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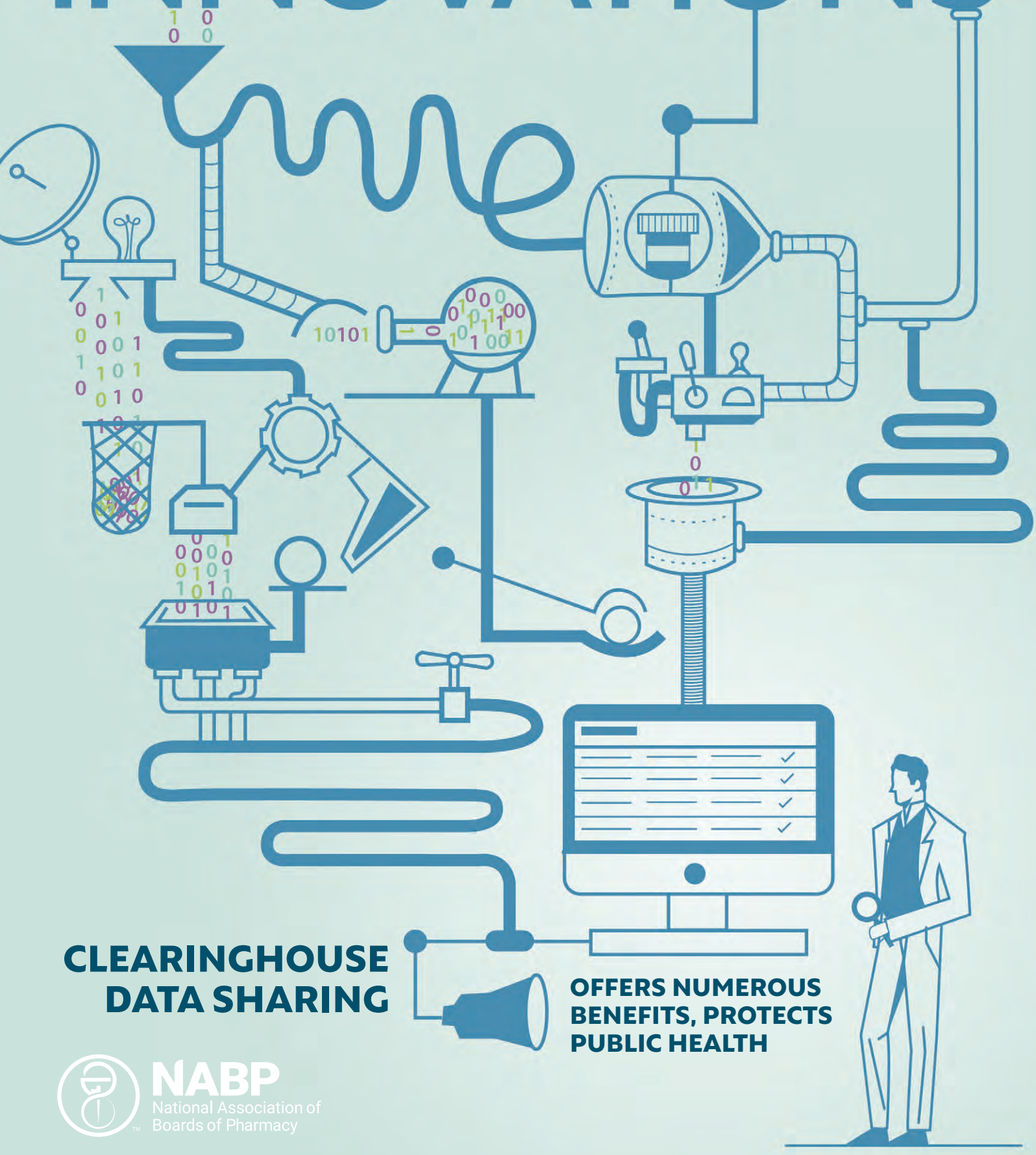
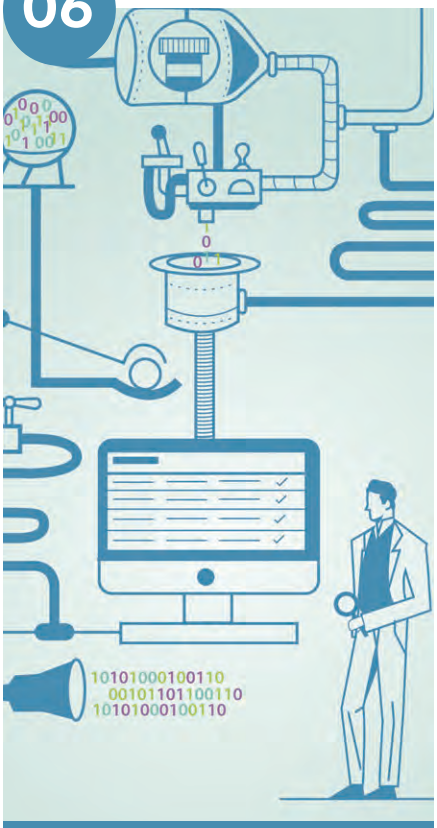
# INNOVATIONS



## CLEARINGHOUSE DATA SHARING

## OFFERS NUMEROUS BENEFITS, PROTECTS PUBLIC HEALTH

NABP
National Association of Boards of Pharmacy




**Feature News**
Disciplinary Data Sharing Through NABP Clearinghouse Offers Numerous Board Benefits, Protects Public Health

**Association News**
NABP Inspectors Identify Dangerous Scheme Involving Over-the-Counter Insulin Products




# iNNOVATiONS

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

NABP
National Association of Boards of Pharmacy

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

# Fellow Members,

We pharmacy regulators know all too well that if there's a will, criminals can find a way. Rapid advances in technology, social media sites, and the long-standing effects of the COVID-19 pandemic have made it easier for bad actors to take advantage of vulnerable consumers and threaten public health. In this issue, we delve into some of these continued threats, including a recent scheme involving diverted nonprescription insulin products that was encountered by NABP surveyors during a routine visit to a pharmacy.

The online pharmacy landscape also continues to threaten patient safety, with rogue websites and social media accounts marketing fake, substandard, and counterfeit prescription medications. As such, NABP educates patients about the risks of buying medication online and, through its accreditation and verification programs, provides patients with tools to help them easily identify safe online pharmacies and pharmacy-related businesses.

As part of this initiative, we are pleased to announce the launch of the newest consumer campaign, which focuses on the dangers of buying medication from unlicensed internet pharmacies and social media sites. This year, the campaign places a family's devastating loss at the forefront with the story of Ed and Mary Ternan, who lost their son Charlie to a fake prescription pill purchased through social media in 2020. We are honored and grateful to have partnered with Ed and Mary, who are founders of the nonprofit charity Song for Charlie. Throughout the campaign, we encourage all boards to actively participate in connecting with consumers about these dangers. There are social media posts, images, video links, and more available in a social media kit that you can all access. More information about the campaign is available on page 5.

This issue also focuses on one of the largest responsibilities that boards of pharmacy have in public health protection – licensure. It is up to us, the boards of pharmacy, to screen for licensees who have failed to uphold state and federal rules and regulations and put patients' safety at risk. We strongly encourage boards to keep up with timely reporting of disciplinary actions to the NABP Clearinghouse as a means to further combat these risks. With many licensees holding licenses in multiple states, keeping the Clearinghouse updated in a timely manner is vital to determining whether a current or prospective licensee is eligible to safely practice pharmacy or operate a licensed facility. I wish to personally thank those board of pharmacy staff members who dedicated their time to sharing their experiences using the Clearinghouse and the benefits it has offered them. For more information on their experiences, see page 6.

