

# INNOVATIONS

## Breaking MAT Barriers

Boards, NABP Continue Promoting  
Pharmacists as Key Providers in  
Addressing Opioid Crisis



**NABP**  
National Association of  
Boards of Pharmacy

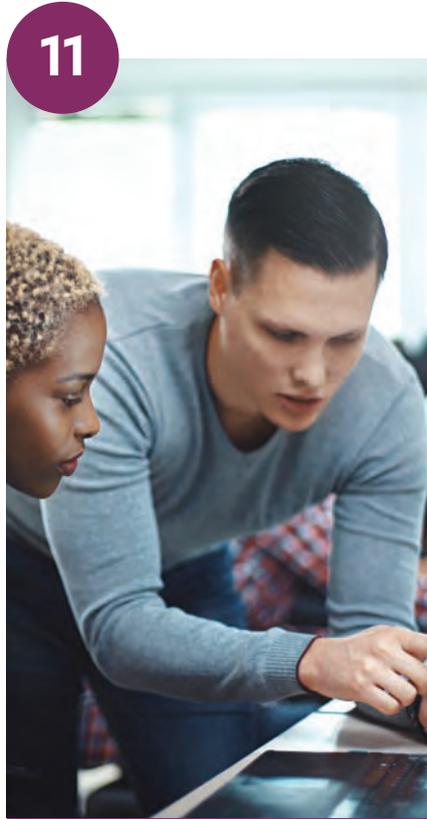


**06**



**Feature News**  
 Breaking MAT Barriers: Boards, NABP Continue Promoting Pharmacists as Key Providers in Addressing Opioid Crisis

**11**



**Association News**  
 NABP's Experience Enabled Swift Development of Passport to Support Member Boards' COVID-19 Response

- 01 Interview With a Board Inspector**  
Sue Mears, RPh
- 02 Policy Perspectives**  
The Evolution of Medicare Part D and Medicare Advantage May Impact Pharmacies
- 10 Association News**
  - 10 Illegal Online Pharmacies Exploit Vulnerable Consumers During Pandemic, Warns NABP
  - 12 Association Seeks Item Writers for NABP Examinations
- 14 Interview With a Board Member**  
Carl Thomas 'Trip' Hoffman III, PharmD, RPh
- 16 State Board News**  
Alabama Emergency Rule Allows Institutional Facilities to Dispense MDIs in Response to COVID-19
- 17 Professional Affairs Update**  
FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

## INNOVATIONS

(ISSN 2472-6850 — print; ISSN 2472-6958 — online) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 65 member boards of pharmacy.

The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is \$70 per year.

**National Association of Boards of Pharmacy**  
 1600 Feehanville Drive, Mount Prospect, IL 60056  
 847/391-4406 | [www.nabp.pharmacy](http://www.nabp.pharmacy)  
[help@nabp.pharmacy](mailto:help@nabp.pharmacy)

**Lemrey "Al" Carter**  
 Executive Director/Secretary

**Amy Sanchez**  
 Communications Manager

©2020 National Association of Boards of Pharmacy. All rights reserved. No part of this publication may be reproduced in any manner without the written permission of the executive director/secretary of the National Association of Boards of Pharmacy.

**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 Executive Committee

**Jack W. "Jay" Campbell IV**  
 Chairperson

**Timothy D. Fensky**  
 President

**Caroline D. Juran**  
 President-elect

**Reginald B. "Reggie" Dilliard**  
 Treasurer

**Bradley S. Hamilton**  
 Member, District 1

**Tejal J. Patel**  
 Member, District 2

**Jeffrey J. Mesaros**  
 Member, District 3

**Fred M. Weaver**  
 Member, District 4

**Shane R. Wendel**  
 Member, District 5

**Lenora S. Newsome**  
 Member, District 6

**Nicole L. Chopski**  
 Member, District 7

**Kamlesh "Kam" Gandhi**  
 Member, District 8

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



## Sue Mears, RPh

Compliance Officer, Iowa Board of Pharmacy

### How long have you been a compliance officer? What was your prior role?

I have been with the Iowa Board of Pharmacy as a compliance officer for eight years. Prior to this position, I worked for 16 years as a staff pharmacist in a variety of pharmacy settings, including mail order, community, and long-term care. As a compliance officer, I conduct routine inspections of licensees (primarily pharmacies, but sometimes controlled substances (CS) registrants, wholesale distributors, and limited distributors) and investigate complaints within my assigned territory. I also assist in various other tasks, such as the Board's rulemaking and legislative processes, periodically representing our state at Food and Drug Administration compounding meetings, and participating in the NABP item writing and review process for the Multistate Pharmacy Jurisprudence Examination®.

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

Draw upon a wide variety of past pharmacy experiences. Curiosity, flexibility, and willingness to learn can make up a lot of ground when an inspector does not have a lengthy résumé. In the middle of the coronavirus disease 2019 (COVID-19) pandemic, flexibility became paramount for our compliance team and Board in being able to allow pharmacists to take care of patients, even when that may have resulted in noncompliance with Board rules. Also, the ability to communicate effectively is very important. Pharmacy rules are not always specific enough to address every possible scenario in a pharmacy, so an inspector needs to be able to effectively communicate how a rule might apply to a pharmacy's unique situation. One skill that I had no idea would be needed was public speaking. The notion of public speaking is still among my most feared, but after a few years of presenting to the Board, legislators, and licensees, I am getting more comfortable with it.

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

There are constant changes with laws, rules, or regulations with other health care licensing boards within our state. With so many changes over the last several years with compounding, drug disposal, the drug supply chain, and now COVID-19, it has been a constant challenge for our team to keep current on those changes so that we can effectively communicate with our licensees.

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

Our compliance team investigates complaints specific to the licenses/registrations of the Board of Pharmacy. Right after I was hired, our Board received an anonymous complaint that a pharmacist was selling hydrocodone from his independent pharmacy. I assisted a senior compliance officer with a deep dive inspection. I assisted with the evaluation of invoices, records, and data, which all led to a public hearing. Another interesting case involved an illegitimate wholesaler. Within an hour of visiting the location, my fellow investigator got a call from the Los Angeles office of the Department of Homeland Security, and we learned that the individual with whom we met was allegedly the head of a criminal organization. On a recent investigation into a veterinarian relating to CS, I spoke with a clinic owner about a previous employee while she was in the middle of a tooth extraction on a large husky and while teaching a veterinary student who was there observing!

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

We will never have all the answers; we should never feel that we are above asking questions when we are not sure of the answer. Also, know that 99% of licensees want to do the right thing and look to us for guidance and for reassurance that they are compliant or on the right path to compliance. ●

## Iowa Board of Pharmacy



#### Number of Board Members

5 pharmacist members and 5 public members



#### Number of Compliance Officers/Inspectors

8



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



#### Number of Pharmacist Licensees

6,073



#### Number of Pharmacies

1,713



#### Number of Wholesale Distributors

1,001

## The Evolution of Medicare Part D and Medicare Advantage May Impact Pharmacies



Vincent C. Giglierano  
Faegre Drinker Biddle & Reath LLP



Michael S. Adelberg, MPP  
Faegre Drinker Biddle & Reath LLP

Medicare is a staple of the pharmacy market, providing prescription drug coverage to more than 45 million Medicare beneficiaries through private health plans (Medicare Part C or Medicare Advantage or “MA”) or stand-alone prescription drug plans (Part D plans).<sup>1</sup> Over 30% of prescriptions filled in the United States are for people with Medicare.<sup>2</sup> While traditional Medicare (Part A and Part B) is run through the federal government, MA plans and Part D plans are market-oriented programs, which the federal government provides through private plan sponsors. The plans compete with each other for members within a highly regulated market. MA and Part D are often portrayed as “managed competition” success stories because they have kept premiums low for Medicare beneficiaries, although utilization management tools that they use to hold down costs sometimes put the plans at odds with pharmacists and other providers.

