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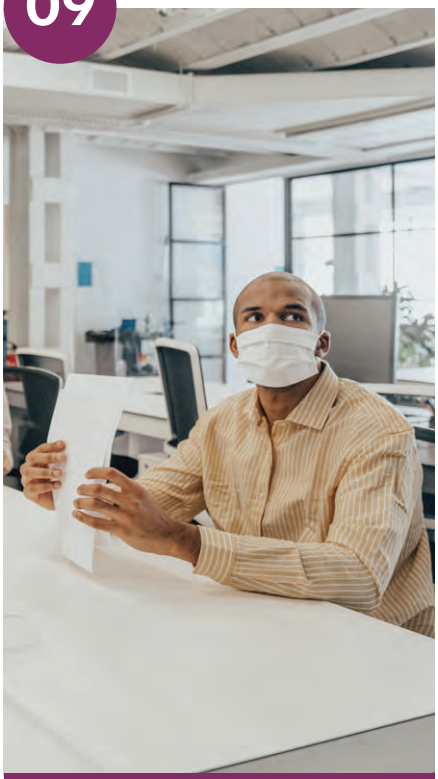
iNNOVATiONS

Telehealth Utilization Grows

as COVID-19 Transforms Regulatory Landscape

NABP
National Association of Boards of Pharmacy

Feature News
Telehealth Utilization Grows as COVID-19 Transforms Regulatory Landscape



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

NABP
National Association of Boards of Pharmacy

Traci Collier, PharmD, RPh

Administrator/Chief Drug Inspector, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy

South Carolina Board of Pharmacy

Number of Board Members
8 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors
4

Rules & Regulations Established by
Board of Pharmacy and approved by the General Assembly

Number of Pharmacist Licensees
9,003

Number of Pharmacies
1,324

Number of Wholesale Distributors
96

How long have you served as administrator/chief drug inspector of the South Carolina Board of Pharmacy? What was your role prior to working with the Board?

I began employment with the Board in April 2016. I initially served as the assistant administrator and have been the administrator/chief drug inspector since August 2018. Prior to joining the Board, I was employed by Kaiser Permanente of Georgia and the Mid-Atlantic states in various roles, ranging from ambulatory care to pharmacy systems and workflow optimization.

What is one of the most significant challenges or issues your Board addressed in the past year or so?

As is most likely the case with all boards, the most significant challenge for the South Carolina Board of Pharmacy has been regulating while supporting the profession during the unprecedented and ongoing coronavirus disease 2019 (COVID-19) pandemic. The nature of the pandemic itself forced us as a Board to act quickly to support our licensees on the front lines.

What actions were taken by the Board to address the issue?

The Board immediately took steps to address the issues presented by COVID-19. Numerous emergency orders were put into place by the Board, including allowing temporary 90-day permits for nonresident facilities actively involved in activities related to fighting the pandemic. This allows South Carolina pharmacies broader access to medication supply chains in the event of drug shortages. In addition, during the declared state of emergency, the Board has allowed for remote order entry from an unpermitted site. The Board recognized that COVID-19 is a risk to health care workers and that allowing the use of remote order entry would reduce the risk for the pharmacists and, therefore, reduce risk for any patients they may come into contact with. Other actions taken by the Board included the temporary allowance of pickup kiosks, extended renewal timelines for all licensees, and a safe harbor for pharmacists regarding compounding in light of potential personal protective equipment shortages. As testing evolved and became more urgent, the Board released guidance on authorizing licensed pharmacists to order and administer COVID-19 tests that Food and Drug Administration authorized. The Board is closely monitoring the pandemic as it continues to present new challenges and will swiftly address these challenges as they present themselves.

What other key issues has the Board been focusing on?

The Board continues to study pharmacy workplace conditions and any potential effect on public safety. In addition, the Board has been working on regulations that will clarify the permitting requirements and processes for the state's licenses.

What insights do you have for other states that may be facing similar challenges?

As the practice of pharmacy has changed, so have the regulatory challenges. In South Carolina, we have found that solid relationships with the regulatory boards from other states have been instrumental in the work we do. If you do not have this already, I would encourage a strong avenue of information sharing with sister boards, which will be invaluable in protecting the citizens of your state. ●

California State Board of Pharmacy Wins Ninth Circuit Appeal: Outsourcing Facilities Subject to State Regulation

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On June 17, 2020, the United States Court of Appeals for the Ninth Circuit issued its ruling in the case, *Fusion IV Pharmaceuticals, Inc. v. Anne Sodergren and California State Board of Pharmacy; et al.*[1] This case has been closely watched by boards of pharmacy as it addresses a state board's ability to concurrently regulate federally registered outsourcing facilities. The June decision affirmed a lower court decision that California's state law regulating outsourcing facilities is not preempted by federal law.

Federal Regulation of Outsourcing Facilities

In 2013, Congress enacted the Drug Quality and Security Act (DQSA), which, among other things, established a new category of pharmaceutical entities known as "outsourcing facilities." Outsourcing facilities are required to register with Food and Drug Administration (FDA) and comply with relevant federal regulations, including current Good Manufacturing Practices, as such entities are permitted to engage in large-scale compounding of drug products for interstate commerce.[2]

Subsequently, in 2017, California passed a state law, which, among other things, requires a facility registered as an outsourcing facility with FDA to be concurrently licensed by the California State Board of Pharmacy.[3] These two laws set the stage for the dispute in *Fusion IV v. Sodergren* and the resulting decision by the Ninth Circuit.

Fusion IV v. Sodergren

Fusion IV Pharmaceuticals, Inc, also known as Axia Pharmaceutical, and its owner, Navid Vahedi (collectively, "Fusion IV"), argued that California is prohibited from licensing outsourcing facilities because such state licensing is preempted by the federal DQSA and also violates the Commerce Clause of the US Constitution.