Please know that NABP is aware of the many resource challenges our member boards face in their day-to-day business. Feel free to reach out to NABP staff with any challenges you may be facing in reporting to the Clearinghouse as we likely have solutions that can help.

The NABP Interactive Forums are another great resource for connecting with fellow members and NABP staff about challenges you may be experiencing in your pursuit of public health protection. Make sure to save the dates for the three upcoming forums taking place in person this fall/winter in Northbrook, IL. Dates for these events are available in the Meetings section of the NABP website. Invitations for the forums will be sent to the executive officers soon. I'm looking forward to these in-person discussions and working on solutions with all of you.

Sincerely,

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

# The Future of Telehealth and the Ryan Haight Act Post-Pandemic

A year into the pandemic, the coronavirus disease 2019 (COVID-19) has radically changed our health care system – from the pace at which new drugs come to market to the way patients access health care and medications. Arguably one of the most dramatic shifts has been the major increase in telehealth usage and the expansion of health care services that can be provided using the internet. According to a Centers for Disease Control and Prevention analysis, the number of telehealth visits increased by 50% during the first quarter of 2020, compared with the same period in 2019. And, generally, telehealth has been well received. In addition, a study recently published by the COVID-19 Healthcare Coalition found that of over 2,000 patients who participated in at least one telehealth visit during the pandemic, the majority found the experience overwhelmingly positive, with 79% responding that they were satisfied with their telehealth visit and 73% expecting to continue using virtual health care services beyond the pandemic. Just over half of those patients (51%) were prescribed a medication during their virtual visit and almost all (92%) found the process of obtaining their prescription easy.

Whether those telehealth services will continue to be a readily available option for many patients largely depends on what actions Congress and government agencies take as we transition into a post-pandemic world. Many of the laws and regulations enacted in response to the COVID-19 pandemic were provisional and set to expire with the conclusion of the federal public health emergency (PHE). While the PHE is not expected to end this calendar year, Congress has already started to explore which laws and regulations to make permanent. Much of the federal attention has been on telehealth reimbursement for certain services through federal programs like Medicare. However, both members of Congress and federal agencies, such as the Office of National Drug Control Policy, have also been contemplating updates to the law that enables providers to remotely prescribe controlled substances (CS) using telehealth.

## Telehealth Involving Controlled Substances: the Ryan Haight Act

At present, prescribers of CS operate under strict federal and state requirements for how and under what circumstances they can issue prescriptions to new and existing patients. Federal requirements for CS are outlined in the 1970 Controlled Substances Act (CSA), which granted Drug Enforcement Administration (DEA) the authority to establish regulations promulgating CSA requirements pertaining to the production, prescribing, and distribution of CS, and to enforce violations. In 2008, Congress also added several new provisions to the CSA in passing the Ryan Haight Online Pharmacy Consumer Protection Act. The act was named in remembrance of Ryan Haight who, at 18 years old, died of an overdose of a combination of painkillers that had been prescribed to him online by a doctor who had never met him in person and did not conduct an adequate medical evaluation. The painkillers were delivered by an online pharmacy that was aware of the physician's dangerous prescribing habits. As the name suggests, the act was designed to impose legal requirements for dispensing CS through the internet, including by way of "rogue" online pharmacies.

## DEA Authority to Implement 'Practice of Telemedicine' Exemptions

Recognizing that there is value in allowing licensed practitioners to prescribe CS using the internet, the Ryan Haight Act outlined several circumstances that would qualify for a "practice of telemedicine" exemption, thereby allowing practitioners to prescribe CS without an initial in-person visit. However, given the rapid evolution of telemedicine over the last decade – especially in the last year – the "practice of telemedicine" as implemented by DEA under the Ryan Haight Act is narrow and outdated, requiring the patient to be physically located in a state-licensed hospital or clinic, or in the presence of another DEA-licensed practitioner, to be prescribed CS.

An additional exemption available to DEA under the law is for the practice of telemedicine performed by a practitioner who has obtained a special registration from the DEA administrator. The original Ryan Haight Act suggested DEA would eventually issue regulations effectuating this provision. Congress reiterated the need for DEA to allow for the practice of telemedicine as part of the SUPPORT for Patients and Communities Act in 2018. Yet, to date, DEA has not acted. Thus, even before the pandemic, DEA had – and continues to have – the legal authority to allow expanded telemedicine prescribing of CS.

## Ryan Haight Flexibility During the COVID-19 Pandemic

During the COVID-19 pandemic, DEA has exercised its authority to waive the in-person visit prescriber requirement under another exception for PHEs. Starting in March 2020, DEA authorized providers to issue prescriptions for CS regardless of the location of the patient and without first conducting an in-person examination, provided that all of the following conditions are met:

- the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice;
- the telemedicine communication is conducted using an audiovisual, real-time, two-way interactive communication system; and
- the practitioner is acting in accordance with applicable federal and state laws.

Thus, in essence, the pandemic has forced DEA to embrace telehealth technology and the new channels to health care access that have exponentially evolved and expanded since the Ryan Haight Act was first passed in 2008. What remains to be seen is whether

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the use of these services over the last year has also introduced weaknesses that are now being exploited in what was previously a completely "closed system" for the manufacture, distribution, prescribing, and dispensing of CS, and whether any negative consequences are overshadowed by increased access to services.

Advocates for a DEA-established telehealth provider special registry system contend that allowing telemedicine providers to continue to prescribe CS without a prior in-person medical evaluation is critical to patients' access to care, especially for addiction treatment and child and adolescent mental health care. Some public health experts argue that DEA and state legislatures should embrace permanent changes to the Ryan Haight Act, but only for select medications. In a report conducted by the George Washington University Regulatory Studies Center, researchers argue that DEA and the Substance Abuse and Mental Health Services Administration should execute their legal authority to extend flexibilities after the PHE by waiving the in-person visit requirement for providers issuing buprenorphine prescriptions to treat opioid addiction. They contend that easing restrictions will allow patients in rural communities who lack access to nearby opioid treatment centers to receive care and improve compliance. Real-world data demonstrating the effectiveness of DEA's pandemic policy changes will take years. Unlike with other telehealth services, the extent of providers' adoption of telehealth to prescribe CS during the pandemic is still largely unknown. A preliminary study conducted by RTI International has shown that while substance use disorder (SUD) providers embraced the adoption of telehealth for outpatient services (97%) and group counseling (77%) during the COVID-19 pandemic, far fewer used it to prescribe buprenorphine (17%) and other medications (16%).

## Do Not Forget State Laws

Adding complexity, providers need to also comply with state law requirements. Pre-pandemic, state laws varied as to whether they allowed, prohibited, or were silent on the remote prescribing of CS without a prior in-person medical evaluation. Further, some states have prohibited online prescribing of CS *even if* there has been a prior in-person consult. During the pandemic, states embraced the expanded use of telehealth and many are already moving to make the temporary provisions permanent. For example, in July 2020, New Hampshire passed a law eliminating the requirement for an in-person exam prior to a virtual visit for providers treating patients with SUD. And in January 2021, Florida lawmakers in both the state's House and Senate introduced bills that would permanently allow the prescription of CS via telemedicine.

## Forecasting the Future of Telehealth for Controlled Substances

Over the coming months, as Americans see the light at the end of the pandemic tunnel, and the state and federal landscape continues to evolve, policymakers in Congress, across federal agencies, and in statehouses will determine the future of health care and whether Americans will be allowed to continue to access care and prescriptions virtually. While CS must be handled with care and only accessed when clinically appropriate, much can be done to update federal rules to ensure that they are not overly restrictive and limiting access to legitimate care. ●

*This article was written by Libby Baney, JD; Jillian K. Brady, MS; and Megan S. Herber, MPH, 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.*

## North Carolina Board of Pharmacy

**Number of Board Members**
5 pharmacist members and 1 public member

**Number of Compliance Officers/Inspectors**
13

**Rules & Regulations Established by**
Board of Pharmacy

**Number of Pharmacist Licensees**
17,009

**Number of Pharmacies**
3,466 (in-state)

**Number of Wholesale Distributors**
Wholesale drug distributors are not regulated by the Board.

# Krystal Brashears Stefanyk, CISCI

Director of Inspections, North Carolina Board of Pharmacy

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

I was an inspector for nine years and associate director of investigations and inspections for three years. I have been director of inspections for the past three years. Prior to joining the Board, I was in college, obtaining a degree in criminal justice and also working as a pharmacy technician.