MA and Part D have seen steady growth in enrollment over the last few years. Part of this is due to the baby boomers aging into Medicare; 64 million beneficiaries are enrolled in Medicare in 2020. This figure is projected to grow to 80 million beneficiaries by 2030. President Donald J. Trump’s Administration has further fueled the growth of these programs through a series of regulatory changes that include relatively generous payment updates and less regulation of plan marketing. The Administration has also offered plan sponsors new flexibilities to design their plans for specific markets and to differentiate themselves within those markets. This poses both challenges and opportunities for pharmacies and pharmacists as they seek to keep pace with this rapidly changing market.

### Medicare Part D

While there is a standard Part D benefit structure, plans can vary from it. Plans also have flexibilities with regard to drugs covered, pharmacy networks, and use of utilization management tools (including prior authorization, step therapies, and quantity limits). Under

the Trump Administration, plans have additional flexibility with respect to drug formularies (including use of indication-based formularies) and pharmacy networks. The Henry J. Kaiser Family Foundation notes that in 2017 almost half (48%) of plans offered basic Part D benefits (although no plan offered the defined standard benefit), while 52% offered enhanced benefits. Most Part D plans (62%) charged a deductible, with 48% of all Part D plans charging the full amount (\$400).<sup>3</sup>

Of particular importance to pharmacies and pharmacists, Part D plans are allowed to select the pharmacies within their network; and, increasingly, Part D plans are choosing to distinguish between preferred and standard network pharmacies. Plans favor preferred pharmacies through lower member cost sharing, thereby incenting members to switch to preferred pharmacies.<sup>4</sup> Part D plans are making greater use of mail-order pharmacy. In 2020, there was a 13.5% increase in the number of Part D plans offering preferred cost sharing for mail order in comparison to the year before. In 2019, there was an 18% increase in preferred mail-order pharmacy in comparison to 2018.

Mail-order prescriptions allow beneficiaries to have their prescriptions delivered to their doorstep – an option that might be preferred by seniors with mobility limitations and long-term prescriptions. Mail-order discounts and preferred pharmacy

**Mail-order prescriptions allow beneficiaries to have their prescriptions delivered to their doorstep – an option that might be preferred by seniors with mobility limitations and long-term prescriptions.**

## Part D Mail-Order Plans 2018–2020

	Total Mail-Order Cost Sharing	Standard Mail-Order Cost Sharing	Preferred Mail-Order Cost Sharing <sup>5</sup>
2020	4,945	1,988	2,957
2019	4,357	1,769	2,588
2018	3,690	1,561	2,129

designations also give Part D plans greater opportunity to drive the members and their prescriptions to a smaller number of pharmacies, particularly those that are the most reliable plan partners from financial and compliance perspectives. Some media reports suggest that these market trends, along with consolidation, may be driving business away from local and independent pharmacies.<sup>6</sup>

### Medicare Advantage

MA's penetration is growing rapidly, roughly doubling enrollment in the last decade. The Trump Administration has given MA plans significant opportunities to enrich the benefits that they offer to Medicare beneficiaries, and a number of these changes can impact how MA plans work with pharmacists and pharmacies.

For the first time, in 2020, MA plans can offer a wide array of non-medical benefits to Medicare beneficiaries when those benefits are appropriate for treating a severe and disabling chronic condition. For example, people with severe asthma may be eligible for air conditioning or exterminator services; people with Parkinson's disease and a history of falls may be eligible for handyman services to improve home safety. Pharmacists may see Medicare beneficiaries more often than other health care professionals and may be uniquely positioned to identify plan members

who can benefit from non-medical benefits. At this time, only a small number of MA plans are offering these new non-medical benefits – but that will surely change over time. It remains to be seen how MA plans and pharmacists will work together to maximize the effectiveness of these new benefits.

MA plans are also increasingly interested in the social determinants of health, which are non-medical circumstances (such as housing and food insecurity) that can greatly impact a person's health. MA plans are increasingly offering tailored food and transportation benefits. Pharmacists may be the first and only medical professionals to hear a Medicare beneficiary comment that the co-pay on a drug will mean skipping meals. They fill prescriptions for beneficiaries who never pick them up because of cost or transportation concerns. In 2020, roughly 40% of MA plans are offering some type of meal benefit, and more than 40% also offer some type of transportation benefit. In both cases, the percentage of Medicare beneficiaries with access to these types of benefits is trending up.<sup>7</sup> The pharmacist can be critical to ensuring that these benefits get to the right people at the right time.

### Conclusion

The race is under way among MA and Part D plans seeking to find competitive advantages

that can drive enrollment, improve outcomes and member experiences, and contain costs. It is important to understand the managed competition within these government-run insurance programs and how they might impact pharmacies and pharmacists. Absent a dramatic health care change such as Medicare for All, the experimentation that has been unleashed by the Trump Administration will likely continue beyond the November 2020 election, and will become more widespread and imaginative each year. This opening of long-established Medicare rules provides an opportunity for pharmacists and pharmacy regulators to reimagine the best long-term role for pharmacists inside of the Medicare program.

While there is much that is unknown about the next few years, two things are certain: 1) Part D and MA will continue to grow in plan diversity and total membership; and 2) these changes will pose both headaches and opportunities for pharmacies and pharmacists. We should expect to see continued rebalancing between regulation and innovation as national policymakers and state regulatory boards continue to react to the rapidly evolving Medicare landscape. ●

*This article was written by Vincent C. Giglierano and Michael S. Adelberg, MPB, 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 August 2020 *Innovations* pdf on [www.nabp.pharmacy](http://www.nabp.pharmacy).

<sup>1</sup> <https://www.kff.org/medicare/issue-brief/10-things-to-know-about-medicare-part-d-coverage-and-costs-in-2019/>

<sup>2</sup> <https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/>

<sup>3</sup> <http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>

<sup>4</sup> [https://q1medicare.com/q1group/MedicareAdvantagePartDQA/FAQ.php?faq=What-is-a-non-preferred-or-standard-network-pharmacy-in-Medicare-Part-D-&faq\\_id=187&category\\_id=135](https://q1medicare.com/q1group/MedicareAdvantagePartDQA/FAQ.php?faq=What-is-a-non-preferred-or-standard-network-pharmacy-in-Medicare-Part-D-&faq_id=187&category_id=135)

<sup>5</sup> Faegre Drinker Analysis of CMC PBP Files 2018-2020: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Benefits-Data>

<sup>6</sup> <https://www.consumerreports.org/pharmacies/consumers-still-prefer-independent-pharmacies-consumer-reports-ratings-show/> and <https://www.healthcarefinancenews.com/news/insurers-favor-preferred-pharmacies-lower-drug-costs>

<sup>7</sup> <https://www.faegredrinker.com/en/insights/publications/2019/10/2020-vision-medicare-advantage-benefits-for-the-coming-year-part-i>

## COVID-19's Impact on Medicare Part D and Medicare Advantage

Due to coronavirus disease 2019 (COVID-19), Centers for Medicare & Medicaid is also incentivizing social distancing by encouraging states to relax restrictions for mail-delivered prescriptions. According to the Henry J. Kaiser Family Foundation, at least eight states have eliminated the need for a signature to show receipt of a prescription.<sup>8</sup> Pharmacies and pharmacists are not immune to the tremendous economic and workforce disruptions that have rocked most of the United States economy in recent months. The effects of COVID-19 may last into 2021 and change consumers' preferences with regard to mail-order pharmacy, 90-day fills, and prescriptions sent through telehealth physicians. This could further disrupt pharmacy traffic patterns and workforce during an uncertain time. And, just when pharmacies and pharmacists adapt to the COVID-19 landscape, there could be a transition back to pre-emergency rules.