Fusion IV was an FDA-registered outsourcing facility located in California that, pursuant to such registration, sought to compound and distribute its drug products in interstate commerce. Under the DQSA, an outsourcing facility is not required to be a licensed pharmacy.[2] However, California law required FDA-registered outsourcing facilities to be concurrently licensed by the Board as outsourcing facilities if such facilities compound non-patient-specific drug products for distribution within or into California.[4] Fusion IV's activities clearly fell within this category.

In 2017, Fusion IV obtained its outsourcing facility registration from FDA and then applied for state licensure with the Board. The Board, however, denied Fusion IV's state licensure application for its outsourcing facility because there was a pending Board disciplinary action against Vahedi and another pharmacy facility he owned.

Unwilling to issue Fusion IV a state outsourcing facility license, the Board subsequently ordered Fusion IV to cease all operations as an outsourcing facility in California. In response, Fusion IV filed a lawsuit in early 2019 in federal district court challenging the Board's authority to require it – as an FDA-registered outsourcing facility – to also be concurrently licensed by the Board. The plaintiffs argued that California's regulation of outsourcing facilities was preempted by the DQSA and that such regulation was an impediment to interstate commerce, violating the Commerce Clause.

The district court rejected both of the plaintiffs' arguments. The court ruled that California's state law regulating outsourcing facilities is not preempted by the DQSA, whether by express or implied preemption. Instead, the district court found that the DQSA contemplates concurrent state regulation of federally

Additionally, the states without licensure requirements for an FDA outsourcing facility may now consider implementing such laws. One thing is clear – state boards of pharmacy now have a federal appellate court opinion ruling that outsourcing facilities are subject to state oversight and regulation.

registered outsourcing facilities. As part of its reasoning, the district court explained that it was possible for Fusion IV to comply with both federal and state licensure regulations and thus, there was no conflict between the DQSA and California law. Lastly, the district court determined that California's concurrent licensure requirement of federally registered outsourcing facilities did not violate the Commerce Clause.

Ninth Circuit Appeal and Decision

Having lost at the district court, the plaintiffs appealed the court's decision to the Ninth Circuit and raised the same two arguments: California is prohibited from licensing outsourcing facilities because state licensure of outsourcing facilities is preempted by the DQSA and the California State law violates the Commerce Clause.

In a concise and clear ruling, the Ninth Circuit affirmed the district court's decision and wholly rejected the plaintiffs' arguments. As to the issue of preemption, the Ninth Circuit explained (emphasis added):

- "There is **no express preemption** because the DQSA does not 'explicitly manifest Congress's intent to displace state law' dealing with mass compounding . . . express preemption, by its very definition, cannot be implied."[1]
- "There is also **no field preemption**, because 'the scheme of federal regulation' at issue here is not 'so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it' . . . the DQSA clearly allows for 'complementary state regulation[s].'"[1]
- "There is **no conflict preemption**, because it is not 'impossible for a private party to comply with both state and federal [compounding] requirements.' Importantly, it is possible to obtain authorization under both the state and federal regulatory schemes, because California does not necessarily require anything more than registration with the FDA before a facility can acquire a state license."[1]

As to the Commerce Clause, the Ninth Circuit found that Fusion IV "failed to establish that the requirements impose a 'substantial burden' on interstate commerce," and thus, there was no violation of the Commerce Clause.

The Ninth Circuit's decision was clear. It unequivocally upheld the lower court's ruling and agreed that California's regulatory oversight of outsourcing facilities is not preempted by the DQSA, nor do such state regulations violate the Commerce Clause's protections against state laws imposing unreasonable burdens on federal law.

The Future of State vs Federal Regulation of Outsourcing Facilities

The *Fusion IV v. Sodergren* case raised interesting arguments regarding federal preemption of state law and the concurrent state regulation of an FDA-registered outsourcing facility. But what will this mean for outsourcing facilities outside of California's jurisdiction and other state boards of pharmacy?

Over 35 states have regulations providing for a state license for facilities registered with FDA as an outsourcing facility. And given the clear ruling by the courts in California, it would not be surprising for these state boards of pharmacy to be emboldened in their future dealings with FDA-registered outsourcing facilities. Additionally, the states without licensure requirements for an FDA outsourcing facility may now consider implementing such laws. One thing is clear – state boards of pharmacy now have a federal appellate court opinion ruling that outsourcing facilities are subject to state oversight and regulation. ●

This article was written by Libby Baney, 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.

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

[1] Fusion IV v. Sodergren, *No. 19-55791, WL 3265221 (2020).*
[2] *Drug Quality and Security Act, 21 U.S.C. § 353b (2013).*
[3] *California Business & Professions Code § 4129 (2016).*
[4] *Cal. Bus. & Prof. Code §§ 4129, 4129.1, 4129.2 (2016).*

Telehealth Utilization Grows

as COVID-19 Transforms Regulatory Landscape

"Social distancing," "shelter in," and "flattening the curve" quickly became household phrases when the coronavirus disease 2019 (COVID-19) swept through the United States. The global pandemic strained and threatened to overflow the capacity of the health care system, making it urgent to contain the volume of COVID-19 cases. At the same time, health care systems – be it hospitals, community clinics, or pharmacies – needed a means to safely provide care and treatments to patients for health issues other than COVID-19. Telehealth and telepharmacy practice were expanded to meet some of this need. Advances in communication technology and access to a regulatory framework already in place for telehealth and telepharmacy gave patients continued access to care needed for both routine and urgent issues while allowing them to follow state and local orders to stay home.