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

One of the most important skills to have is logical thinking. The best class I ever took in college, which has helped me every day in my career, had nothing to do with criminal justice or pharmacy. It was a deductive logic class. That class taught me to look at several different components at the same time and separate what was important from what was not important to get a complete picture of a situation. To me, that describes pharmacy inspections and investigations perfectly. As an inspector, you must be able to look at everything that is going on in a pharmacy in a very detailed manner and put those details together for a complete picture of how the pharmacy is operating.

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

We have been focusing on compounding over the last several years. A lot of common issues that we see on the compounding side are lack of documentation, a need for staff training, and gaps in knowledge of the standards of compounding. On the retail pharmacy side, which is a majority of our pharmacies, we also see a lack of documentation. In addition, we see a lot of pharmacies that are overwhelmed and filling a lot of prescriptions. This can lead to issues such as cluttered shelves and disorganization.

### In North Carolina, do inspectors also conduct investigations for other health regulatory boards?

We work in conjunction with other regulatory boards if it is related to pharmacy and whatever professional practice a regulatory board is investigating. For example, if an investigation involves a dispensing physician or nurse practitioner who was dispensing, we work those cases with the Medical Board or Board of Nursing, respectively. Those investigations are pretty straightforward, and we are there to look at the dispensing side.

We also work a lot of cases with Drug Enforcement Administration (DEA). Those cases can be pretty complicated. I have worked an investigation involving a large volume of diversion, where over 100,000 dosage units were taken out of a pharmacy. A pharmacist and three technicians – who were working independently of each other – were diverting for their own uses. That was a very interesting case because it took many different twists and turns. I worked with several agencies, local law enforcement, the North Carolina State Bureau of Investigation, and DEA.

### What advice would you give to a new board inspector?

Ninety percent of the time our job is to educate and teach our pharmacists and pharmacy staff how to get into compliance. The advice that I give to new inspectors is to take the time to learn the rules and regulations and the meaning behind those rules and regulations, so they can be ready to educate our pharmacists and pharmacy staff. There is a time and place to do what we need to do if there is a disciplinary matter that needs to be addressed immediately, but for the most part, 90% of our job is educating and teaching. ●

# NABP Educates Consumers on Dangers of Rogue Online Pharmacies

Educating consumers about the dangers of buying medicine from unlicensed pharmacies online and through social media sites is the focus of NABP's 2021 consumer awareness campaign. NABP has found that patients continue to buy medicine online because they think it is easy, cost-effective, and safe, and are unaware of the dangers of rogue websites and social media accounts selling fake, substandard, and counterfeit prescription medications online. These unlicensed sites often sell unapproved or fake medications that may contain toxic fillers such as drywall, rat poison, sawdust, or deadly amounts of fentanyl. The various elements of the campaign seek to educate patients on these dangers, and provide safe alternatives.

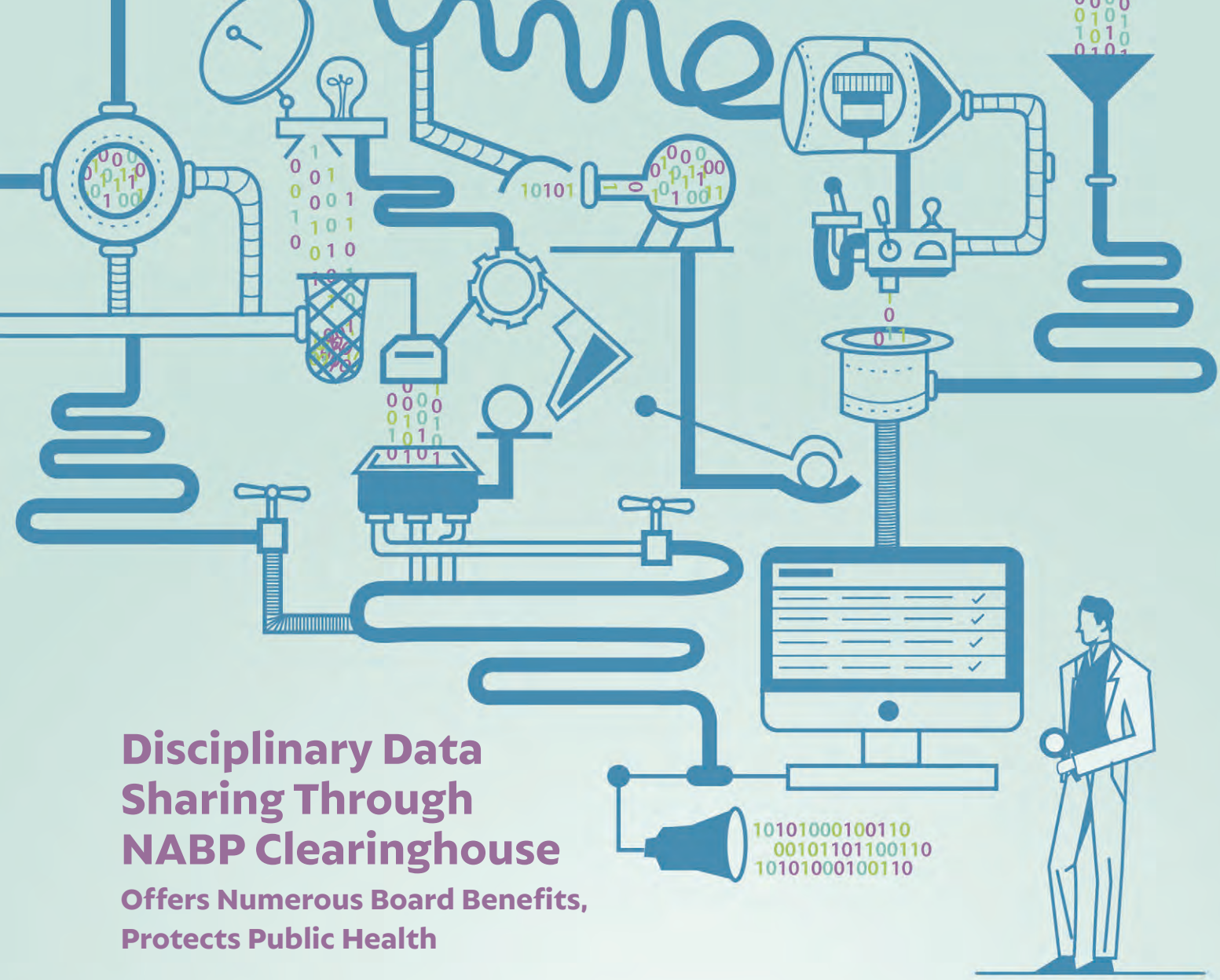
## Campaign Overview

Throughout the campaign, NABP urges patients to visit its consumer website at *www.safe.pharmacy* to use its free search tool to check whether the online pharmacy they are using is safe. Sites that have been verified through NABP's .Pharmacy Verified Websites Program or have earned NABP's Digital Pharmacy Accreditation will display as "Verified," and the campaign urges consumers to use these resources when buying medication online. Sites that appear to be out of compliance with NABP patient safety and pharmacy practice standards, or applicable law, will display as "Not Recommended."