<sup>8</sup> <https://www.kff.org/coronavirus-policy-watch/states-are-shifting-how-they-cover-prescription-drugs-in-response-to-covid-19/>

## NABP Announces Accreditation Program for Home Infusion Therapy Pharmacy

NABP has added a Home Infusion Therapy Pharmacy Accreditation to its accreditation offerings. The program is designed to meet a new requirement by the Centers for Medicare & Medicaid Services (CMS) for suppliers billing home infusion therapy services. Starting in January 2021, CMS will require accreditation for home infusion therapy services billed to Medicare. NABP is one of eight organizations that the United States Department of Health and Human Services has designated as an accrediting organization of home infusion therapy suppliers.

“We are excited to launch our new Home Infusion Therapy Pharmacy Accreditation and add it to our robust portfolio of offerings,” said NABP Chairperson Jack W. “Jay” Campbell IV, JD, RPh. “As a CMS-deemed durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accrediting organization since 2006, NABP is working with CMS on expanding our coverage to include home infusion therapy services billed to Medicare. We look forward to assisting current DMEPOS-accredited customers to realize their full potential within this space and to be recognized for the valuable services they provide.”

The addition of NABP's Home Infusion Therapy Pharmacy Accreditation, along with its other accreditation offerings, provides current and prospective customers with a comprehensive set of accreditation options delivered in a streamlined and cost-effective way. Information about NABP's new Home Infusion Therapy Pharmacy Accreditation is available in the Programs section of the NABP website. ●

NETWORK

EXCHANGE

INNOVATE



**NABP**  
National Association of  
Boards of Pharmacy



## **INTERACTIVE** EXECUTIVE OFFICER FORUM

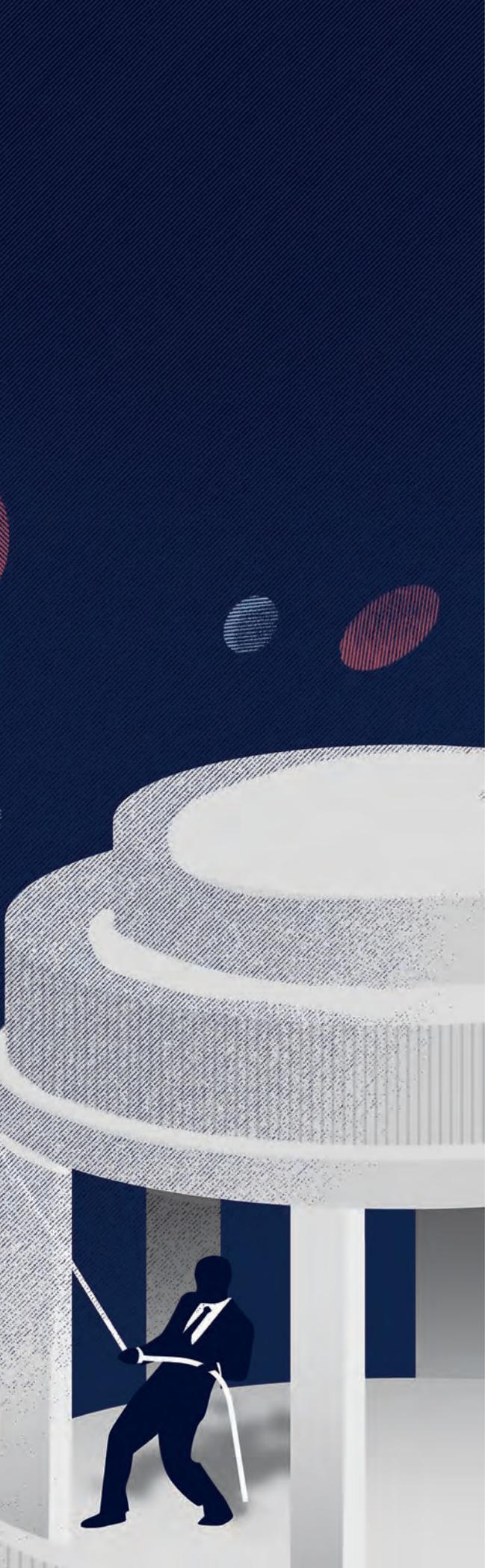
September 30, 2020 | Virtual Meeting

The NABP Interactive Executive Officer Forum will return this fall as a virtual meeting offering a variety of opportunities for dialogue on shared challenges faced by boards of pharmacy. Invitations and details for the forum will be sent to executive officers in August 2020.



# Breaking MAT Barriers

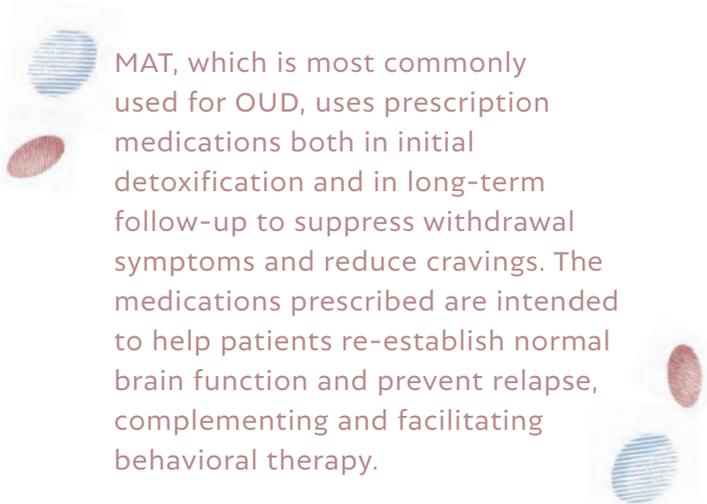
Boards, NABP Continue  
Promoting Pharmacists  
as Key Providers in  
Addressing Opioid Crisis



Promoting pharmacist-provided, medication-assisted treatment (MAT) for patients diagnosed with opioid use disorder (OUD), the initiative of NABP President Timothy D. Fensky, RPh, DPh, FACA, will build on the efforts of the state boards of pharmacy to combat the opioid crisis over the past decade. Board of pharmacy efforts have expanded the reach and collaboration of prescription monitoring programs and helped to limit overdose deaths by advocating and facilitating easier access to naloxone. Fensky's presidential initiative, published in May 2020, seeks to continue this momentum by having the Association work with the boards of pharmacy to help promote pharmacists as vital members of the health care team authorized to provide MAT. A combination of behavioral counseling and other psychosocial services with certain medications such as buprenorphine, MAT has been widely acknowledged as an effective treatment for OUD, and the federal government has prioritized expanding access to MAT as an important element in reducing OUDs and overdoses. Pharmacists – long lauded as being among the most accessible and trusted of health care providers and with a time-tested record of providing advanced care to patients with other chronic disease states – are well placed to help eliminate barriers to MAT and allow more patients with OUD access to the treatment they need.