Regulation Changes Increase Utilization

When the virus first began to spread in the US, patients and health care providers began utilizing telemedicine to limit in-person interactions. As part of a wave of regulatory changes spurred by the public health emergency, Centers for Medicare & Medicaid Services (CMS) directed an expansion of telehealth services that would allow doctors, pharmacists, and other health care providers to deliver a wider range of care to Medicare beneficiaries in their homes. Among other provisions, CMS waived limitations on the types of clinical practitioners that can furnish Medicare telehealth services. Before this change, only doctors, nurse practitioners, physician assistants, and certain others could deliver telehealth services for Medicare patients. With the adoption of the new rule, pharmacists were authorized to deliver these services to Medicare beneficiaries. In addition, CMS relaxed certain Health Insurance Portability and Accountability Act (HIPAA) requirements, intended to protect patient privacy, by issuing waivers that allowed greater utilization of available technologies to provide telehealth services during the pandemic.

These regulatory changes have helped to drive a massive increase of telemedicine use, at least in some areas. Illustrating the effect this has had, one study found that virtual urgent care visits at NYU Langone Health increased by nearly seven times, and non-urgent virtual care visits increased by more than 43 times the previous daily averages between March 2 and April 14, 2020. Of those telemedicine visits, 56.2% of urgent care and 17.6% of non-urgent visits were COVID-19-related. Additionally, data showed that telemedicine use was highest among patients aged 20 to 44 years old, particularly for urgent care. However, patients of all ages demonstrated use of the technology.

"Beyond the clinical benefits and more effective utilization of providers in very atypical circumstances, the changes instigated initially by the COVID-19 pandemic have likely irreversibly altered the position of telemedicine in the US health care system," noted the investigators of the study, published in the *Journal of the American Medical Informatics Association.*

This exponential growth does not appear to be limited to NYU. According to *US News and World Report*, an analysis of insurance claims in March 2020 showed that telehealth claims increased 4,347%. In the Northeastern US, the area hit hardest by the pandemic during that month, claims rose from 0.1% to 11.1%, an increase of 15,503%.

Telehealth and telepharmacy have enabled patients to access needed health care services while maintaining a lower risk of exposure to or inadvertent transmission of COVID-19. In fact, according to guidelines published by the Centers for Disease

Control and Prevention, expanding access to telehealth may have reduced the strain on health care systems and helped offices conserve personal protective equipment, which has been in short supply in many facilities since the pandemic began.

Although there are still questions about any long-term effect these temporary increases will have on the practice of pharmacy beyond the scope of the pandemic, there are benefits and conveniences associated with telepharmacy that some patients may be eager to continue. For example, patients with mobility issues or limited access to transportation may find that telepharmacy visits make the process of getting their medications much easier. Similarly, patients with chronic conditions may be able to simplify routine pharmacy visits via telehealth technology, with medications being mailed or delivered directly to their homes.

Is This the New Normal?

This unprecedented growth in telemedicine is expected to have a long-lasting effect on pharmacy, and on health care as a whole. However, there is some disagreement among industry professionals regarding what that transformation – the new normal – will look like.

Operation of the technology used to provide telepharmacy involves training patients, troubleshooting technological issues, and other information technology skills. Placing the burden of these tasks on existing pharmacy staff can lead to burnout and reduced patient satisfaction. These issues are explored in an April 2020 article published in *Pharmacy Times* in which the authors suggest that "hybrid pharmacy-telemedicine technicians" would be needed to sustain such services on a permanent basis. Such technicians would be technically trained workers who could act as care extenders by optimizing technical aspects of delivering a telepharmacy service while also providing patients with IT training and ongoing support, assisting in billing, and ultimately improving patients' ability to use the communication technology necessary for effective delivery of telepharmacy services.

Another barrier to pharmacies and other health care providers delivering telehealth services comes in the form of privacy regulations, particularly the rigorous requirements of HIPAA. The protections of HIPAA are intended to help safeguard patients' personal information, but since it became law in 1996, some communication technologies that could be used for telehealth do not meet all the security requirements. To provide more flexibility, the US Department of Health and Human Services and Office for Civil Rights announced in March 2020 that they would not impose penalties for HIPAA violations against providers working in good faith to provide telehealth using technologies such as Zoom, FaceTime, and Skype. Experts believe that this flexibility will be removed as the pandemic subsides, but see the potential benefit of permanently revising the law to allow greater access to telehealth services. The balance of patient demand for these services may encourage government agencies to consider allowing more permanent relaxation of regulations to meet that demand.

Telepharmacy is not always defined as communication between provider and patient. In the case of practicing pharmacy, telepharmacy technologies have been used to supervise pharmacy technicians. During the 2017 Task Force on the Regulation of Telepharmacy Practice, members expressed concern that compounding and drug dispensing that occurs in medical clinics and other facilities is not generally regulated by the boards of pharmacy. For example, some oncology clinics hire pharmacy technicians to compound and mix chemotherapy under the supervision of a remote pharmacist via telepharmacy. This supervision is not under the purview of boards of pharmacy, which may indicate there are insufficient regulations and public protections in place. As a result of this discussion, the task force recommended that NABP collaborate with its member boards to better regulate telepharmacy practice between pharmacies and medical clinics or other facilities that are not currently regulated by the board of pharmacy.

Potential Limitations

Despite the benefits of telepharmacy and other telehealth practices, there are some known limitations that may present obstacles to pharmacies that wish to utilize these technologies. These include situations in which in-person visits are more appropriate due to urgency, underlying health conditions, or the need to perform certain tasks. There are also concerns that remote health care may make it harder to address sensitive topics, especially in situations when patients are experiencing discomfort, or where privacy may be a concern. In addition, both health care providers and patients are sometimes limited by their access and comfort level with telehealth technologies.

Another major concern, particularly for pharmacies, involves interstate licensure. Because telehealth allows providers to work with patients who may be hundreds or even thousands of miles away, demand for licensure in multiple states may increase. In fact, during the COVID-19 pandemic, NABP issued over 51,000 NABP Passports to pharmacists seeking emergency licensure in multiple states to better serve patients during the crisis. Additional information on that service is available in the article "NABP's Experience Enabled Swift Development of Passport to Support Member Boards' COVID-19 Response" in the August 2020 issue of *Innovations*.