This year's campaign includes television and radio public service announcements (PSAs) that feature Ed and Mary Ternan (pictured above), founders of the nonprofit charity Song for Charlie (*www.songforcharlie.org*), who share how they lost their son to a fake prescription pill purchased through social media in 2020. The television and radio PSAs are being sent to broadcast stations around the country, are available on NABP's YouTube channel, and will be used in various digital advertising campaigns throughout the year. Also, in August 2021, Ed Ternan and NABP President Caroline D. Juran, BSPharm, DPh (Hon), will be interviewed by several local and national television and radio stations during a satellite media tour. ●

### You Can Help Share the Buy Safely Message

Boards of pharmacy interested in sharing the message about safe ways to buy medications online are encouraged to use the sample social media posts, images, video links, and sample articles included in the social media kit that NABP provided to all board executive officers. The kit is available on the NABP website at *https://safe.pharmacy/resources*.




# Disciplinary Data Sharing Through NABP Clearinghouse

## Offers Numerous Board Benefits, Protects Public Health

**When pharmacists face disciplinary action, they are required to disclose that information to the boards of pharmacy in jurisdictions where they are licensed. However, some licensees neglect to do so in a timely manner. For this reason, it is possible for licensees who have faced serious repercussions for professional misconduct to continue to operate in other states without those states knowing. This has long been an issue with licensed professions managed at the state level. In pharmacy, NABP helps by providing its member boards with access to alerts created by the NABP Clearinghouse, a national database of disciplinary information and other important licensee records submitted by the Association's member boards.**

**These records serve as a vital resource in helping boards make the best-informed decisions about licensure for all applicable licensees. However, to be most effective, these records must be submitted by the boards in a timely manner.**

### NABP Clearinghouse Review

As of summer 2021, there are more than 91,000 records currently in the NABP Clearinghouse. These records are submitted by member boards of pharmacy on all actions taken against all license holders, including wholesale distributors, pharmacies, pharmacists, pharmacy technicians, and interns. NABP has estimated that about 1% of the country's pharmacist population has at least one record in the database. When a new record is submitted by one state against a licensee who is registered in other states, the other states receive an alert that contains the report and any other available information about the action. The receiving states

or jurisdictions may then determine if any action needs to be taken by their board as well. Making member boards aware of disciplinary actions taken against licensees who may be registered in multiple states is vital to protecting the public health.

The reports generated by the NABP Clearinghouse can also be used for tracking less critical but still important licensee data. Notably, this includes whether licensees are current on their continuing pharmacy education (CPE) requirements. While CPE compliance is rarely a disciplinary issue, licensee continuing education status is still something that some states and individual boards prefer to track and record, when appropriate.

The NABP Clearinghouse also plays a vital role in license verification, which is required by some NABP services such as the Electronic Licensure Transfer Program® (e-LTP™). When verifying a license through the e-LTP process, NABP manually checks the database for any disciplinary records. As with disciplinary alerts, these checks help boards make well-informed licensure decisions.

"The biggest advantage of using the Clearinghouse is getting a clear disciplinary history of North Carolina licensees or permit holders who are located in other states," said Cindy Parham, CISCI, an enforcement specialist with the North Carolina Board of Pharmacy. "Reports give us a clear picture of disciplinary history during facility applications with the state. This also helps us to weed out the bad actors before they become licensed or permitted."


**Boards of pharmacy now have the option to report "zero" when they have no disciplinary actions to submit on individuals or organizations. Contact clearinghouse@nabp.pharmacy for more information.**

## Timely Reporting Is Vital

NABP has long considered its Clearinghouse database to be extremely important to the shared mission of the Association and its member boards of pharmacy in protecting the public health, particularly in situations that involve dangerous misconduct and/or severe disciplinary actions. In fact, because timely reporting is essential to maintaining the integrity and value of the database, NABP's Constitution and Bylaws require member boards to report their disciplinary actions to the Clearinghouse as part of their membership to the Association.

Unfortunately, reporting is sometimes delayed in some states. When other priorities take precedence, such as the coronavirus disease 2019 pandemic, it may seem less important to devote resources to submitting disciplinary reports. However, the boards of pharmacy may want to keep in mind how vital this data can be for other states.

Compliance Analyst David Meryman, PTR, and Enforcement Program Manager Robert Rivera, PTR, of the Texas State Board of Pharmacy make regular use of the reports received by the NABP Clearinghouse. "My advice to anyone who would be using these records is to review the reports routinely and not let too much time elapse before acknowledging incoming reports," Meryman stated.

Meryman also noted, "I would encourage participation from states that may not think they have the resources or manpower. In Texas, we have found that the process is not too involved. We receive the notification and decide what we need to do. We usually do not need to expend a lot of staff resources at our agency to process the incoming notifications."

Rivera added, "It is surprising how often we get a notification we never heard about, even years after the action. We are getting a chance to take a look at information that we might not have known about had the licensee not reported it. If we determine we need more details regarding the reported action, we find that most states are willing to cooperate in providing additional information."

Ellen Mitchell, recently retired investigation support coordinator for the Idaho State Board of Pharmacy, had similar advice for other boards. "The most critical thing for states to do is to report on a regular basis," she said. "We have been reporting consistently for about 17 years. NABP staff was key in helping us to understand the importance of reporting and how we support our sister boards by doing so. While older information can be helpful, it is much more helpful to see the actions as they happen."

## NABP Can Help With Reporting

There are some burdens that may make submitting timely reports to the Clearinghouse more difficult. Among these, NABP recognizes that the federal requirement for state boards of pharmacy to submit disciplinary records to the National Practitioner Data Bank (NPDB) may take priority over submitting these records to NABP. In these cases, boards may also be concerned that their staff may need to duplicate work by submitting disciplinary reports multiple times. NABP has taken steps to help boards of pharmacy in these circumstances.

Specifically, NABP and 34 state boards of pharmacy have entered into agreements that allow the Association to be their reporting agent to NPDB. This can reduce the amount of board time and staff needed and make it easier to keep reports for both databases up to date. More information about using NABP as an NPDB reporting agent is provided in the Members section of the NABP website under Clearinghouse.

However, even if boards choose not to utilize NABP as a reporting agent to NPDB, there are other ways that the Association can make reporting easier for its member boards. NABP wants the boards of pharmacy to take full advantage of the NABP Clearinghouse and works directly with them to help identify the best reporting methods. In many cases, automated reporting to NABP is possible. NABP Clearinghouse staff can also assist boards to determine the best and most efficient option that works with their current processes and resources.

In addition, the NABP Clearinghouse services and access are regularly improved. Upgrades are planned for the coming year, and more information will be shared through the appropriate channels. NABP thanks its member boards for all they do to keep their numbers updated regularly. ●

# Association Seeks Item Writers for NABP Examinations

NABP is seeking volunteers to apply to serve as item writers for the Association's examination programs. Item writers develop test questions for NABP programs, including the North American Pharmacist Licensure Examination® (NAPLEX®), the Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

## Item Writer Selection Process

The opportunity to participate as an item writer is currently available to pharmacists in all areas of practice and to faculty from schools and colleges of pharmacy. Item writers will be selected based on the specific needs of the programs. Those who are selected will be asked to participate in an item development workshop and training. Attendees will receive detailed instructions and training materials describing the item development process and content-related requirements for their designated examination program. Item writers will then engage in the development of new test items that will be considered for inclusion in NABP licensure, certification, and assessment examination programs.

Some item writing workshops may be held virtually and others will be at NABP's Headquarters in Mount Prospect, IL. Please check the Meetings section of the NABP website for updates.

## Overview of Exams

The **NAPLEX** focuses on content relating to the knowledge, judgment, and skills that an entry-level pharmacist is expected to demonstrate. There are six competency areas for the examination:

- obtain, interpret, or access data, medical, or patient information;
- identify drug characteristics;
- develop or manage treatment plans;
- perform calculations;
- compound, dispense, or administer drugs, or manage delivery systems; and
- develop or manage practice or medication-use systems to ensure safety and quality.