## MAT Overview

MAT, which is most commonly used for OUD, uses prescription medications both in initial detoxification and in long-term follow-up to suppress withdrawal symptoms and reduce cravings. The medications prescribed are intended to help patients re-establish normal brain function and prevent relapse, complementing and facilitating behavioral therapy. The most common medications used are methadone, buprenorphine, buprenorphine-naloxone, and naltrexone. Methadone, an opioid agonist and a Schedule II controlled substance (CS), may only be prescribed and administered in opioid treatment programs (OTPs), which are certified by the United States Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by a SAMHSA-approved accrediting body, along with any additional state requirements. It is generally taken daily as an oral dosage form. Buprenorphine, a partial opioid agonist and Schedule III CS, may be prescribed and administered outside a certified OTP in what is sometimes referred to as an office-based opioid program. It is available as two oral dosage forms and in two longer-term options: a once-a-month injection and a subdermal implant that lasts six months. Naloxone, an opioid antagonist, is sometimes added to oral formulations of buprenorphine to discourage misuse or abuse. Naltrexone, an opioid antagonist, is not a scheduled medication and therefore faces fewer regulatory restrictions; however, patients must be opioid-free before starting its use. It is available as an oral dosage form to be taken daily, or as a once-a-month injection.



MAT, which is most commonly used for OUD, uses prescription medications both in initial detoxification and in long-term follow-up to suppress withdrawal symptoms and reduce cravings. The medications prescribed are intended to help patients re-establish normal brain function and prevent relapse, complementing and facilitating behavioral therapy.

Health care providers prescribing buprenorphine or buprenorphine/naloxone outside an OTP must obtain what is sometimes referred to as a DATA 2000 waiver (named after the Drug Addiction Treatment Act of 2000 that established it), which allows them to treat opioid dependency with Schedule III, IV, and V drugs that have Food and Drug Administration approval for that purpose, without fulfilling the registration requirements of the Narcotic Addict Treatment Act of 1974. Despite the fact that eligible providers can prescribe CS for pain management, they must apply for this separate waiver with Drug Enforcement Administration (DEA) before treating an OUD patient with these medications. The DATA 2000 waiver carries its own requirements and limitations on providers, including completion of a training course, and the

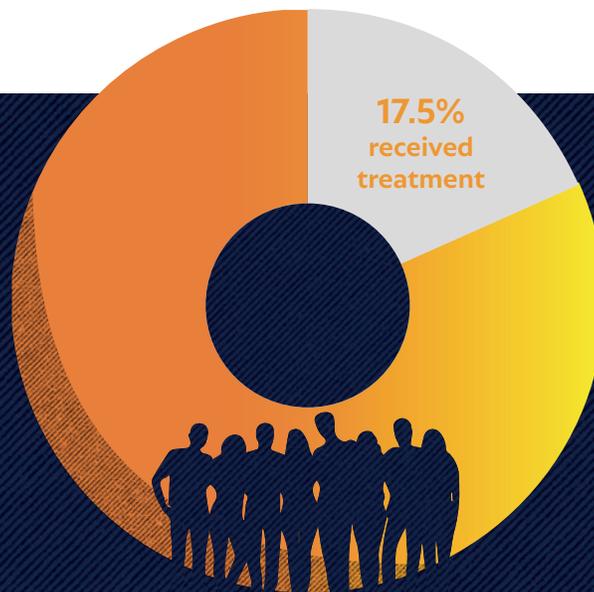
provider's practice must also meet various federal requirements, including the capability to provide patients with access to recovery support services. In addition, there is a cap on the number of patients each provider can treat with MAT. Federal law requires that OTPs provide patients with medical, counseling, vocational, educational, and other assessment and treatment services, along with prescribed medication. Originally, only physicians could apply for a DATA 2000 waiver to prescribe buprenorphine in a non-OTP setting; federal legislation in 2016 added nurse practitioners and physician assistants to the list of providers eligible for a waiver. More recently, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives were also granted waiver eligibility until 2023. However, even with the expansion of eligible providers, the majority of providers have not obtained the required waiver to treat their patients, and access to care remains limited. In fact, it is estimated that fewer than 3% of eligible providers have a DATA 2000 waiver, and in 2017, 1.7 million Americans in need of MAT could not access treatment. Unfortunately, the DATA 2000 waiver creates an unnecessary barrier to care that is not backed by evidence, puts additional burdens on eligible practitioners, and excludes qualified providers like pharmacists from providing needed care.

## Barriers to Access

As noted above, only a fraction of those in the US needing treatment for OUD appear to be receiving it. SAMHSA's National Survey on Drug Use and Health indicated that 21.2 million people aged 12 or older needed treatment for substance use in 2018; only 17.5% of them received any treatment that year. Barriers to treatment – and to MAT in particular – are vast. Rural counties, which have been hit hard by the opioid crisis, face an especially notable practitioner supply scarcity: one study found that nearly 30% of rural Americans live in a county without a potential buprenorphine provider, for example, compared to about 2% of urban dwellers. And just because a physician holds a waiver does not mean he or she is providing MAT services. A survey of rural physicians found fewer than half of waived physicians were treating MAT patients. Providing MAT is difficult, time-consuming, and complex, the survey administrators noted, and finding adequate subspecialty backup or psychosocial support services can be daunting in rural areas. Health care providers report a number of barriers to apply for a DATA 2000 waiver, including the hours of training required, lack of available mental health support services, time constraints, financial risk, fear of intensified DEA oversight, and concerns about diversion. With MAT providers scarce, patients seeking care often have a significant transportation problem on top of everything else – a major barrier in rural areas.

Obstacles are not limited to rural areas or to questions of provider availability and transportation. Intangibles like the stigma attached to OUD (and other substance use disorders) and a residual misunderstanding of MAT, with some detractors telling patients they are merely replacing one addiction with another, also prevent some from seeking or adhering to needed treatment. A 2020 report from the Governmental Accountability Office examining barriers to Medicaid beneficiaries' access to MAT (in 2017, Medicaid provided health care coverage for 38% of non-elderly adults with OUD) identified some of these, including a lack of evidence that

SAMHSA's National Survey on Drug Use and Health indicated that **21.2 million people aged 12 or older needed treatment** for substance use in 2018; **only 17.5% of them received any treatment** that year.



21 states covered all forms of buprenorphine, particularly the long-acting implantable and injectable forms; cumbersome and time-consuming prior authorization requirements; medication reauthorization; and manufacturer or insurance requirements to talk to a patient prior to authorization. While some of these are standard policies designed to reduce fraud or ensure patient safety, when applied to OUD, they raise issues of treatment delays that could have dire consequences, the report noted.

#### Pharmacists and MAT

Currently, pharmacists largely play a dispensing role in the provision of MAT. In order to achieve SAMHSA certification, OTPs must ensure that any scheduled drugs are administered or dispensed by federally and state-authorized health care professionals, including pharmacists. Depending on the state, a pharmacist may be a required member of the team. In Virginia, for example, OTPs must be licensed by the state board of pharmacy, and OTP staffing requirements call for “a minimum of one pharmacist.” A Mississippi rule stipulates that a Mississippi-licensed pharmacist must be present and overseeing medication dispensing at each OTP program location. Some pharmacists may help in such roles as developing treatment plans, monitoring patients, and coordinating care. For MAT delivered outside the OTP framework, pharmacists may dispense prescriptions directly to patients, or may deliver medications to a provider for later administration to a patient.