At the state level, at least 33 jurisdictions allow the practice of telepharmacy under varying conditions, according to the 2020 NABP *Survey of Pharmacy Law*. These policy differences include:

- Geographic restrictions, such as telepharmacy sites not being allowed within a certain radius of existing pharmacies
- Facility limitations, such as only allowing telepharmacy services in remote rural clinics, health centers, or health care facilities located in medically underserved areas
- Staffing and education requirements, such as allowing pharmacy technicians to work under the supervision of a licensed pharmacist connected via telepharmacy technology

Through the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, NABP offers model language to its member boards that may be used to help establish and clarify telepharmacy-related regulations, including definitions of telepharmacy technologies and practice, and a section detailing the practice of telepharmacy and all that it entails. This language was last updated according to recommendations from the Task Force on the Regulation of Telepharmacy Practice.

NABP will continue to monitor the effect of the COVID-19 pandemic on the practice of telepharmacy and provide up-to-date information to its members.

New Benefit Available to Boards Using the .Pharmacy Domain – NABP Can Handle Annual Renewals

Boards of pharmacy that utilize a .pharmacy domain name as a path to their board's website address now have an option to eliminate the administrative task of annual renewals. NABP can now handle .pharmacy domain name renewals on behalf of the boards of pharmacy, if they so choose.

Launched in 2014, the .Pharmacy Verified Websites Program is dedicated to patient safety and protecting the public health online by making it easier to recognize a verified and safe site by simply having ".pharmacy" at the end of the web address. To date, 34 boards of pharmacy, including those representing 10 Canadian provinces, have joined NABP in creating a safe online environment through the .Pharmacy Program. By taking part in this initiative, boards are helping to educate patients and pharmacists alike about the dangers of illegal online drug sellers. Nearly six years since its inception, the program is growing strong, and the .pharmacy domain is gaining recognition as a cyber "seal of approval."

Boards that do not currently have a .pharmacy domain name are encouraged to register one to set themselves out as an example for their licensees and a leader in patient safety online. Through the .Pharmacy Program, NABP can provide boards with a short, simple domain name that represents their jurisdiction at no cost, while allowing them to keep their current website address. While boards have the option to use the .pharmacy domain name as their primary web address, the .pharmacy domain name can also simply be configured to direct users to the board's official website safely and easily.

Boards interested in registering a .pharmacy domain name for the first time, or reregistering an expired domain name, may contact NABP at info@safe.pharmacy. More information about .pharmacy is available in the Programs section of the NABP website. ●

Why .Pharmacy Verification?

- Displays a "seal" of safety in a website address that cannot be faked by bad actors
- Raises consumer awareness about illegal online drug sellers that dispense unsafe products over the internet, endangering the public health
- Cements a board's reputation as a leader contributing to the protection of public health

.Pharmacy Annual Renewal Form

Boards interested in having NABP handle their annual .pharmacy domain name renewals may indicate their preference on the form found at *nabp.pharmacy/dotpharmacy-renewal/*.

NABP Accreditations and Verifications

NABP awarded a total of 53 accreditations and verifications from April 1 to May 31, 2020. The breakdown by program is as follows:

Drug Distributor Accreditation: 19
formerly known as Verified-Accredited Wholesale Distributors®

Digital Pharmacy Accreditation: 4
formerly known as Verified Internet Pharmacy Practice Sites®

.Pharmacy Verified Websites: 30

To see the names of businesses accredited and verified by NABP, visit the Programs section of the Association's website at *www.nabp.pharmacy.* ●

Compounding Pharmacy Information Sharing Network Begins With Pilot Project

Through an expansion of its information sharing network, NABP's e-Profile systems will soon accommodate the collection, management, and sharing of information related to compounding pharmacies in the United States. As announced in October 2019, the Association was awarded funding from Food and Drug Administration (FDA) to create a network with the goal of sharing critical information that will help reduce the risk of injury to patients from improperly compounded drug products.

Pilot Project Kicks Off With Three Main Goals

Development of the network began in June 2020 as part of a three-year pilot project that will extend into 2022. Implementation of the network is expected to begin in early 2021 with the collection of information from compounding pharmacies. Boards of pharmacy will have access to this information and the ability to supplement it. Subsequently, NABP will evaluate the usability of the network and the accuracy of the information collected during the pilot and present a final analysis to FDA. The pilot focuses on three goals:

- establish a novel information sharing network capable of collecting, managing, and exchanging data pertaining to state-licensed pharmacies engaged in human drug compounding;
- improve upon and increase the amount of information that will be made available to the state boards of pharmacy and FDA about compounding pharmacies that distribute interstate; and
- foster better and more targeted regulation and oversight of compounding pharmacies for the purpose of reducing risk to patients.

To expand the current information sharing network, NABP is revising its existing e-Profile system for licensees and NABP e-Profile Connect for boards of pharmacy by adding new fields and uploading capabilities (see the chart titled "NABP e-Profile System Changes for Licensees and Boards of Pharmacy" on page 8). Upon implementation, licensees and state boards will both be able to enter compounding data and related documentation into the system. Licensees will do so through their business e-Profile. Boards will be able to enter or annotate data in a pharmacy's facility e-Profile page, as well as enter complaints related to drug products compounded at the facility. These revisions will align with the reporting requirements of the FDA final standard memorandum of understanding (MOU) titled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [Insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration."