The **MPJE** combines federal and state-specific questions that test an individual's knowledge in pharmacy jurisprudence and includes the following areas:

- pharmacy practice;
- licensure, registration, certification, and operational requirements; and
- general regulatory process.

Writers for the MPJE are typically assigned by the participating jurisdiction; however, in some cases, individuals may be selected to participate independently of board of pharmacy affiliation.

The **FPGEE** content areas cover curricula of accredited United States pharmacy programs, including:

- basic biomedical sciences;
- pharmaceutical sciences;
- social, behavioral, and administrative pharmacy sciences; and
- clinical sciences.

The **PCOA** is suitable for students in all four professional years. The assessment follows a blueprint that is representative of curricula of accredited US pharmacy programs, including:

- basic biomedical sciences;
- pharmaceutical sciences;
- social, behavioral, and administrative pharmacy sciences; and
- clinical sciences.

## How to Apply

Interested individuals should complete the online NABP Item Writer Volunteer Interest Form located on the Meetings page of the NABP website and upload a current résumé or curriculum vitae. ●

# NABP Inspectors Identify Dangerous Scheme Involving Over-the-Counter Insulin Products

With decades of experience providing accreditations and inspections on a national level, NABP inspectors and surveyors have a unique perspective when it comes to drug safety issues and trends. That perspective recently allowed NABP staff to observe several schemes related to nonprescription insulin that may pose a serious health risk to patients.

Recently, unscrupulous distributors posing as patients have purchased a brand of over-the-counter (OTC) insulin made for and sold exclusively at retail pharmacies of a large national pharmacy chain. The insulin is collected in large quantities, then resold into the wholesale market. Wholesalers have then purchased this diverted insulin and resold it to retail pharmacies and, in some cases, to other wholesalers. This deliberate scheme to subvert the supply of insulin is exposing patients to the high risk of receiving an adulterated drug in the form of subpotent insulin due to unknown storage conditions.

While the specific pharmacies and wholesalers involved in these schemes cannot become accredited by NABP until they take corrective action and have ceased these activities, patients may still be at risk from non-accredited facilities.

## Review of Insulin Regulation and Proper Handling

Diabetes medications, including insulin, usually require a prescription. However, some older forms of insulin can be purchased OTC. In fact, they remain the only injectable human drugs that can be sold without a prescription under federal law. These drugs were on the market without a prescription prior to the enactment of certain provisions of the Federal Food, Drug, and Cosmetic Act, which created prescription-only status drugs, and are grandfathered in to retain OTC status. As a result, these forms of insulin are not subject to the same state and federal supply chain regulations as prescription insulins.

Diabetes advocacy groups, including the American Diabetes Association, support availability of nonprescription insulin as an important treatment option for diabetes patients who lack or have inadequate insurance to help with the high cost of prescription treatment options. Although these insulins are not displayed in the OTC section of retail pharmacies, upon request, they can be sold to patients. In this situation, the pharmacist is a frontline resource for these patients.

According to NABP's 2021 *Survey of Pharmacy Law*, only 15 states require a license for wholesale distribution of OTC drugs, including nonprescription insulin. Notably, these insulin products are not subject to the traceability requirements that are part of the Federal Drug Supply Chain Security Act of 2013 (Title II of the Drug Quality and Security Act), which was enacted to protect the integrity of drugs from adulteration and counterfeiting by implementing requirements for traceability, among other protections.

Insulins are complex biological products that are sensitive to temperature variations. As a result, manufacturers recommend that insulin be stored in refrigerated conditions (36°-46° F). At these temperatures, insulin maintains its potency through the labeled expiration date. Once opened, insulin will continue to be effective for up to 28 days at room temperature (59°-86° F). Insulin can degrade and lose efficacy when exposed to extreme temperatures, either freezing temperatures or high heat.

## Scheme Exploits Insulin Laws

To make nonprescription insulin more accessible to patients, one of the top manufacturers of insulin began working with community pharmacy chains. The drug's retail price for patients is often below the wholesale price of other insulin products sold to pharmacies. A label on this insulin states, "ONLY FOR RETAIL SALE BY [CHAIN DRUGSTORE] AND ITS AFFILIATES."

NABP became aware of a scheme involving insulin purchased by a facility it was inspecting that was collected from several chain drugstore pharmacies over a single weekend. This scheme was carried out by an organized group that sold the purchased insulin to a wholesale distributor, which then sold it to a mail-order pharmacy. Upon further investigation, NABP discovered that this is the typical pathway in which diverted insulin is resold into the marketplace.

The risk to patients with this type of corrupt distribution is very high, as they are receiving and injecting potentially adulterated insulin that is very likely subpotent due to improper storage.

To combat the nationwide threat posed by this scheme, Georgia has enacted a law that criminalizes the resale of nonprescription insulin that was first obtained through an OTC sale. Insulin sold in this manner is deemed adulterated under the law.

NABP encourages the boards of pharmacy to be aware of and to watch for variations of this scheme. Pharmacies and wholesalers should maintain awareness and verify the source of insulin products before purchasing. Pharmacies that turn a blind eye to the purchase and sale of insulin that is clearly labeled as being exclusively for sale by a chain pharmacy cannot claim ignorance of the source of the diverted insulin.

In the interest of the shared mission of NABP and the boards of pharmacy to protect the public health, the Association will continue to monitor these issues and trends and report on any relevant updates. ●

# Task Force Offers Recommendations for Improving Pharmacy Technician Regulations and Policies

The Overview Task Force on Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment was the fifth task force established in response to Resolution 115-4-19, which was approved by the NABP membership at the Association's 115th Annual Meeting in May 2019. The task force met in December 2020 and members reviewed the recommendations of the previous task forces in order to synthesize and consolidate them and review the NABP *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to determine whether any updates are warranted. (See the bottom of page 11 for the official charge.)

In reviewing the recommendations of the Task Force on Requirements for Pharmacy Technician Education and the Task Force on Pharmacy Technician Competence Assessment, task force members discussed the career progression and time frame for each level of pharmacy technician practice – from applying as a candidate to becoming certified to earning an advanced certification. Members agreed that it is crucial to require technicians to complete an accredited education and training program in order to increase standardization across the country. Members also agreed with the previous task forces' conclusions that the training component must be site-specific. In addition, they recognized that the current certification examinations measure knowledge, but not necessarily competence, and they noted that it is difficult to measure the competence of a certified pharmacy technician candidate.

Upon further review of the recommendations of the Task Force on Requirements for Pharmacy Technician Education, task force members questioned whether it was feasible to encourage state boards of pharmacy to license or register ancillary personnel, including cashiers, clerks, and delivery drivers. After extensive discussion, members agreed that NABP should not encourage boards to register ancillary personnel or add a definition for such personnel to the *Model Act*. However, members did agree that NABP should continue to encourage state boards of pharmacy to license all certified pharmacy technician candidates and certified pharmacy technicians and to maintain the definitions of both terms, as revised by the previous task forces and 2020 Committee on Law Enforcement/Legislation report.

Task force members also discussed and agreed with the addition to the *Model Act*

## Task Forces Convened in Response to Resolution 115-4-19

### 2019 Task Forces

- Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment
- Task Force on Requirements for Pharmacy Technician Education
- Task Force on Pharmacy Technician Competence Assessment

### 2020 Task Forces

- Task Force on Pharmacy Technician Practice Responsibilities
- Overview Task Force on Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment

In 2020, NABP held two task force meetings related to pharmacy technician practice and education. Both task forces were established in response to Resolution 115-4-19, which was approved by the membership at the Association's 115th Annual Meeting. This 2019 resolution was also the impetus for three other pharmacy technician task forces held in 2019.

regarding a definition of and licensing process for "advanced level certified pharmacy technician." However, the 2021 Committee on Law Enforcement/Legislation agreed that a new pharmacy technician category may be burdensome to boards of pharmacy and ultimately decided not to add the definition to the *Model Act*.

