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News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

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New Board Officers

At its June 2020 virtual meeting, the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy elected new officers for the upcoming year.

Addison Livingston, PharmD, RPh, representing the Second Congressional District, will serve as chairperson for the upcoming year. Dr Livingston is the co-owner of Hawthorne Pharmacy in Columbia, SC, where he has practiced for the past 23 years. He currently resides in Swansea, SC, with his wife, Kelly, and daughters, Carter and Riley.

Rob Hubbard, RPh, was elected to serve as vice chair. Mr Hubbard was appointed in 2011 to represent the Third Congressional District and was reappointed for a second term in 2016. He has been practicing pharmacy for more than 50 years. He was co-owner of Hubbard/Young Pharmacy in Clemson, SC, where he continues to practice as a staff pharmacist and consultant pharmacist. He resides in Clemson with his wife, Claudia.

Each will serve a one-year term to end on June 30, 2021.

The Board would like to take this opportunity to thank Eric Strauss, PharmD, RPh, for his time and dedication in serving as chair for the previous year. Please see below for a message from Dr Strauss.

Letter From Outgoing Chair, Eric Strauss

Serving as the chairman of the Board has been a humbling experience. Over the previous six years, it has been eye opening to discover the many facets of pharmacy practice and the expertise the professionals within it demonstrate. As we have seen in the past months during the pandemic, this knowledge is now more vital than ever. On behalf of the Board, I would like to extend our gratitude to licensees for serving the citizens of South Carolina. This pandemic has shown even more clearly that our profession is at a pivotal crossroad. The medical landscape is changing daily, and our profession is not keeping stride. This is illustrated by diminished employment opportunities, shrinking third-party reimbursements, and the limited services we can provide to the citizens in our great state. We need to use our insight as professionals to expand the scope of practice.

The expansion of testing and treatment for illnesses – such as flu, strep, and even the coronavirus disease 2019 (COVID-19) – is one niche that could be provided to our local communities and will become more essential in the fall with the continuation of current trends. I will continue to be that voice for change regarding expansion of practice and regulation, but I am only one voice in a world of many. The Board is also only one voice, and that voice is for regulating the practice of pharmacy and enforcing the current statutes. Individually, we are all only one voice, which is why it is of the utmost importance to get involved.

I implore everyone to take steps to broaden your knowledge by attending a Board meeting or participating on a Board committee. Joining a state pharmacy organization would be another avenue for representation of the profession on items for which the Board cannot lobby. Finally, my last request is that you reach out to your state senators and representatives to facilitate the changes the profession needs to continue to protect the citizens of South Carolina. Once again, thank you all for what you do, and I hope you will advocate for pharmacists and the profession.

Eric Strauss
Outgoing Chair

Thank You

As the country faces an unprecedented pandemic, pharmacists, interns, and technicians across the state have

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National Pharmacy Compliance News

August 2020

NABPF
National Association of Boards of Pharmacy Foundation

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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the 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 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 updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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continued to care for patients since day one. From virtual rotations for students, to COVID-19 testing, and finding new ways to care for the most vulnerable populations, we have seen resilience and out-of-the-box thinking from many licensees. The Board and staff would like to express their sincere thanks for all that you have done.

Overview of State of Emergency Orders

COVID-19 drastically changed the way we all operate, at least in the short term. The quarantines and social distancing prompted the Board to develop several orders to assist with operations during this unprecedented time. Below are the highlights of some areas the Board addressed during the state of emergency. The full listing can be found on the Board's website at *https://llr.sc.gov/bop.*

- Temporary 90-day permits for those facilities supporting COVID-19 relief efforts
- Deadline extensions for renewals for facilities, pharmacists, and technicians
- Remote order entry during state of emergency
- Temporary allowance for automated pharmacy pickup kiosks
- Safe Harbor guidance for personal protective equipment shortages
- Pharmacists conducting COVID-19 testing
- Consultant pharmacist inspection alternatives

Please continue to monitor the Board's website and social media sites for up-to-date information.

Consultant Pharmacist Duties During COVID-19

Since the beginning of the COVID-19 pandemic, there have been numerous challenges facing the pharmacy community. One of these has been the ability of consultant pharmacists to access their respective clinics.

At its June 10, 2020 meeting, the Board issued a statement that a virtual monthly visit could be conducted in lieu of an in-person visit if access was limited and the pharmacist was comfortable. This temporary measure allows the consultant pharmacist to continue his or her responsibility as consultant while reducing the risk of exposure and increasing the health and safety of staff and patients.

The Board will revisit this topic at a later meeting and provide any necessary updates at its November 2020 meeting.

Legislative Updates

The Board introduced two new regulations, which are now in effect.

- **Regulation 99-47** clarifies that pharmacists may compound office use drug preparations for veterinarians, which may be dispensed by the veterinarian in certain circumstances. Practitioners of human patients may not dispense compounds that are intended for office use as reiterated in Policy 132 and in the Drug Quality and Security Act.

  A. A licensed pharmacist, practicing in a permitted pharmacy, may compound veterinary drug preparations to be used by veterinarians in their offices for administration to animals.

  B. Compounded office use drug preparations may be dispensed by a veterinarian to an owner of an animal for the treatment of a bodily injury or disease of the animal only in an urgent or emergency situation for use in a single course of treatment, not to exceed a 168-hour supply.

  C. The compounded veterinary drug preparations may not be distributed by an entity other than the pharmacy that compounded such veterinary drug preparations. This does not prohibit administration of a compounded drug preparation in a veterinary health care setting or dispensing of a compounded drug preparation pursuant to a prescription drug order executed in accordance with federal and state law.
- **Regulation 99-43** clarifies the classifications of permits issued by the Board and provides the minimum standards required for the issuance of such permits. The purpose of this proposed amendment is to comply with the Board's obligations under the Practice Act, to update its regulations to reflect changes in the pharmacy industry since the regulations were last amended, and to provide clarity to applicants as to what permits are required and the minimum standards necessary to obtain the permits.

The full regulation was published June 26, 2020, and can be found on the South Carolina State Register by visiting *https://www.scstatehouse.gov/state_register.php.*

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