On May 14, 2020, FDA published a version of the final MOU for submission to the US Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. Once the version intended for use by FDA and the states is published, FDA will provide a one-year period for states to make any necessary legislative or regulatory changes so that they may sign the MOU. After that time, FDA has indicated that it will begin enforcing the 5% limitation on interstate distribution. Section 503A of the Federal Food, Drug, and Cosmetic Act limits distribution of compounded drugs outside the state by a pharmacist, pharmacy, or physician located in a state that has not entered into the MOU to 5% of its total prescription orders dispensed or distributed. States that sign the MOU agree to identify for FDA those pharmacies that are compounding human drug products and distributing inordinate amounts of such products interstate. The amount is considered inordinate if it is greater than 50% of the total number of prescription orders for compounded human drug products that were sent out of or dispensed from the facility in which the drug products were compounded during the identified calendar year. The boards will identify these pharmacies by using surveys or reviews of inspection records, data submitted to the information sharing network, or other available mechanisms.

The MOU does not require boards to enter data into the information sharing network. It does, however, allow boards to rely exclusively on the data that has been reported to the system by their licensees. Using that data, boards will be required to identify for FDA, on an annual basis, pharmacies that distribute inordinate amounts of compounded human drug products interstate.

State boards that do not sign the FDA MOU will still have access to the information sharing network. The information will be part of each pharmacy's facility e-Profile, which boards can currently access.

Pharmacies Encouraged to Self-Report

NABP will encourage pharmacies to voluntarily self-report information and will incorporate the requirement to input this data into the Verified Pharmacy Program® (VPP®) application and certain other accreditation program applications. To further incentivize pharmacies to enter their information into the system, NABP will offer each pharmacy the chance to receive a VPP inspection at no cost if they supply the requested information. The inspection will be adapted to serve the dual purpose of a traditional blueprint inspection and an audit for the pilot project.

Benefits for Member Boards

The expanded information sharing network will provide state boards of pharmacy with several benefits. It will give them a tool to report interstate compounding pharmacy information to other state boards of pharmacy and FDA. This tool will also organize and make available information and data needed to make informed oversight determinations.

The system will also enable boards to prioritize their limited resources to address the compounding pharmacies that pose the greatest risks to patients. Upon completion, the project will provide a tool to reduce risksto patients by fostering better and more targeted oversight of compounding pharmacies.

In addition, the system improves upon the information currently available to the state boards of pharmacy and FDA about compounding pharmacies, allowing the boards of pharmacy and FDA to gain a better understanding of the interstate distribution of compounded drugs. Boards will be able to uniformly track pharmacies that ship inordinate amounts of compounded drug products out of state and the kinds of compounded drug products that they are shipping and flag these pharmacies for FDA.

Further, the system will enable state boards to collect and share information about complaints concerning compounded drug products and compounding pharmacies. For example, upon a board's directive, the system will provide FDA with information about complaints of adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy and distributed interstate. It will also inform FDA if a board receives any complaints relating to human drug products compounded by a physician or regarding the distribution of any amount of human drug products compounded by a physician and distributed interstate.

For more information about the FDA grant, see the October 2, 2019 news release "NABP Receives FDA Funding to Develop Data-Sharing System for Improved Oversight of Compounding Pharmacies," in the Newsroom section of the NABP website. In addition, information about recent compounding pharmacy safety efforts by the boards of pharmacy is available in the article "Sharing Compounding Data, Regulators Strive to Increase Patient Safety," in the January 2020 issue of *Innovations*.

For more information about NABP's expanded information sharing network for compounding pharmacies, email the NABP Executive Office at ExecOffice@nabp.pharmacy. ●

NABP e-Profile System Changes for Licensees and Boards of Pharmacy

For Licensees	For Boards of Pharmacy
In their business e-Profile, pharmacies will enter the following information:	Through NABP e-Profile Connect, boards of pharmacy will be able to enter information regarding, and upload documents relating to, complaints of the following:

• the number of prescription orders for compounded human drug products that the pharmacy sent out (or caused to be sent out) of the facility in which the drug products were compounded during that same calendar year
• the number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which the drug products were compounded during that same calendar year
With this information, the system will calculate the total number of prescription orders for compounded human drug products that were sent out of or dispensed from the facility in which the drug products were compounded during that same calendar year
• the total number of prescription orders for compounded human drug products distributed interstate during that same calendar year
With this information, the system will calculate the percentage of compounded human drug products distributed interstate
• the number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year
• names of states in which the pharmacy is licensed
• names of states into which the pharmacy distributed compounded human drug products
• whether or not the compounded human drug products are being distributed without patient-specific prescriptions
	• adverse drug experiences and product quality issues relating to human drug products compounded at a pharmacy and distributed outside the state. Such information includes:
	  ○ name and contact information of complainant, if available
	  ○ name and address of the pharmacy that is the subject of the complaint
	  ○ description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
	  ○ board's or state agency's assessment of whether the complaint was substantiated, if available
	  ○ description and date of any actions the board or state agency has taken to address the complaint
	• adverse drug experiences and product quality issues relating to human drug products compounded by a physician and distributed outside the state. Such information includes:
	  ○ name and contact information of complainant/notifier, if available
	  ○ name and address of the physician who is the subject of the complaint/notification
	  ○ description of the complaint/notification, including a description of any compounded human drug product that is the subject of the complaint

NABP Quickly Shifted Gears to Meet Pandemic Challenges

When state governments across the country began ordering residents to stay at home and shelter in place during the early stages of the coronavirus disease 2019 (COVID-19) pandemic, NABP, like many other organizations, met an unprecedented challenge head on. The Association quickly mobilized to support member boards of pharmacy responding to the public health crisis by modifying and expanding certain NABP services and creating new channels of communication about the pandemic. To support these responses, NABP was able to quickly transition staff to a work-from-home model across all program and service areas.