Regarding existing technician certification examinations, the task force agreed that it was not necessary for NABP to perform a gap analysis on the examinations or to develop an additional examination. Members agreed, however, that NABP should perform a gap analysis of accreditation standards for pharmacy technician education programs, with the goal of recommending accreditation standards that encompass future growth of pharmacist and pharmacy technician scopes of practice, as recommended by the Task Force on Requirements for Pharmacy Technician Education.

Lastly, the task force discussed remote practice and shared services – particularly related to the coronavirus disease 2019 (COVID-19) pandemic – and agreed that relevant *Model Act* language that restricts or prohibits these types of practices should be reviewed.

After careful review and deliberation, the task force submitted the following recommendations:

- NABP should encourage state boards of pharmacy to recognize, as a best practice, pharmacy technician education that includes a didactic curriculum from an accredited provider and experiential training for all levels of pharmacy technicians.
- NABP should encourage state boards of pharmacy to license all certified pharmacy technician candidates and certified pharmacy technicians. The Association should not, however, encourage boards to register other ancillary personnel, such as cashiers, clerks, or delivery drivers.
- NABP should perform a gap analysis of accreditation standards for pharmacy technician educational programs.
- NABP should retain and/or amend *Model Act* language pertaining to "certified pharmacy technician" and "certified pharmacy technician candidate" and include a definition for "advanced level certified pharmacy technician," but, as noted previously, was subsequently removed.
- NABP should review *Model Act* language that prohibits remote practice and consider removing or qualifying other provisions that have been recently amended or waived due to the COVID-19 pandemic.

Task force members included:

- **Malcolm Broussard, RPh (chair)**
- **Cindy Fain, PD**
- **Jacqueline L. "Jackie" Hall, MBA, RPh**
- **Kristina Jonas, PharmD, RPh**
- **Franklin J. "Rocky" LaDien, RPh**
- **Julie Lanza, CPhT, CSPT**
- **Edward G. McGinley, MBA, RPh, DPh**
- **Helen Pervanas, PharmD, RPh**
- **Jeenu Philip, RPh**
- **Kari Shanard-Koenders, MSJ, RPh**
- **Kristen Snair, CPhT**
- **Mitchell G. "Mitch" Sobel, MAS, RPh, FASHP, CPGx**
- **Julienne Tran, PharmD, RPh**
- **Bradley S. Hamilton, BSPharm, RPh, Executive Committee liaison**

The task force report was approved by the Executive Committee during its February 2021 virtual meeting and is available in the Reports section at *www.nabp.pharmacy.*

## Task Force Charge

The task force was charged with the following objectives:

1. Review the reports of the Task Force on Requirements for Pharmacy Technician Education, the Task Force on Pharmacy Technician Competence Assessment, and the Task Force on Pharmacy Technician Practice Responsibilities.
2. Synthesize these task forces' recommendations into one consolidated set of recommendations.
3. Examine the language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* addressing all aspects of pharmacy technician regulation and recommend amendments, if necessary, that support technician education, competence assessment and practice, all in the best interest of patient care.

# Sharing Solutions, **Advancing Regulation**

**NABP Interactive Executive Officer Forum** | September 28-29, 2021 | Northbrook, IL

Executive officers, join your colleagues in person on September 28-29, 2021, to network, gain new insights, and discover solutions to shared challenges facing the boards of pharmacy.

No registration fees. Travel, hotel, and meals paid by NABP.

The Interactive Executive Officer Forum will take place at the Hilton Chicago/Northbrook in Northbrook, IL. Executive officers will be sent invitations in August 2021. For questions, contact meetings@nabp.pharmacy.

# Task Force on Medication-Assisted Treatment Recommends Adding MAT Definition to NABP *Model Act*

During the Task Force on Medication-Assisted Treatment virtual meeting held in November 2020, members reviewed current federal and state laws and regulations related to medication-assisted treatment (MAT) and examined relevant language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).*

The task force meeting began with guests sharing their experiences with the current trends that they are witnessing in various parts of the country regarding opioid use disorder (OUD) treatment, including progress in addiction treatment, the increase in OUD patients due to the coronavirus disease 2019 pandemic, the lack of available and/or willing providers, how some patients feel stigmatized because of their disorder, and the redundant shift to the use of methadone from the use of buprenorphine in some areas.

Task force members also discussed the term "medication-assisted treatment" and how it compares to "medications for opioid use disorder" (MOUD), the current term used by the Substance Abuse and Mental Health Services Administration (SAMHSA). While there was extensive discussion regarding which term should be used to best further the presidential initiative of former NABP President Timothy D. Fensky, RPh, DPh, FACA, task force members agreed that both terms should be referenced in the *Model Act*. They also agreed that the barriers to OUD treatment are more at issue than the term that is used.

Regarding patient outcomes, task force members and guests engaged in a robust discussion as to whether counseling was necessary for OUD patients. After some conversation, all agreed that psychological counseling should not be an eligibility requirement of MAT for OUD patients seeking immediate treatment. Discussion also ensued regarding whether pharmacies are an appropriate setting for patients who are going through withdrawal to seek treatment. The task force determined that the pharmacist's role should involve initiation of short-term MAT therapy, including counseling on the medication and the need for further care, thus providing a "bridge" to long-term care.

In addition, task force members discussed how to best implement pharmacist-initiated MAT in light of current state and federal restrictions, as many states do not allow pharmacists to obtain a state controlled substance (CS) license. Task force members acknowledged that many states currently allow pharmacists to prescribe MOUD through the use of collaborative practice agreements with practitioners who are licensed to prescribe CS at the state and federal levels. Members agreed, however, that access to treatment would be greatly expanded if pharmacists had independent authority at the state level to initiate MOUD for patients suffering from opioid withdrawal, rather than having to enter into collaborative practice agreements.

Lastly, task force members discussed the likelihood of pharmacists being added to the list of Drug Addiction Treatment Act of 2000 (DATA 2000)-waived practitioners, as well as the likelihood that the Mainstreaming Addiction Treatment Act (MAT Act) of 2019, which would eliminate the DATA 2000 waiver requirement, would be passed. The task force was informed that NABP is supportive of the MAT Act and is working to educate federal legislators and regulators about the importance of the act in treating OUD patients.

After careful review and deliberation, the task force recommended that NABP amend the *Model Act* by adding a definition of MAT that includes a footnote to clarify that MOUD is the new term used by SAMHSA, and by adding an emergency-use prescribing and dispensing provision to Section 6. Pharmacist Care Services that allows a pharmacist to prescribe and dispense MAT on an emergency-use basis for patients with OUD. The language specifies that when initiating MAT, pharmacists must use professional judgment to assess the clinical appropriateness of the request and the length of treatment needed until the patient obtains treatment by an authorized practitioner.

The task force also recommended that NABP encourage state boards of pharmacy to promulgate regulations that allow pharmacists to obtain CS licenses in order to prescribe

## Task Force Charge

1. Review current state laws and regulations related to medication-assisted treatment.
2. Examine the language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* and, if necessary, recommend amendments that allow pharmacists to be key leaders in opioid safety and patient care.

CS at the state level and obtain a federal CS mid-level practitioner registration from Drug Enforcement Administration.

