

May 2020

News



# Alabama State Board of Pharmacy

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## **Recent COVID-19 Actions**

### **A Message From Board Executive Secretary Donna Yeatman**

This has been an unprecedented time for our country, our state, and our pharmacies. The Alabama State Board of Pharmacy is charged with ensuring safe and effective care for the citizens of Alabama. At no time in my memory has this charge been so vital.

With the coronavirus disease 2019 (COVID-19) pandemic, many issues and opportunities came to the attention of the Board. New relationships were developed and established relationships grew as individuals worked tirelessly with the Board to address how to consistently and proactively care for the needs of Alabamians.

I want to extend my sincere gratitude to the pharmacists, technicians, and pharmacy staff who provided, and continue to provide, immeasurable care for the patients of Alabama. Your efforts to address the needs of your patients on the front line are inspiring.

To address the obstacles identified throughout the pandemic, the Board strives to provide timely and efficient action and communication. What follows is a brief summary of the actions taken and supported by the Board.

Early on, the Board worked to identify upcoming challenges and steps to tackle those challenges. The Board addressed concerns institutional facilities had with potential staffing issues due to COVID-19 exposure within the facilities and subsequent quarantine of pharmacists by approving remote order verification for institutional orders.

In an effort to address potential exposure, the Board sent out guidance to limit contact for pharmacy staff and patients. This guidance reflected Centers for Disease Control and Prevention information, as well as best practices that were in place in Alabama and other states. The Board shared information on proper compounding

of hand sanitizer utilizing United States Pharmacopeial Convention guidelines.

The Board partnered with Drug Enforcement Administration (DEA) to assist pharmacists with questions about emergency guidance issued by DEA. In addition, the Board worked closely with DEA to expedite controlled substance orders, particularly with wholesalers where a previous relationship had not existed, to ensure that medications required for ventilated patients were received by institutions.

The Board worked in conjunction with the DEA to aid in facilitation of the spread of inventory between hospitals when supply allowed.

Partnering with the Alabama Board of Medical Examiners, the Board of Pharmacy authored a joint statement to address DEA temporary exceptions regarding the issuance of oral Schedule II prescriptions in light of the nationwide public health emergency. The joint statement detailed DEA's temporary exceptions and the processes and documentation required by pharmacists and physicians to be compliant with DEA guidance. This statement can be viewed on the Board of Pharmacy [website](#).

The Board contacted wholesalers in an effort to increase order size and delivery of needed medications. The Board communicated with wholesalers to stay abreast of impending shortages in hopes to identify other supply opportunities.

Technician training deadlines were extended to December 31, 2020, to enable pharmacy staff to place all their efforts on patients.

With all the media attention on antivirals, the Board provided materials on hydroxychloroquine and chloroquine for pharmacists.

The Board worked with Governor Kay Ivey's office, pursuant to a proclamation, to write emergency rules to

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# National Pharmacy Compliance News

May 2020



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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

## **President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues**

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the “third wave” of the opioid crisis, as detailed in the October 2019 issue of *Innovations*<sup>®</sup> (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy<sup>®</sup>'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

## **Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018**

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of

counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the “primary driver” of the current opioid crisis, according to the report.

“Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States,” a DEA press release states. “As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States.”

## **Drug-Resistant Infections Are Increasing**

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. “More action is needed to fully protect people,” the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the [CDC website](#).

## **NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain**

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain*:

*Developing the Evidence*, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

“We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines,” said Janet Woodcock, MD, director of FDA’s Center for Drug Evaluation and Research in a statement. “However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA’s efforts to address the opioid crisis must focus on encouraging ‘right size’ prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids.”

FDA will next consider the recommendations included in the report as part of the agency’s efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the [NASEM website](#).

## ***New Research Shows Pharmacists Positively Impact Hospital Care Transitions***

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients’ medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients’ perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

“Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety,” said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

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provide temporary pharmacist and pharmacy permits to those meeting certain requirements and qualifications. The temporary pharmacist permit allows for an expedited process to permit a pharmacist to practice in Alabama during the state of emergency. Likewise, the temporary in-state pharmacy permit allows for an expedited process for a pharmacy to be permitted, in the event that another pharmacy location is needed, to provide care for the patients of Alabama.

An emergency rule to allow institutional facilities to dispense metered dose inhalers (MDIs) was implemented. Hospital pharmacies that did not have a retail license were unable to dispense medications for those COVID-19 patients to take home without being in violation of Board rules. Prior to the emergency rule, 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 a shortage of MDIs already, this process greatly cut into the supply of those inhalers. The emergency rule, for the duration of the governor's emergency declaration, to allow institutional dispensing of MDIs upon discharge eliminated waste of much needed treatment.

In addition to COVID-19 activities, Board staff continues normal day-to-day activities with the majority of staff working remotely. A few staff members are working rotating schedules for essential functions of the office that could not be done remotely, and a handful of staff work at the office (at a six-foot distance) daily. The investigators address emergent issues and have been available to answer innumerable questions during the pandemic. Licensing staff continues to review applications and issue permits and licenses, while answering an abundance of questions from licensees. Board members were also active through an emergency meeting for rulemaking while caring for their own patients.

During this trying time, the Board worked diligently to provide communication and information for pharmacists, technicians, and pharmacy staff in this state.

I am very proud of the work the Board has done. But I have overwhelming pride for the pharmacists, technicians, and pharmacy staff of this state. The pharmacy community provides essential care to patients. This care

was supplied efficiently, timely, and in compliance with all regulatory requirements.

I believe that during this time of unparalleled difficulty, pharmacists exhibited their value to health care in a manner that exemplified the *Oath of a Pharmacist*.

### **Oath of a Pharmacist**

Adopted by the [American Association of Colleges of Pharmacy](#) and approved by the [American Pharmacists Association](#).

*"I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow:*

- ◆ I will consider the welfare of humanity and relief of suffering my primary concerns.
- ◆ I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for my patients.
- ◆ I will respect and protect all personal and health information entrusted to me.
- ◆ I will accept the lifelong obligation to improve my professional knowledge and competence.
- ◆ I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct.
- ◆ I will embrace and advocate changes that improve patient care.
- ◆ I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists.

*I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."*

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