section of the NABP website.

US Surgeon General Releases New Toolkit to Help Health Care **Providers Combat COVID-19 Health Misinformation**

US Surgeon General Dr Vivek Murthy has released a new toolkit that addresses health misinformation and how to stop it. The toolkit, A Community Toolkit for Addressing Health Misinformation, was created to offer specific guidance to health care providers, teachers, and other community leaders as a new phase of the coronavirus disease 2019 (COVID-19) vaccination campaign begins for children ages five to 11 years old.

The toolkit offers the following resources:

- a health misinformation checklist;
- tips for talking with loved ones about health misinformation;
- an outline of common types of health misinformation and disinformation tactics; and
- examples of health misinformation.

More information can be found on the US Department of Health and Human Services website by visiting www.hhs.gov/ sites/default/files/health-misinformation-toolkitenglish.pdf.

SAMHSA Awards Grants to Support Opioid Overdose Prevention Strategies

The Substance Abuse and Mental Health Services Administration (SAMHSA) will award up to \$850,000 in grants to health departments in 12 different states and Puerto Rico to support opioid overdose prevention strategies. The US states and jurisdictions receiving the grants include Alabama, Alaska, Maine, Michigan, Mississippi, Missouri, New Mexico, New York, North Carolina, Oklahoma, Puerto Rico, South Carolina, and Washington.

The purpose of the grants is to reduce the number of prescription drug/opioid overdose-related deaths and adverse events among individuals 18 years of age and older by training first responders

and other key community sectors on the prevention of prescription drug/ opioid overdose-related deaths and implementing secondary prevention strategies, including the purchase and distribution of naloxone to first responders.

More information can be found on SAMHSA's website by visiting www.samhsa .gov/grants/2021/grants-prevent-prescriptiondrug-opioid-overdose-related-deaths.

Final Guidance Released on Biosimilar Development and BPCI Act

Food and Drug Administration (FDA) issued a guidance document on biosimilar development and the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The document provides answers to common questions from applicants and other interested parties regarding the BPCI Act and is intended to inform prospective applicants and facilitate the development of proposed biosimilars and interchangeable biosimilars, as well as describe FDA's interpretation of certain statutory requirements added by the BPCI Act. FDA will regularly update the guidance document with new questions and answers.

More information can be found by visiting FDA's website at www.fda.gov/ media/119258/download.

AMA Report Shows Decrease in Opioid Prescribing Nationwide

Opioid prescribing has decreased by 44.4% since 2011 throughout the country, according to the American Medical Association (AMA). A report from AMA highlights actions taken by physicians to help end the opioid overdose epidemic. AMA notes that since 2014 there has been a significant increase in the use of prescription drug monitoring programs by physicians and others - more than 910 million times in 2020, compared to 750 million times in 2019, for example. The report can be found by visiting AMA's website at www.ama-assn .org/press-center/press-releases/report-showsdecreases-opioid-prescribing-increase-overdoses.





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UPCOMING EVENTS

Committee on Law Enforcement/Legislation

January 19-20, 2022 | NABP Headquarters

NABP Interactive Member Forum

January 26-27, 2022 | Virtual Meeting

Advisory Committee on Examinations
April 7, 2022 | NABP Headquarters

Committee on Constitution and Bylaws

April 11, 2022 | Virtual Meeting

118th NABP Annual Meeting May 19-21, 2022 | Phoenix, AZ

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