Given their accessibility and expertise, pharmacists could expand their roles while helping to remove barriers to MAT. Noting that pharmacists in almost every state may enter into collaborative practice agreements with physicians to provide advanced patient care, and that in some states expanded scope of practice laws have allowed pharmacists to prescribe Schedule III medications such as buprenorphine, stakeholders have urged Congress to pass legislation that would remove the DATA 2000 waiver process altogether, allowing states to decide what providers can and should appropriately offer MAT within their communities. A pharmacy setting could provide an easily accessible location, not only for prescribing and dispensing of MAT, but also for the provision of counseling and support

services. In addition, pharmacists could contribute to the development of treatment plans, communicate with patients, coordinate care, and monitor adherence and improvement.

#### State Actions

A number of states and jurisdictions are working to remove barriers to MAT. In 2019, New Jersey announced that it was removing its preapproval requirement for that state’s Medicaid recipients, allowing treatment to begin as soon as it is prescribed; the District of Columbia also removed pre-authorization requirements. Ohio removed its prior authorization requirement for oral buprenorphine the same year. Also in 2019, Minnesota implemented a uniform preferred drug list for its Medicaid programs to make MAT medication requirements uniform across plans; Ohio and North Carolina had plans to enact similar reforms.

More states can look to their regulations to see if changes could facilitate pharmacists’ ability to improve MAT accessibility and effectiveness. At present, few pharmacy laws address the pharmacist’s role in helping provide MAT.

When public health crises occur, such as the current coronavirus disease 2019 (COVID-19) pandemic, access to MAT services can become even more urgent depending on the situation. For example, current studies have shown that the social isolation and economic challenges brought on by COVID-19 have caused a surge in opioid abuse and overdoses. As one of the most accessible health care providers, pharmacists are well equipped to provide MAT to patients during these types of public health emergencies. An article that addresses the impact of the COVID-19 pandemic on the opioid epidemic will be available in an upcoming issue of *Innovations*.

In his written remarks as NABP’s incoming president, Fensky urged the state boards of pharmacy to continue to push for progress in addressing the opioid crisis, and encouraged members to “promote pharmacists as key health providers” by engaging with federal and state agency stakeholders on the issue. NABP will continue to work on getting the support of federal agencies on this issue, reminding those in power that pharmacists are qualified professionals. Pharmacists have long been on the front lines of the opioid crisis, but they still remain underutilized, to the detriment of the public health. ●



## Illegal Online Pharmacies Exploit Vulnerable Consumers During Pandemic, Warns NABP

Illegal online pharmacies are using the coronavirus disease 2019 (COVID-19) to expand operations and prey on consumer fears, according to NABP's May 2020 Rogue Rx Activity Report, *Rogue Online Pharmacies in the Time of Pandemic: Capitalizing on Misinformation and Fear*.

NABP has identified dozens of rogue online pharmacies claiming to sell prescription drugs marketed for COVID-19 treatment. Drugs such as chloroquine, hydroxychloroquine, lopinavir, and ritonavir are being sold online after they gained media attention; however, these are unproven as treatments for COVID-19 and are dangerous when taken without proper medical supervision.

Attempting to capitalize on the pandemic, illegal online pharmacies are:

- adding coronavirus-related images to pre-existing websites;
- purchasing domain names that include COVID-19 words and phrases;
- registering domain names with fraudulent "safe haven" registrars; and
- creating new website facades linking to non-coronavirus-related stores.

NABP has confirmed that over 90% of the COVID-related domain names identified are registered anonymously,

making it difficult for law enforcement agencies to investigate these sources.

In response to the rise of these fraudulent websites, regulators have called for assistance from the private sector, including internet intermediaries that have been successful in shutting down fraudulent face mask, vaccine, and test kit sellers. NABP calls for the implementation of long-term policies to combat rogue internet pharmacies, including immediately locking and suspending domain names engaged in illegal commercial activities. Furthermore, in the absence of significant voluntary action, the Association supports legislation that would require registrars to validate domain name registration information and lock and suspend any domain name that is used for public health scams and similar illicit activity.

NABP continues to identify rogue websites that are seeking to exploit consumers during COVID-19. These sites and other illegal pharmacies are being added to NABP's Not Recommended List. A list of safe online pharmacies and related resources can be found on the Buy Safely page of [www.safe.pharmacy](http://www.safe.pharmacy) to help consumers identify legitimate websites from which to purchase medications. Read the full report and learn more about rogue internet pharmacies in the wake of the COVID-19 pandemic by visiting the Publications and Reports section of [www.nabp.pharmacy](http://www.nabp.pharmacy). ●

## NABP Joins Other National Pharmacy Organizations in Public Statement Taking a Stand Against Racial Injustice

NABP, along with 12 national pharmacy organizations, issued a public statement outlining how the pharmacy profession should address racism and discrimination as a public health crisis that impacts communities of color throughout the United States. In a joint statement, the organizations invoke the pharmacists' oath, reminding pharmacists that they have agreed to "consider the welfare of humanity and relief of suffering [their] primary concerns." The statement stresses that "[a]dvocating against racism, all forms of discrimination and injustice can improve patient care."

Among several key focus points, the statement highlights the following as urgent priorities:

- We advocate for measures that eliminate inequities resulting from racism and discrimination in every facet of our profession, including patient care, pharmacist and pharmacy technician continuing education, student pharmacist education, workplace practices, pharmacy school admissions, leadership opportunities, and organizational policies.
- We advocate for health equity in marginalized communities to eliminate disproportionate health outcomes.

These focus points intersect with NABP's mission to assist "its member boards and jurisdictions for the purpose of protecting the public health." The joint statement also outlines several actions that will be taken by the 13 organizations to achieve such public health goals. The full joint statement is available in the Position Papers section of the NABP website. ●

## NABP's Experience Enabled Swift Development of Passport to Support Member Boards' COVID-19 Response

In March 2020, when it became clear that the coronavirus disease 2019 (COVID-19) pandemic was a public health emergency touching every part of the United States, NABP sprang into action to launch NABP Passport. The service was successfully developed and launched within just a few weeks, and NABP almost immediately began processing NABP Passport applications. As a companion to its already existing Electronic Licensure Transfer Program®, NABP Passport allowed those seeking temporary or emergency nonresident licensure to submit state-specific requests for an NABP Passport through their NABP e-Profile. NABP then conducted the necessary license verification and disciplinary history review at no cost to the individual or the boards of pharmacy.

Launched in late March 2020, the service was leveraged by participating jurisdictions in two ways. First, some jurisdictions recognized NABP Passport as a credential in and of itself. For these jurisdictions, NABP screened applications and issued the NABP Passport to approved applicants. When approved, applicants were considered to have temporary or emergency licensure that the relevant boards viewed, tracked, and managed through NABP e-Profile Connect.

As an alternative, some boards instead used NABP Passport as a prerequisite for temporary or emergency licensure. In these cases, boards directed nonresident individuals and businesses requesting such licensure to first apply for NABP Passport. NABP screened applications and provided them to the applicable boards. After any necessary board approvals, an NABP Passport was issued to the applicants and then provided to the applicable boards. For these jurisdictions, NABP Passport recipients were not granted licensure until the relevant board reviewed the applicant's information and granted licensure based on state requirements.

Interstate licensure transfer has been an integral part of NABP's offering to its member boards since the Association was founded in 1904, and therefore the Association was able to quickly identify this as a key

means of supporting boards of pharmacy, and in turn supporting pharmacists and pharmacy technicians doing their part to meet the COVID-19 pandemic.