The Task Force on Medication-Assisted Treatment was established pursuant to former NABP President Fensky's initiative, which is to promote pharmacist-provided MAT for patients diagnosed with OUD. Task force members included:

- **Jeanne D. Waggener, RPh, DPh (chair)**
- **James "Jim" Bracewell**
- **Luke Daniel, JD**
- **Debra Feinberg, JD, RPh, FASHP**
- **Robert Giacalone, JD, RPh**
- **Michael J. Godek, RPh**
- **Fiona Karbowicz, RPh**
- **Samuel Lanctin, MBA**
- **William T. "Bill" Lee, MPA, DPh, FASCP**
- **Karen M. Ryle, MS, RPh**
- **Katy Wright, MBA, PharmD, DPh, BCPS**
- **Nicole L. Chopski, PharmD, BCGP, ANP, Executive Committee liaison**

Invited guests for the task force included James J. Gasper, PharmD, BCPP, College of Psychiatric and Neurologic Pharmacists; Jake Nichols, PharmD, Professional Recovery Associates; and Erica Schlesinger, PharmD, Tennessee Department of Mental Health and Substance Abuse Services.

The task force report was approved by the Executive Committee during its February 2021 virtual meeting and is available in the Reports section at *www.nabp.pharmacy.*

## AROUND THE ASSOCIATION

### Board Member Appointments

- **Young Chang, MBA, RPh,** has been appointed a member of the Georgia State Board of Pharmacy. Chang's appointment will expire July 1, 2022.
- **Charles E. Page, RPh,** has been appointed a member of the Georgia State Board of Pharmacy. Page's appointment will expire October 31, 2025.
- **Christina Solis** has been appointed a member of the Guam Board of Examiners for Pharmacy. Solis' appointment will expire May 12, 2023.
- **Erik Maki, PharmD, RPh,** has been appointed a member of the Iowa Board of Pharmacy. Maki's appointment will expire April 30, 2024.
- **Christopher Harlow, PharmD, RPh, BCGP,** has been appointed a member of the Kentucky Board of Pharmacy. Harlow's appointment will expire January 1, 2024.
- **Jonathan Van Lahr, RPh,** has been appointed a member of the Kentucky Board of Pharmacy. Van Lahr's appointment will expire January 1, 2024.
- **Jeffrey Nikolaisen, RPh,** has been appointed a member of the Montana Board of Pharmacy. Nikolaisen's appointment will expire July 1, 2025.
- **Kevin C. Borcher, PharmD, RP**, has been appointed a member of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit. Borcher's appointment will expire November 30, 2021.
- **Todd M. Larimer, RP,** has been appointed a member of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit. Larimer's appointment will expire November 30, 2024.
- **Charles T. Tomlinson, PharmD, RP,** has been appointed a member of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit. Tomlinson's appointment will expire November 30, 2025.
- **Mischelle Johnson Corbin** has been appointed a public member of the North Carolina Board of Pharmacy. Corbin's appointment will expire June 1, 2025.
- **Wallace Nelson, RPh,** has been appointed a member of the North Carolina Board of Pharmacy. Nelson's appointment will expire April 30, 2025.
- **Eileen Ortega, RPh,** has been appointed a member of the Puerto Rico Board Pharmacy. Ortega's appointment will expire November 23, 2024.
- **Tiffany O'Hagan, MBA, PharmD, RPh,** has been appointed a member of the Wisconsin Pharmacy Examining Board. O'Hagan's appointment will expire July 1, 2024.
- **Anthony D. Peterangelo, PharmD, RPh,** has been appointed a member of the Wisconsin Pharmacy Examining Board. Peterangelo's appointment will expire July 1, 2023.
- **Michael Walsh** has been appointed a public member of the Wisconsin Pharmacy Examining Board. Walsh's appointment will expire July 1, 2024.
- **Shana Weiss** has been appointed a public member of the Wisconsin Pharmacy Examining Board. Weiss' appointment will expire July 1, 2023.

### Board Member Reappointments

- **J. Andrew "Andy" Bowman, PharmD, RPh,** has been reappointed a member of the North Carolina Board of Pharmacy. Bowman's appointment will expire May 1, 2026.
- **Rachael DeBarmore, RPh,** has been reappointed a member of the Oregon State Board of Pharmacy. DeBarmore's appointment will expire June 30, 2024.
- **Cyndi Vipperman, CPhT,** has been reappointed a member of the Oregon State Board of Pharmacy. Vipperman's appointment will expire February 16, 2024.
- **Teri Ferreira, RPh,** has been reappointed a member of the Washington State Pharmacy Quality Assurance Commission. Ferreira's appointment will expire January 28, 2024.

## Massachusetts Board of Registration in Pharmacy

**Number of Board Members**
8 pharmacist members
2 public members
1 pharmacy technician
1 physician
1 nurse

**Number of Compliance Officers/Inspectors**
1 compliance officer and 12 inspectors

**Rules & Regulations Established by**
Board of Registration in Pharmacy

**Number of Pharmacist Licensees**
13,936

**Number of Pharmacies**
1,124 (includes home infusion, mail-order pharmacies, and nuclear pharmacies)

**Number of Wholesale Distributors**
37

# Julie Lanza, CPhT, CSPT

Member, Massachusetts Board of Registration in Pharmacy

### When were you appointed to the Board and as what type of member?

I am a pharmacy technician who was appointed to the Massachusetts Board in December 2017. In 2019, I was elected secretary, and I am currently president for 2021.

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

The most important thing a board member should do is listen to their fellow board members. There is a wide range of specialty areas within the world of pharmacy, and we cannot be an expert in every area. Being able to listen to other board members who have the expertise and knowledge in an area unfamiliar to you may help you make informed decisions. As a hospital-based pharmacy technician, I have been able to expand my knowledge in a host of areas simply by listening and learning from other board members.

### What are some recent policies, legislation, or regulations your Board has implemented?

Recently, the Board has approved a policy allowing vaccine administration by qualified pharmacy technicians. As a technician, this was very exciting and another step in the right direction toward technicians in advanced roles. This past year, I believe it has become more evident that pharmacy technicians in advanced roles have a positive overall impact on the practice of pharmacy. They allow pharmacists to have more patient-facing time and for the implementation of more clinical services. Being involved with NABP gave me the opportunity to connect with board members from other states that already allowed this regulation. Being able to ask questions and learn from them allowed me to bring back to the Board information that was important for the development and implementation of this policy.

### Has the Board encountered any challenges to developing new policies or regulations?

Implementation of any new regulation or legislation takes time. My Board does a great job developing and approving policies and guidelines to assist the pharmacy community while new regulations are waiting for promulgation.

### What advice would you give to a new board member?

Get involved and enjoy every moment. The opportunity to serve on a board is an honor and a privilege. That said, every regulation, every meeting, every discussion is an opportunity to learn something and become more well-rounded. It is okay to ask questions. I was nervous and did not know what to expect when I was first appointed, but I quickly learned that everyone on the Board was on the same team and working toward the same goal. In my three years on the Board, I have had the honor of serving with some amazing members of the pharmacy community.

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

In January 2020, I attended the NABP Interactive Member Forum and participated in the panel discussion *Compounding by the Numbers – Unlocking the Data of the MOU.* Additionally, I participated virtually in December 2020 in the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment. Both experiences were wonderful, but very different. The virtual meeting was very informative, and I was able to hear other thoughts and opinions on the topics presented. The benefits of the in-person meeting were gaining knowledge, but then also talking to others about it. Comparing thoughts, ideas, and processes with colleagues from other states in real time was beneficial for me to be able to bring back what I learned to the Board. I was able to connect with multiple people at the in-person meeting whom I have since been able to contact for their opinions on my quest for technician advancement. I feel as though any involvement with NABP is beneficial, and what I was able to take away from those experiences was far greater than what I expected. ●

## California Board Develops Sample Collaborative Practice Agreement for Providing MAT

The California State Board of Pharmacy has developed a sample collaborative practice agreement for pharmacists to provide medication-assisted treatment (MAT) to patients with an opioid use disorder in collaboration with a medical care provider. In 2019, the Board adopted a policy statement to encourage greater access to MAT and support pharmacists providing direct care and assisting medical providers in caring for patients with an opioid addiction. Pharmacists can use the sample agreement to provide MAT in collaboration with a practitioner who has a Drug Addiction Treatment Act of 2000 waiver.