NABP Staff Goes Remote

Illinois began to close in mid-March 2020, therefore the Association's headquarters, located in Mount Prospect, IL, became subject to state orders limiting gatherings and eventually requiring schools and businesses to close. Although NABP is qualified as an "essential business" under the governor's orders, the majority of employees were transitioned from working at NABP Headquarters to working exclusively from home by the end of March to better protect themselves and their families from the virus. Because there was already a basic infrastructure in place, the transition went very well. There were only minor disruptions as staff adjusted, and minor tweaks were made to workflows and electronic communication tools.

New Services Supported COVID-19-Related Regulation

That success was instrumental as it enabled NABP to continue to act as a valuable resource for its member boards with little to no disruption. In fact, during this transition, NABP was able to successfully develop and launch the NABP Passport service, which provided boards of pharmacy with an efficient means to grant temporary or emergency licensure to nonresident pharmacists, pharmacy technicians, interns, and pharmacies. As an added benefit, those seeking a Passport could apply for multiple states, thereby giving them the flexibility to help respond to the pandemic where they were needed most. Additional details on the NABP Passport service and its development are available in the August 2020 issue of *Innovations*.

NABP also held weekly phone calls with boards of pharmacy executive directors, staff, and members to provide updates, gather input on board challenges, and create an online forum for boards to share information and guidance. NABP Passport, Pearson VUE test site availability, pharmacy closures, pharmacy staff protocols, and COVID-19 testing were among the many topics discussed during these weekly calls. In addition, guest speakers from Food and Drug Administration, Drug Enforcement Administration, and other partner organizations were invited to provide updates on federal guidelines and other related information.

NABP Meetings Went Virtual

For the first time in the Association's history, the NABP Annual Meeting was held online. Plans for the traditional 116th NABP Annual Meeting originally scheduled to take place in Baltimore, MD, were quickly shifted due to travel bans, shelter-in-place orders, and other COVID-19 safety measures. In less than three months, NABP transitioned the meeting's three-day, in-person format to a one-day, virtual meeting format focused on conducting the Association's annual business of electing officers and discussing and voting on proposed Constitution and Bylaws amendments and proposed resolutions. The online meeting also featured an address from outgoing Executive Director/Secretary Carmen Catizone, the NABP treasurer's report, the annual award ceremony, and the report of the executive director delivered by incoming Executive Director/Secretary Lemrey "Al" Carter. In addition, the scheduled continuing pharmacy education sessions transitioned to webinars held at a later date. Though attendees certainly missed the networking opportunities, participants overall found the meeting engaging and valuable. The Interactive Executive Officer Forum on September 30, 2020, will also be held online

in a condensed format, and staff is working to create virtual ways for attendees to network and interact. In addition, NABP has begun offering webinars on topics that would have been included in the Annual Meeting agenda.

Providing Examination Seats in a Pandemic

NABP's examination programs met several challenges, particularly in the early months of the pandemic, when shelter-in-place orders were the most strict and widespread. NABP utilizes Pearson VUE testing centers to administer all of its examination programs and due to state-mandated closures, candidate scheduling was initially closed. The testing centers slowly reopened across the country, but with limited capacity and prioritizing those taking examinations for licensure in fields deemed essential. NABP worked with Pearson VUE and state governments to ensure that pharmacist candidates were among those deemed essential. As a result, candidates slowly began to have more access to schedule a test at a Pearson VUE site. As states opened up, and more Pearson VUE sites became available, this meant that pharmacy students and other candidates were positioned to schedule their tests. NABP worked with Pearson VUE to open additional testing sites.

Simultaneous to these efforts, NABP considered the feasibility of nontraditional alternate testing strategies, including offering a remote testing option for the Multistate Pharmacy Jurisprudence Examination® (MPJE®). After careful consideration, NABP chose not to pursue the remote option, and

instead upheld the requirement that the MPJE be administered at a Pearson VUE testing center. One factor in this decision was the result of test center openings and all the previous groundwork between NABP and Pearson VUE on making more seats available for those needing to take NABP examinations. In fact, at least 420 testing sites – 138 more sites than last year – are now available to candidates across the country.

Increased Member Communication

NABP also broadened its communication avenues in an ongoing effort to support its member boards during the COVID-19 pandemic. Most visibly, NABP launched a Coronavirus Updates section on its website, to relay important updates about NABP programs as well as vital information pertaining to pharmacy and pharmacy practice. For boards of pharmacy, the web page included a state-by-state compiled chart of emergency and temporary orders, policies, board statements, and results from a board of pharmacy survey related to remote processing. In addition, NABP provided boards with information regarding preemption of state and local legal requirements related to the US Department of Health and Human Services Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act. For NABP customers, information was posted on testing center availability and updated requirements, changes to exam and accreditation processes, and a list of states allowing inspections during the pandemic. Also housed in this section is the web page "What Pharmacists Should Know," which provided a list of resources on key topics such as controlled substances, emergency use authorizations, and personal protective equipment. In addition, *NABP e-News* was temporarily expanded to twice a week distribution to allow for more timely reporting on vital COVID-19-related information during the pandemic. NABP continues to utilize its Twitter, Facebook, and LinkedIn accounts for timely COVID-19 pandemic updates.

Through close collaboration with its member boards and partner organizations, the Association has navigated the challenges and obstacles posed by the COVID-19 pandemic thus far. As we are all well aware, more pandemic-related challenges lie ahead, and the Association remains ready and able to continue assisting its member boards during this crisis. ●

New Online CPE Series Will Keep You Up to Date

Live and recorded webinars on topics ranging from technician roles to cannabidiol (CBD) now offer more educational opportunities for NABP members. These complimentary online courses are eligible for Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) credit.

The live webinar series kicked off on June 16 with a two-part series titled "Virtual Educational Poster Session: Uniting to Protect the Public Health." Each part featured educational posters that were originally intended to be presented during the 116th NABP Annual Meeting in Baltimore, MD, before the meeting was moved to a virtual format. Seventeen board of pharmacy and school and college of pharmacy representatives presented nine poster displays related to working together to educate on pharmacy practices to further protect the public health. Presentations included "Preventative Measures for HIV Vulnerable Patients in the LGBTQ+ Community," "Maximizing HPV Vaccination Rates Through Community Pharmacist Utilization," "Standard of Care: A National Three-Profession Survey of Health Care State Agencies," and "Expanding the Roles of Pharmacy Technicians: Why Not North Dakota?," among others.