With member boards expressing support, staff began in earnest to develop the new service on March 16, 2020. In light of the rapidly developing public health emergency, NABP staff in multiple departments worked tirelessly to develop the program and began coordinating with member boards to understand and best respond to their needs.

"Pharmacists and pharmacy technicians are key health care providers on the front lines in the battle against the COVID-19 pandemic. As they face the prospect of needing multiple temporary licenses or approvals to support the country's pandemic response, NABP and the boards of pharmacy have created a process to provide expediency while continuing to uphold basic standards for public health protection," said NABP Chairperson Jack W. "Jay" Campbell IV, JD, RPh, in a press release about the launch of the service. "The NABP Passport consolidates the processes for temporary licensure that can vary by state. NABP recognizes that there is no time to waste when facilitating a quick response to the pandemic."

Officially, the NABP Passport service launched on March 26. By April 1, over 15 jurisdictions had indicated they were utilizing or preparing to utilize NABP Passport, and NABP had received more than 300 applications for a passport.

Member boards were notified that they could customize the expiration date to match their jurisdiction's current policies and actions related to the pandemic; the default expiration of NABP Passports in participating states was June 30, 2020. As of that date, 19 jurisdictions recognized NABP Passport for pharmacists and pharmacy technicians. In addition, six of these jurisdictions approved the service for pharmacy interns, and four approved it for pharmacy businesses. At press time, Alabama, Connecticut, District of Columbia, Iowa, and Louisiana had set an expiration date for NABP Passports in July 2020, and Arizona, Idaho,



Massachusetts, North Carolina, Oregon, South Dakota, Texas, Virginia, and West Virginia had set an expiration date for December 31, 2020. NABP provides updates on the Passport page of the Association's website.

As of publication, NABP has received more than 7,700 applications for an NABP Passport and issued over 51,000 passports. Note that to streamline the process for applicants, multiple states were included in each request; therefore, the number of passports issued is higher than the number of requests. In fact, most applicants for NABP Passport requested temporary or emergency licensure in each participating jurisdiction.

NABP Passport is not the first service NABP has launched in response to public health emergencies. For example, following the 2012 fungal meningitis outbreak linked to contaminated products compounded at the New England Compounding Center, NABP, at the request of its member boards, created the Verified Pharmacy Program® to provide inspection and licensure verification services, ensuring that the boards have complete and accurate information to make pharmacy licensure decisions. Similarly, in response to the ongoing opioid overdose epidemic, NABP continues to support prescription drug safety education through its AWA<sub>R</sub>x<sub>E</sub>® Prescription Drug Safety Program and its consumer-focused website, [www.safe.pharmacy](http://www.safe.pharmacy).

As the NABP Passport service demonstrates, the Association will continue to provide services and information to support member boards in their efforts to respond to COVID-19 and other public health emergencies. ●

## 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.

Item writing for the remainder of 2020 will be done virtually due to the coronavirus disease 2019, and will move back to NABP's Headquarters in Mount Prospect, IL, or a nearby location when it is deemed safe to do so.

### Overview of Exams

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

- ensure safe and effective pharmacotherapy and health outcomes; and
- assess safe and accurate preparation, compounding, dispensing, and administration of medications.

The **MPJE** combines federal and state-specific questions that test an individual's



Pictured above, item writers Benjamin Miles, PharmD, RPh, BCPS, and Shauna White, MS, PharmD, RPh, both from the District of Columbia Board of Pharmacy, collaborate as they develop questions during the Multistate Pharmacy Jurisprudence Examination® Item Development Workshop at NABP Headquarters in March 2020.

**Item writing for the remainder of 2020 will be done virtually due to the coronavirus disease 2019, and will move back to NABP's Headquarters in Mount Prospect, IL, or a nearby location when it is deemed safe to do so.**

knowledge in pharmacy jurisprudence and includes the following areas:

- legal aspects of pharmacy practice;
- licensure, registration, certification, and operational requirements; and
- regulatory structure and terms.

Writers for the MPJE are typically assigned by the participating jurisdiction; however, in some cases, individuals may be selected to participate independent 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 required for P3 pharmacy students, however, it is frequently given to 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. ●

## Revised NAPLEX Blueprint and Passing Standards to Be Implemented in January 2021; Recommendations Follow Thorough Analysis



Every five years, NABP reevaluates the competency statements and passing standard for the North American Pharmacist Licensure Examination® (NAPLEX®) in accordance with commonly held practices in licensure testing. As such, new NAPLEX

competency statements will go into effect January 2021. In addition, a standard-setting review process will be conducted to determine whether the current passing standard also needs adjustments. If so, a revised passing standard will also go into effect in January 2021.

In November 2019, NABP distributed the Pharmacy Practice Analysis Survey to help evaluate and ensure that the NAPLEX competency statements, otherwise known as the examination “blueprint,” are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. Pharmacist practitioners in all areas of practice, as well as pharmacy academicians, were solicited by NABP to participate.

### Standard-Setting Process

NABP conducted a remote standard-setting in July 2020. Participants were provided with an overview of the NAPLEX and how the examination is used by the boards of pharmacy in licensure decisions. During the

review process, participants provided ratings for NAPLEX items. After the participants finished rating each item on the reference form, ratings were collected and analyzed. The outcome of the ratings was applied to historical score data from past exams to estimate the impact to expected pass rates.

The outcome of the standard setting produces a recommendation that takes into consideration all of the expert participants’ contributions to the process. The recommendation will be reviewed by the NAPLEX Review Committee and the Advisory Committee on Examinations on July 8-10, 2020. Then it will go to the NABP Executive Committee for review and approval.

More information will be provided to the boards of pharmacy and schools and colleges of pharmacy regarding the review and possible revision to the passing standard. Additional information about the NAPLEX and NABP’s other examinations is available in the Programs section of the NABP website, [www.nabp.pharmacy](http://www.nabp.pharmacy). ●

## NABP Members Approve Bylaws Amendment, Hear Proposed Constitutional Amendment at Annual Meeting

NABP members voted to approve an amendment to the NABP Bylaws that removes the Pharmacy Board of Australia from District 4. This amendment was proposed, discussed, and voted on during the 116<sup>th</sup> NABP Annual Meeting in May 2020, in response to the Board’s request to cease its NABP membership.

During the meeting, members also were presented with two proposed amendments to the Constitution, which will be discussed and voted on at the 117<sup>th</sup> NABP Annual

Meeting. The District Meeting Elections Amendment would revise Article IV, Section 3 of the Constitution to instruct a district to nominate two candidates for consideration in the event two or more eligible candidates exist for an open member position in that district. The District Submission of Resolutions Amendment would revise Article IV, Section 6 of the Constitution to provide that any resolution submitted at a district meeting must be submitted to the district secretary and/or treasurer and the NABP

executive director/secretary at least 20 days prior to that district meeting.

More details about all of these amendments are included in the Report of the Committee on Constitution and Bylaws, available in the Publications and Reports section of the NABP website at [www.nabp.pharmacy](http://www.nabp.pharmacy). The complete, updated NABP Constitution and Bylaws is available in the About section of the NABP website. ●



## Carl Thomas 'Trip' Hoffman III, PharmD, RPh

Former Member, Utah Board of Pharmacy

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

I am a pharmacist and was appointed to the Utah Board of Pharmacy in January 2013. I served as chair from January 2018 to January 2020.

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

One of the best ways to become a solid, productive board member is to learn from experienced veteran board members. Discovering how things work in a board room is critical, but getting them done in a timely and accurate manner is equally as important. As the Board embarked on changing large regulatory items or initiating new ones, we realized the value of including experts in particular arenas on small task forces, led by one or two board members, to formulate the best ideas and bring them to the Board for final drafts and approval.