To learn more and view the policy statement, read the Board's March 2021 issue of *The Script*, which can be accessed at *www.pharmacy.ca.gov/publications/21_mar_script.pdf.*

## Louisiana Updates Rules Related to Automated Medication System Requirements

The Louisiana Board of Pharmacy revised its chapter of rules for automated medication systems (AMS). As part of that rule revision process, the requirement for a pharmacy hosting an AMS device located within the building housing that pharmacy to obtain an AMS registration was removed. Although pharmacies hosting an AMS device located within the building housing that pharmacy are now exempt from the registration requirement, they are still obliged to comply with the operational standards in that chapter of rules (Chapter 12). In the event the pharmacy supplies medications to an AMS device located outside the building housing the pharmacy, then AMS registrations for those locations are still required.

## North Carolina Deschedules Epidiolex Under Its Controlled Substances Act

In August 2020, Drug Enforcement Administration completed a rulemaking that descheduled Epidiolex® (previously a Schedule V controlled substance (CS)) under the federal Controlled Substances Act (CSA). The North Carolina Department of Health and Human Services' Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services has completed its own rulemaking to deschedule Epidiolex under the North Carolina CSA. Effective March 1, 2021, the amended rule removes "approved cannabidiol drugs" (eg, Epidiolex) from North Carolina's list of Schedule V CS. More information is available in the Board's April 2021 *Newsletter*, which can be accessed on the NABP website.

## Virginia Requires Statewide Protocols for Initiation of Treatment Under Emergency Regulation

Emergency regulations in Virginia authorize pharmacists to initiate treatment with certain drugs for patients 18 years of age or older, effective January 3, 2021. Pharmacists in Virginia may now prescribe and dispense these drugs in accordance with the regulations and the statewide protocols. As authorized in House Bill (HB) 1506, the statewide protocols specifically address pharmacist initiation, dispensing, and administration of the following drugs to persons 18 years of age or older:

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

The emergency regulations as well as the statewide protocols are available on the home page of the Board's website at *www.dhp.virginia.gov/pharmacy/.*

In addition, HB 2079 was signed into law, which authorizes the development of additional statewide protocols for persons 18 years of age or older for the following conditions: human immunodeficiency virus pre-exposure and post-exposure prophylaxis; tuberculin purified protein derivative tuberculosis testing; vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from United States Food and Drug Administration; and devices, controlled paraphernalia, or other supplies or equipment available OTC when covered by the patient's health insurance carrier. More information is available in the Board's April 2021 *Newsletter,* which can be accessed on the NABP website. ●

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.

## FDA Warns of Biological Products Being Offered to Patients Outside the Scope of an Approved BLA

Food and Drug Administration (FDA) has issued a warning regarding biological products that appear to have been prepared by state-licensed pharmacies, registered outsourcing facilities, and health care providers outside the scope of an approved biologics license application (BLA). FDA reminds licensees that federal law does not provide a legal pathway for marketing biological products that have been prepared outside the scope of an approved BLA. State boards of pharmacy are encouraged to submit to FDA any issues or questions involving the preparation of biological products outside the scope of an approved BLA.

## APhA Creates Useful Resource for Pharmacists on COVID-19 Vaccine Comparisons

The American Pharmacists Association (APhA) has created a comparative summary chart of the three COVID-19 vaccines available by emergency-use authorization from FDA. The chart contains useful resources for pharmacists; includes detailed information about the Pfizer-BioNTech, Moderna, and Johnson & Johnson vaccines; and compares important information on all three vaccines. The COVID-19 vaccine summary chart can be accessed on the APhA website at *https://aphanet.pharmacist.com/coronavirus/practice-resources.*

## Survey Finds Many Pharmacists Are Unfamiliar With Safe Online Pharmacy Resources

A new survey of pharmacists throughout the United States found that 58% of respondents lack confidence in identifying and counseling patients on illegal pharmacy websites. In addition, many pharmacists who responded to the survey underestimated the number of illegal online pharmacies currently in operation, as well as the number of patients utilizing online pharmacies. Survey results also showed that many pharmacists are unfamiliar with the resources available to help customers protect themselves when shopping online. Survey results can be found on the *Sage Journals* website at *https://journals.sagepub.com/doi/10.1177/23992026211005642.*

## New Web Page Addresses Pharmacy Boards' Questions on FDA MOU for Compounded Products

FDA created a new web page to help answer questions regarding the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU) from boards of pharmacy and other state agencies. The web page will continue to be updated by FDA as additional questions on the MOU are received. FDA worked with NABP to develop a standard MOU for use by the state boards of pharmacy to aid with their compliance of section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act. As part of the MOU, boards must identify pharmacies that are compounding human drug products and distributing inordinate amounts of such products interstate and report those pharmacies to FDA. Additional resources and information on the FDA MOU and the Compounding Pharmacy Information Sharing Project can be found through the Members section of the NABP website.

## HHS Expands Access Toward Lifesaving Addiction Treatment

The US Department of Health and Human Services (HHS) has expanded practice guidelines allowing certain practitioners who are state licensed and registered by Drug Enforcement Administration (DEA) to more easily prescribe buprenorphine to patients with opioid use disorder (OUD). The expansion scales back the DEA "X-waiver" to further expand patient access to the lifesaving medication. The Mainstreaming Addiction Treatment Act (MAT Act) would permanently remove the DEA X-waiver and lay the groundwork for states to utilize pharmacists to provide medication-assisted treatment (MAT).

As part of his 2020-2021 presidential initiative, former NABP President Timothy D. Fensky, RPh, DPh, FACA, along with NABP and its member boards, has been urging Congress to pass the MAT Act to allow states to recognize pharmacists as MAT providers for patients diagnosed with OUD.

## Scam Targeting Pharmacists – DEA Warns

DEA has issued a warning about a scam that is targeting pharmacists in different regions of the US. In a recent case, a pharmacist received a phone call from an individual claiming to be from the Federal Bureau of Investigation (FBI). The caller told the pharmacist that their license was currently under investigation. According to DEA, the scammer warned the pharmacist to not let anyone know about the call and to leave the pharmacy saying they had an urgent family matter, so they could go to the post office to receive faxed details of the FBI investigation. The scammer also told the pharmacist that they were being watched and to remain on the phone until receiving the documents at the post office. The pharmacist was also directed to send $18,000 to the scammer.

The above-mentioned scam is just one version of a much broader scam targeting health care providers. Scammers are also claiming to be board of pharmacy investigators in order to obtain sensitive personal information and money over the phone.

DEA warns pharmacists and other health care providers to be alert, and that scams can appear in many different forms. Always report anything suspicious to DEA or the FBI. To report a scam, visit *https://reportfraud.ftc.gov/#/?pid=A.* ●

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## UPCOMING EVENTS

**NABP/AACP Districts 6, 7, and 8 Meeting**
August 29-31, 2021 | Carefree, AZ

**NABP/AACP Districts 1 and 2 Meeting**
September 7-10, 2021 | Annapolis, MD

**NABP Interactive Executive Officer Forum**
September 28-29, 2021 | Northbrook, IL

**NABP/AACP District 3 Meeting**
October 3-6, 2021 | Hilton Head Island, SC

**NABP/AACP District 4 Meeting**
October 20-22, 2021 | Columbus, OH

**NABP Interactive Compliance Officer and Legal Counsel Forum**
November 30-December 1, 2021 | Northbrook, IL

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