The webinar "The CBD Explosion – Keeping Out of Harm's Way," presented on July 15, described the pharmacological effects of CBD on various human physiological systems; discussed how CBD may interact with other drugs; and explained the regulatory framework of CBD. The August webinar (the only 2020 webinar not eligible for CPE), presented on August 19, focused on cybersecurity.

The educational poster sessions, CBD, and cybersecurity webinars, in addition to an NABP conflict of interest webinar that was held in March, are now available on demand in the Publications section of the NABP website under Educational Programs. All of the 2020 CPE live webinars will also be offered as home study activities that are eligible for ACPE-accredited CPE credit. The home study versions will be released about three weeks after the live versions. Recordings of the live webinars are not eligible for CPE credit.

Tentative topics for the live and home study webinars slated for fall 2020 are a discussion of legal cases and decisions relevant to board attorneys in September and a look at pharmacist-provided, medication-assisted treatment for patients diagnosed with opioid use disorder in October.

Promotional emails will be sent to board members and other stakeholders prior to live webinars with information about the topic, scheduled speakers, and CPE credit information (if applicable). Links to a registration form and an ACPE Activity Information Guide will also be provided. ●

Indiana Board of Pharmacy

Number of Board Members
6 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors
7

Rules & Regulations Established by
Board of Pharmacy

Number of Pharmacist Licensees
11,497

Number of Pharmacies
1,370

Number of Wholesale Distributors
409

Donna S. Wall, PharmD, RPh

Member, Indiana Board of Pharmacy

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

I was appointed to the Board in 1994 as a hospital pharmacist representative. My term on the Board will end at the end of August 2020, but I will continue to serve on the Board until replaced.

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

Ask questions of everybody involved with the board. Get an idea of what is expected of a board member and what you can and cannot do. Arm yourself with that information. Also, spend time researching and reading the laws in your state. The language that the laws are written in is a little different, so it may take you a while to understand them. Discuss the laws with other board members. Everything you do as a board member must be based on the law.

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

After the March 2020 meeting, the Board minimized its activities due to the coronavirus disease 2019. The Board has continued to have virtual meetings for emergency items or functions required by law (licensure and hearings). All other Board work, like committees and discussion items, was halted. The August meeting was the first time that the Board had an opportunity to discuss other topics and to start addressing issues surrounding technicians, white bagging, and issues confronting current practices.

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

Because the Board is under the Indiana Professional Licensing Agency, everything it does has to go back to the governor's office. Anything that the Board would like to create a regulation on must undergo an 18-month approval process. At the end of the process, the governor's office will review the proposed regulation and determine if it will go into law.

What advice would you give to a new board member?

My advice is to never forget that you are accountable to the public for patient safety. Learn as much as you can about safe practice and make educating yourself a lifelong, ongoing commitment. Knowing what is going on in the practice of pharmacy – good and bad – makes you a better board member. It is also important to ask questions and develop confidence in yourself to express your opinions. That is the only way the Board has really good, solid conversations.

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

I was NABP president from 2003–2004 and have also served on many task forces and committees. Since 1994, I have missed one annual meeting and a few district meetings. Important issues – many of which go beyond the normal work environment – are discussed at these meetings. I have had so much exposure to people and information that I feel made me a better board member and a more knowledgeable and contributing pharmacist to my employer. I have also met lots of new people who I would never have had the opportunity to meet and to learn what is happening in their lives, in their states, and at the national level. To me, these meetings are very enriching opportunities that not only helped me grow and become a better pharmacist and a better board member, but, hopefully, a better person. ●

Idaho Requires Mandatory PDMP Checks, Launches Data Dashboard

Beginning October 1, 2020, Idaho will require all prescribers to check the prescription drug monitoring program (PDMP) and review the previous 12 months of data regarding a patient's prescription history prior to issuing the patient a prescription for an opioid analgesic or benzodiazepine listed in Schedules II, III, or IV. Exceptions to this requirement include patients receiving treatment in an inpatient setting, patients being treated at the site of an emergency or in an ambulance, patients in skilled nursing facilities or under hospice care, or if the prescription is for three days or less.

The Idaho State Board of Pharmacy is also implementing a new Tableau reporting program that will allow prescribers to monitor their use of the PDMP. The report will be generated based on the user's personal Drug Enforcement Administration (DEA) number. If the user has more than one DEA number, there will be a report for each number. This report will allow each prescriber to ensure that they follow the mandatory checking PDMP statute.

West Virginia Rule Changes Impact Pharmacy Practice

The West Virginia Board of Pharmacy implemented a number of rules that impact the practice of pharmacy. Such changes include the following:

- Transfers of prescriptions from one pharmacy to another can now be legally done for non-controlled prescriptions by pharmacy interns. Controlled medication prescription transfers must still be completed between two pharmacists, as required by DEA.
- All records in West Virginia pharmacies are required to be kept on site for one year, then may be kept off site in a Health Insurance Portability and Accountability Act-compliant manner for years two through five. Depending on the type of records, the pharmacy would have had a varying time frame to produce the necessary records. These time frames have all been standardized to 72 hours for record production, regardless of the record type.
- The white lab coat is no longer a legal requirement in West Virginia. Wearing a name tag identifying the individual and showing his or her job designation remains a requirement for all pharmacy employees. The only individuals who may wear a white coat in the pharmacy are the pharmacists or pharmacy interns.
- Emergency dispensing rules have been updated. If a pharmacist is unable to obtain a refill authorization from a health care professional who issued the prescription and the pharmacy at which the pharmacist works has a record of the prescription for the drug in the name of the patient who is requesting it, a pharmacist may dispense an emergency supply of a prescription drug of life-sustaining medication or continue therapy for a chronic condition of the patient, when, in the professional judgment of the pharmacist, failure to dispense could result in harm to the health of the patient. An amount not to exceed a 30-day supply or the standard unit of dispensing of a non-controlled substance (CS) may be provided to the patient as demonstrated by records maintained by the pharmacy. An amount not to exceed a 72-hour supply of a Schedule III, IV, or V prescription may be provided to the patient as demonstrated by records maintained by the pharmacy. A pharmacist shall not dispense a particular drug to a patient as an emergency supply more than once in any 12-month period.
- The daily required "printout" of all refills completed and signed within 72 hours has been deleted from the regulations. A verified record must now be retrievable within 72 hours of when the refill was dispensed when it was requested.

Additional rule changes that went into effect on March 6, 2020, are available in the Board's June 2020 *Newsletter*, which can be accessed via the Boards of Pharmacy section of the NABP website.

Wyoming Updates Prescription Tracking Program Rules

The Wyoming Legislature passed and Governor Mark Gordon signed House Bill (HB) 0085, which amends the requirements for using the prescription tracking program by requiring a practitioner to search the prescription tracking program as needed when issuing non-opioid prescriptions based on best practices for CS other than opioids, and every three months for prescribed opioids for as long as the opioids remain a part of the patient's treatment. The act provides the Wyoming State Board of Pharmacy with rulemaking authority related to the prescription tracking program and specifies that the rules may apply to practitioners, pharmacists, and others who are authorized to use the tracking program. HB 0085 also authorizes the Board to survey the use of the prescription tracking program and report inappropriate use to the professional licensing board of any offending practitioner. ●

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

Federal Pilot Program May Help Stop Online Availability of Unapproved Opioids

Food and Drug Administration (FDA) and the National Telecommunications and Information Administration (NTIA) have launched a 120-day pilot program to help reduce the availability of unapproved opioids illegally offered for sale online. Under the program, FDA will notify internet registries that are participating in the pilot when a company does not adequately respond to a warning letter within the required time. These registries will review FDA's notifications and assess whether to take voluntary action against the company, which may include domain name suspensions or blocks. NTIA will work with the registries to assess the impact of the program.

On June 17, 2020, NABP responded to the launch of the pilot program in a letter to FDA Commissioner Stephen Hahn, MD. The letter describes the program as being "consistent with NABP's longstanding effort to urge internet intermediaries, registries and registrars, to implement policies that could significantly protect patient safety upon notification from authoritative sources." The letter also refers to NABP's most recent *Rogue Rx Activity Report*, published in May 2020, which details how rogue online pharmacies use crises such as the coronavirus disease 2019 (COVID-19) pandemic to market potentially dangerous products.

The NABP report is available in the Publications and Reports section of the NABP website under Program and Committee Reports. More information about the pilot program is available in an FDA news release at *www.fda.gov/news-events/press-announcements/federal-government-announces-new-pilot-program-help-stop-illegal-availability-unapproved-opioids*.

NABP Urges Congressional Leaders to Continue Supporting Federal Programs to Combat Both Opioid Epidemic and COVID-19

Emphasizing the role that pharmacists and state boards of pharmacy play in protecting the public health, NABP has sent a letter to congressional leadership urging Congress to continue supporting robust investments in federal programs to combat both the ongoing opioid epidemic and COVID-19 pandemic. Signed by NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, the letter expresses specific concern about reports that opioid overdoses and abuse may be increasing during the pandemic.

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

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

The full letter can be accessed in the Newsroom section of the NABP website under News.

FDA Revokes EUA for Chloroquine and Hydroxychloroquine for Treatment of COVID-19

FDA has revoked the emergency use authorization (EUA) for the anti-malaria drugs chloroquine and hydroxychloroquine to be used for treatment of COVID-19 under certain conditions. Citing ongoing analysis and results of recent clinical trials, FDA has determined that the drugs are unlikely to be effective in treating COVID-19, and that the risk of serious adverse events outweigh the potential benefits of using the drugs to treat the disease.

"While additional clinical trials continue to evaluate the potential benefit of these drugs in treating or preventing COVID-19, we determined the emergency use authorization was no longer appropriate. This action was taken following a rigorous assessment by scientists in our Center for Drug Evaluation and Research," said Patrizia Cavazzoni, MD, acting director of FDA's Center for Drug Evaluation. "We remain committed to using every tool at our disposal in collaboration with innovators and researchers to provide sick patients timely access to appropriate new therapies. Our decisions will always be based on objective and rigorous evaluation of the scientific data. This will never change."

Early data has demonstrated that the economic downturn, prolonged periods of social distancing, and overall uncertainty of COVID-19 have caused an increase in opioid-related mortality in at least 30 states.

Role of Pharmacists Emphasized in Surgeon General's Report on Smoking Cessation

Pharmacists can play an important role in helping patients quit smoking, as highlighted in the Surgeon General's 2020 report on smoking cessation. The report advises pharmacists to recommend the use of both prescription and over-the-counter medications, when appropriate. In addition, the report notes that authorizing pharmacists to prescribe cessation therapies and allowing them to bill for interventions could increase the number of successes.

According to the American Pharmacists Association, pharmacists in Colorado, Idaho, Indiana, and New Mexico are currently authorized to prescribe all cessation medications. Pharmacists can also provide behavior counseling resources, and should continually support and follow up with patients to help prevent relapses.

The Surgeon General's report can be accessed at *www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf*. ●

NABP
National Association of Boards of Pharmacy

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UPCOMING EVENTS

NABP Interactive Executive Officer Forum
September 30, 2020 | Virtual Meeting

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

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

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