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

Through a task force, we determined the need to expand the role of pharmacy technicians, including administering vaccines and emergency medications pursuant to delegation by a pharmacist. We are also excited about the Advisory Pharmacy Compounding Education Committee to the Board of Pharmacy and the Utah Department of Commerce Division of Occupational and Professional Licensing (DOPL) that was created in March 2020. In addition, in conjunction with the Utah Pharmacists Association, we are in the process of rewriting and reevaluating our laws and rules. It is vital to make sure our regulation allows us to practice at the top of our profession (expanding our roles) and that we allow technology to flourish within our profession, but at the same time promote our professional duties of getting the right medication to the right patient and that we remain the medication experts.

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

One of the challenges we face is balancing the oversight of compounding pharmacies, while allowing these pharmacies to thrive in the setting of ever-changing regulatory demands. It is important to differentiate between meeting United States Pharmacopeia and Drug Quality and Security Act standards versus best practices standards. In our inspection efforts, DOPL is putting an emphasis on education when patient safety is not compromised. I believe this collaboration between the Board and DOPL, in regard to inspections, creates a healthy atmosphere where entities simply become better pharmacies and are able to comply with more regulations and standards, which subsequently leads to our most important mission – improved patient safety.

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

It is important to network with board members from other states as well as within national organizations. Being able to reach out to other state leaders when topics come up with which they have experience only makes your job easier. Learning from other states' successes and mistakes makes for better regulation. Utilize *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* and the *NABP State Boards of Pharmacy Member Manual*.

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

I served on the Task Force on Mutual-Recognition Licensure. Participating on a task force facilitates collaboration with members from other boards on items, initiatives, and resolutions that were promoted at the NABP Annual Meeting. It is the epitome of networking and learning from great minds in pharmacy. ●

## Utah Board of Pharmacy



#### Number of Board Members

5 pharmacist members, 1 public member, and 1 pharmacy technician



#### Number of Compliance Officers/Inspectors

Centralized investigations pool



#### Rules & Regulations Established by

Division of Occupational Professional Licensing



#### Number of Pharmacist Licensees

4,094



#### Number of Pharmacies

1,830

### Executive Officer Change

- **Christian A. Albouras, MBA**, has been named executive director of the Wisconsin Pharmacy Examining Board. He currently serves as executive director of several other professional boards for the State of Wisconsin Department of Safety and Professional Services, including the Controlled Substances Board and the Dentistry Examining Board. In addition, Albouras is alderperson for the City of Madison, WI, Aldermanic District 20 and serves on several committees for the city. Previous positions include business development specialist for Summit Credit Union and education consultant for the Wisconsin Department of Public Instruction. Albouras holds a master of business administration from the University of Wisconsin-Whitewater.

### Board Member Appointments

- **Allison Hill, PharmD, RPh**, has been appointed a member of the District of Columbia Board of Pharmacy. Hill's appointment will expire in March 2022.
- **Gregory Allan Cendana** has been appointed a consumer member of the District of Columbia Board of Pharmacy. Cendana's appointment will expire in June 2022.
- **Kelli Oldham** has been appointed a public member of the Michigan Board of Pharmacy. Oldham's appointment will expire June 30, 2022.
- **Grace Sesi, PharmD, RPh**, has been appointed a member of the Michigan Board of Pharmacy. Sesi's appointment will expire June 30, 2023.
- **Sandra C. Taylor, RPh**, has been appointed a member of the Michigan Board of Pharmacy. Taylor's appointment will expire June 30, 2023.
- **Maria Young, RPh**, has been appointed a member of the Michigan Board of Pharmacy. Young's appointment will expire June 30, 2023.
- **Anthony Charles Waits** has been appointed a member of the Mississippi Board of Pharmacy. Waits' appointment will expire June 30, 2025.
- **Rolf Zakariassen, RPh**, has been appointed a member of the Nevada State Board of Pharmacy. Zakariassen's appointment will expire October 30, 2020.



- **Mishele Dufour, CPhT**, has been appointed a member of the Oregon State Board of Pharmacy. Dufour's appointment will expire in February 2024.
- **Nichole Watson** has been appointed a public member of the Oregon State Board of Pharmacy. Watson's appointment will expire in February 2024.
- **Gary A. Hale, RPh**, has been appointed a member of the Utah Board of Pharmacy. Hale's appointment will expire June 30, 2023.
- **Autumn Hawks** has been appointed a member of the Utah Board of Pharmacy. Hawks' appointment will expire June 30, 2021.
- **Patrick Lynn Fitzgerald, APRN**, has been appointed a public member of the Wyoming State Board of Pharmacy. Fitzgerald's appointment will expire March 1, 2025.
- **Thomas A. "Tom" Maertens, RPh**, has been appointed a member of the Wyoming State Board of Pharmacy. Maertens' appointment will expire March 1, 2021.
- **Matthew D. Balla, RPh**, has been reappointed a member of the Indiana Board of Pharmacy. Balla's appointment will expire March 31, 2023.
- **David Hills** has been reappointed a public member of the Michigan Board of Pharmacy. Hills' appointment will expire June 30, 2023.
- **Starla Blank, PharmD, RPh**, has been reappointed a member of the Montana Board of Pharmacy. Blank's appointment will expire July 1, 2024.
- **Paul Brand, PharmD, RPh**, has been reappointed a member of the Montana Board of Pharmacy. Brand's appointment will expire July 1, 2024.
- **Charmell Owens** has been reappointed a public member of the Montana Board of Pharmacy. Owens' appointment will expire July 1, 2023.
- **Ashley Duggins, PharmD, RPh**, has been reappointed a member of the North Carolina Board of Pharmacy. Duggins' appointment will expire in July 2025.
- **Shawn C. Wilt, RPh**, has been reappointed a member of the State of Ohio Board of Pharmacy. Wilt's appointment will expire June 30, 2023.
- **Victoria "Vicky" Skaff, RPh**, has been reappointed a member of the West Virginia Board of Pharmacy. Skaff's appointment will expire June 30, 2024. ●
- **Kevin Dang, PharmD, RPh**, has been reappointed a member of the Arizona State Board of Pharmacy. Dang's appointment will expire January 20, 2025.
- **Kristen Snair, CPhT**, has been reappointed a member of the Arizona State Board of Pharmacy. Snair's appointment will expire January 20, 2025.

### Board Member Reappointments

## Alabama Emergency Rule Allows Institutional Facilities to Dispense MDIs in Response to COVID-19

In response to the coronavirus disease 2019 (COVID-19), the Alabama State Board of Pharmacy implemented an emergency rule to allow institutional facilities to dispense metered dose inhalers (MDIs) for the duration of Governor Kay Ivey's emergency declaration. Prior to the emergency rule, hospital pharmacies that did not have a retail license were unable to dispense medications for COVID-19 patients to take home without being in violation of Board rules. The MDI the patient used while in the hospital was discarded upon patient discharge, and the patient received a prescription to be filled at his or her local pharmacy. With an already existing shortage of MDIs, this process greatly cut into the supply of those inhalers. The emergency rule, to allow institutional dispensing of MDIs upon discharge, eliminated waste of much needed treatment.

## Idaho Medicaid Grants Provider Status to Pharmacists

The Idaho Legislature passed and Governor Brad Little signed the Idaho Medicaid rules docket that included language to recognize Idaho pharmacists as non-physician practitioners, previously referred to as mid-level practitioners, who are comprised of the following types: certified registered nurse anesthetists, nurse practitioners, nurse midwives, clinical nurse specialists, pharmacists, and physician assistants.

