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News

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

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The Board Welcomes New Administrator

Congratulations to the new Board administrator! Traci Collier, PharmD, was named as the administrator/chief drug inspector for the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy on August 2, 2018. Traci has served as the Board's assistant administrator since 2016. Prior to joining the Board staff, she spent 17 years with Kaiser Permanente working in various practice settings including ambulatory care, pharmacy management, and pharmacy systems optimization. Traci lives in Chapin, SC, with her husband and two daughters.

Two Upcoming Board Vacancies

If you are interested in representing either the Fifth or the Seventh Congressional District on the Board, you must meet the following requirements:

- Reside in the Fifth or the Seventh Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Submit a biography and a petition bearing signatures of at least 15 pharmacists practicing in your respective congressional district to the Board office before December 1, 2018.

The terms begin on July 1, 2019, and end on June 30, 2025. After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by January 15, 2019, to all pharmacists who have notified the Board that they reside in the Fifth and the Seventh Congressional Districts; and
- Certify as true and valid all ballots postmarked before February 15, 2019, and received by the Board office before February 25, 2019.

Before March 1, 2019, the Board will certify in writing to the governor the names of the three candidates for each congressional district who received the most votes in the election and the names of the persons who the nominees will replace on the Board. The new members, when appointed by the governor, will take office on July 1, 2019. If you are interested in becoming a candidate for these positions, or have any questions, please contact the Board office at 803/896-4700.

Thank You

As the waters from Hurricane Florence recede, the Board would like to thank everyone for going above and beyond for their patients and community. We have heard stories of pharmacists dealing with flooding on a personal level, yet still found time to take care of their patients. We are proud to serve and be part of such a dedicated group of health care professionals.

REAL IDs

The South Carolina Department of Motor Vehicles (SCDMV) has recently started issuing REAL IDs, as well as driver's licenses and identification cards that do not qualify as REAL IDs. Those that do not qualify will say "Not For Federal Identification" somewhere on the card. However, they are still valid licenses/identification cards in the state of South Carolina. The SCDMV website states, "This is a federal law that affects federal agencies, federal buildings, and military bases." An identification that does not qualify as a REAL ID can still be used for identification in nonfederal buildings, such as pharmacies. Pharmacists should accept these identifications as valid if they are presented by a patient. Some examples of these licenses are shown in the image on page 4. They are all valid forms of identification for patients in a pharmacy.

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National Pharmacy Compliance News

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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Changes to Schedule II CS

By Debra Black, DEA Columbia Office

On November 19, 2007, Drug Enforcement Administration (DEA) published in the *Federal Register* the final rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that rule, DEA stated, "the essential elements of the [Schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed . . .) may not be modified orally." The instructions contained in the rule's preamble are in opposition to previous DEA policy, and this issue is under current legal review. Until this issue is resolved, pharmacists are instructed to adhere to state regulations regarding changes to Schedule II prescriptions. Current South Carolina policy on changes to Schedule II prescriptions states:

(a) After oral consultation with the prescribing practitioner, the pharmacist is permitted to change the patient's address, drug strength, drug quantity, dosage form, and directions for use.

(b) The pharmacist **is not permitted to make changes** to the patient's name, controlled substance (CS) prescribed (except for generic substitution), prescriber's signature, or issue date. This includes the "Do Not Fill Until" date on multiple Schedule II prescriptions.

Updates From DAODAS

By Sara Goldsby, MSW, MPH, Director of the South Carolina Department of Alcohol and Other Drug Abuse Services (DAODAS)

As consequences of the opioid epidemic are felt throughout the United States, public health officials have called for policy and clinical strategies aimed at both the supply and demand for opioids. Naturally, policy responses targeting the supply have been executed relatively quickly. Although there have been complexities to consider with clinical circumstances, restricting access to prescription opioids has been a common-sense tactic that has been used nationwide – almost effortlessly – during the past few years. While prescription limitations will ultimately be effective, we have always been aware that secondary consequences will arise should the clinical strategies aimed at curbing demand not correspond with the attempts to craft a holistic approach. Unfortunately, and as every health care practitioner knows, changing clinical practice is hard, and the challenges to changing practice during this epidemic are intensified by the need to address what all too frequently is very deep patient suffering.

So while clinical strategies catch up to policy implementation, pharmacists are left in precarious positions, having to both inform and guide patients facing new limitations, and to liaise with prescribers who might have questionable patterns. Challenges in these conversations, which can become quite contentious, are further compounded because the stakes are so high. Pharmacists must often pay distinct attention to risks – the risk of diversion, the risk of a patient turning to illicit substances to meet his or her needs, and the risk of overdose. That is not to say that prescribers are not aware of those risks, but pharmacists are potentially the last professional with a chance to intervene on those risks with a patient. Often, they are also the **first** professional to have to deal with the reactions of angry, suffering individuals who are trying to get their needs met with prescriptions. It seems like pharmacists are caught at a complex intersection, navigating the threshold between preexisting practices and patient expectations, along with new policies and patient safety concerns.

There are no clear-cut solutions for course-plotting, but there is a sentiment to hold onto throughout the navigation, and that is one of solidarity. Everyone shares responsibility for turning this epidemic around in the same way that everyone shares responsibility for a patient's health. It might be easy to place blame or cast a negative assumption on what looks like questionable prescribing practices. And it is a frightening and desperate moment when an opioid-dependent patient is dismissed from a practice without a referral. But these situations should be viewed as the results of a prescriber who does not yet have a clinical toolbox for working with opioid-dependent

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or addicted patients. Health professionals must be supportive of one another as we strengthen our system-level and patient-level approaches in this epidemic.

There are a few options for pharmacists to consider when faced with a prescriber-patient opioid quandary. If it is at all possible with limited time and tight scheduling, reach out to the prescriber with a gentle inquiry about patient tapering with partial-agonist substitution therapies such as buprenorphine maintenance. Does the prescriber with questionable patterns know about the Drug Addiction Treatment Act of 2000 waiver to treat opioid dependency in his or her own practice? What about screening, brief intervention, and referral to treatment? Is this evidence-based method used to identify, reduce, and prevent misuse and dependence on alcohol and drugs implemented in the practice? At the very least, does the prescriber know where to refer a patient to medically treat dependency and addiction?

Most importantly, guide patients and caregivers on obtaining naloxone when there is any concern about the risk of opioid overdose. Especially now that it is available via a statewide protocol, pharmacists play a key role in reducing the consequences of overdoses. Every conversation is an opportunity to fortify collaboration, change norms, reduce stigma, and help. These are the things that are going to turn the epidemic around, it is just going to take some time.

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