Idaho Medicaid has completed the final stages of system modifications to allow Idaho-registered pharmacists to enroll as ordering and referring or prescribing providers (ORP). Enrolled pharmacists will be able to prescribe and provide services within the specifications allowed under the Idaho Pharmacy Act and bill Idaho Medicaid for their respective pharmacies for Idaho Medicaid payable drugs, medical supplies, and services. All pharmacists wishing to become an ORP for Idaho Medicaid must be formally enrolled. While the Idaho State

Board of Pharmacy has no role in third-party reimbursement, the Board agreed to collaborate with Idaho Medicaid to assist with enrollment.

Additional details and a note from Idaho Medicaid on the process of enrollment to be a provider are available in the Board's June 2020 *Newsletter*.

## Massachusetts Required to License and Inspect Institutional Sterile Compounding

The proposed regulation Draft 247 Code of Massachusetts Regulations 6.00: Licensure of Pharmacies will require the Massachusetts Board of Registration in Pharmacy to license and inspect institutional sterile compounding pharmacies. In preparation, "voluntary assessments" are available for those future licensees (eg, clinic and hospital pharmacies) to have the opportunity for a Board inspector to assess sterile compounding areas for compliance with current United States Pharmacopeia (USP) standards, as well as make recommendations in view of future Massachusetts regulations and USP revisions. The Board noted this is an opportunity for education, informal feedback, development of cross collaboration, and help with resource planning.

The assessments would evaluate the following areas: facility, standard operating procedures, certifications, environmental monitoring, employee training, cleaning, personnel garbing, compliance, and verification practices. As reported in the Board's May 2020 *Newsletter*, 15 assessments were performed with many observational findings supporting the need for some upgrades or renovations in order to become compliant with USP General Chapters <797> and <800>. Additional details are available in the Board's May 2020 *Newsletter*.

## Utah Passes Legislation That Impacts Pharmacy Practice, PBMs

The state of Utah has passed the following bills related to pharmacy practice and pharmacy benefits managers (PBMs):

- **Senate Bill (SB) 145** allows for the dispensing of emergency use epinephrine auto-injector and/or albuterol inhaler, per a physician's standing order, to a qualifying adult. When either are dispensed, education must be provided regarding indications, side effects, and when to seek medical attention.
- **House Bill 272** was a collaborative bill seeking to provide pharmacies with certain protections and additional information to help curb the rising costs of drugs. It requires that PBMs administering direct and indirect remuneration fees give notice to a pharmacy of the fees within 30 days. A PBM may not reimburse a network pharmacy less than a PBM pharmacy affiliate or restrict mail-order or medication delivery services.
- **SB 138**, sponsored by Senator Evan Vickers, focused on PBM contracts specifically with 340B entities and their contracted pharmacies. It requires that PBMs reimburse 340B prescriptions at the same rate as they would non-340B medications. ●



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.

### FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

Food and Drug Administration (FDA) has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the coronavirus disease 2019 (COVID-19) pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure that patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The guidance document can be downloaded from the guidance section of the FDA website or directly by visiting [www.fda.gov/medial136841/download](http://www.fda.gov/medial136841/download).

### HHS Advises Pharmacies May Order, Administer COVID-19 Tests

The US Department of Health and Human Services (HHS) Office of the General Counsel (OGC) has issued an advisory opinion that states licensed pharmacists may order and administer COVID-19 tests regardless of state or local restrictions. The advisory opinion addresses guidance issued on April 8, 2020, which authorized licensed pharmacists to administer COVID-19 tests, including serology tests, that FDA has authorized.

In providing background for the advisory opinion, OGC explained that it has been asked whether the PREP Act allows licensed pharmacists to order and administer COVID-19 tests even in states that prohibit licensed pharmacists from ordering and administering those tests.

### COVID-19 Pandemic May Lead to New Complications in the Opioid Crisis

Due to strains on the health care system, and the consequences of precautions being taken to limit the spread of COVID-19, experts are warning that the ongoing opioid crisis may see a new wave of negative outcomes.

According to Peter Grinspoon, MD, a primary care doctor who treats opioid use disorder, those who are suffering from opioid addiction are at greater risk of contracting COVID-19 and more likely to have worse health outcomes. In an article in *Harvard Health Publishing*, Grinspoon also warned that these individuals may have treatment and support systems disrupted by the pandemic, and may be at increased risk for addiction and overdose during isolation. In addition, disruptions in illegal drug markets caused by COVID-19 could lead to possible increases in health complications related to withdrawal.

These concerns appear to have already been realized in some parts of the country. Several Chicago-area counties have shown increases in opioid deaths so far in 2020, and some other Illinois counties are up as much as 50% in the last few months, according to ABC7. “Over the past several weeks we’ve noticed an increase in the number of overdose deaths,” said Richard Jorgensen, MD, the coroner for DuPage County, IL, in an interview. “I spent most of the day reviewing the past three weeks to try and see what kind of trends or what kind of reality we’re seeing out there, and unfortunately, I was able to identify 20 most likely overdose deaths within the last three weeks. To put that in context, we had 96 deaths for the whole year [of 2019].”

NABP will continue to monitor how the COVID-19 public health emergency affects the opioid crisis and provide updates as needed.

### FDA, FTC Take Additional Action Against Companies Selling Fraudulent COVID-19 Treatments

A federal judge in Oklahoma has entered an injunction order against Xephyr LLC, doing business as N-Ergetics, requiring it to immediately stop distributing colloidal silver products, which the company has marketed as a treatment for COVID-19. FDA and

**To further combat fraudulent COVID-19 treatments, FTC has issued 45 new letters warning marketers to stop making claims that their products and therapies can effectively prevent or treat COVID-19.**

the Federal Trade Commission (FTC) have previously issued a warning letter to Xephyr about its colloidal silver products. The sellers removed their COVID-19-related web pages, but resumed marketing them as a treatment for COVID-19 by the end of April 2020.

To further combat fraudulent COVID-19 treatments, FTC has issued 45 new letters warning marketers to stop making claims that their products and therapies can effectively prevent or treat COVID-19. These “treatments” include herbal medications, music therapy, homeopathic treatments, and more. In a press release explaining the warning letters, FTC reminded readers that there is “no scientific evidence that these, or any products or services can treat or cure coronavirus.”

Individuals can report suspected COVID-19 fraud by contacting the National Center for Disaster Fraud at 866/720-5721 or [disaster@leo.gov](mailto:disaster@leo.gov). Health care providers and consumers can report adverse events or quality problems experienced with the use of these products to FDA’s Medwatch Adverse Event Reporting Program. ●



1600 Feehanville Dr  
Mount Prospect, IL 60056

Presorted First Class  
U.S. Postage  
**PAID**  
Permit #583  
Schaumburg, IL 60173

## UPCOMING EVENTS

### **NABP/AACP District 3 Meeting**

August 12, 2020 | Virtual Meeting

### **NABP/AACP District 1 and 2 Meeting**

September 8, 2020 | Virtual Meeting

### **NABP Interactive Executive Officer Forum**

September 30, 2020 | Virtual Meeting

### **NABP/AACP District 4 Meeting**

October 8, 2020 | Virtual Meeting

### **NABP/AACP District 6, 7, and 8 Meeting**

October 13, 2020 | Virtual Meeting

Never miss a minute. Follow us on social.

