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News

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

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2018 Pharmacist Renewal Notices Are on the Way!

The 2018 renewal notices will be mailed in late February. You will receive a renewal notice containing your **user ID and a password,** which will allow you access to the online renewal website. If you choose not to renew online, you may request a paper renewal form from the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy office and renew by mailing the completed form and proper fees to the office. Applications for renewal must be filed no later than March 31, 2018, in order to avoid penalty. If you do not renew online, please document the date the application is mailed. The Board recommends the paper renewal be sent via **certified mail with a return receipt requested.** Postage machines do not provide acceptable proof of mailing.

Applications submitted for renewal between April 1 and April 30, 2018, must include a $50 renewal penalty in addition to evidence that the applicant meets the renewal requirements and has paid the appropriate fees. If you do not renew your license by April 30, 2018, it will be considered lapsed. You can be disciplined for unlicensed practice if you work in South Carolina with a lapsed license.

Pharmacist CE Requirements for Renewals

To renew online, you must indicate you have completed the required 15 hours of continuing education (CE). Six of those hours must be live, and 50% of the total must be in drug therapy or patient management. At least one hour must be related to approved procedures for monitoring the controlled substances (CS) listed in Schedules II, III, and IV of the schedules provided for in Sections 44-53-210, 44-53-230, and 44-53-250 of the South Carolina Code of Laws. Please refer to the Board's website under Board News for "Important Information about Opioid Monitoring Continuing Education."

If you are a pharmacist administering vaccinations, you must complete at least one hour of continuing medical education Category I CE or Accreditation Council for Pharmacy Education-approved CE related to the administration of vaccines as part of your annual licensure requirements. **You cannot renew until you have completed the CE requirements.** A random CE audit will be conducted after renewals are processed. Please respond promptly if you are selected for the audit. Disciplinary action will be taken if you cannot show you completed the CE requirements or if proof of the required CE is dated **after** your renewal is received in the Board office.

Delivery of Patient-Specific Medications to a Patient's Agent

The Board has received a number of inquiries regarding the delivery of patient-specific medications to an agent designated by the patient. This situation frequently arises in the case of free medical clinics that work with a transient population who may not have access to a pharmacy for a number of reasons (eg, transportation). In such cases, the clinics have inquired as to whether they may receive patient-specific medications and store them for the patients and, if so, whether a permit from the Board would be required.

The Board formed a workgroup to study this issue and provide a recommendation to the Board. The workgroup met on July 20, 2017, and its recommendation was reviewed and adopted by the Board during its November 2017 meeting. In looking at this issue, the workgroup first noted that under the definition of "dispense" contained in South Carolina Code Annotated §40-43-30(15), "the actual sales transaction and delivery of a drug or device is not considered dispensing . . ." Further, the definition of "dispense" contemplates the transfer of a drug to a patient or a "patient's agent." Indeed, the South Carolina Pharmacy Practice Act contemplates the involvement of a patient's agent in several contexts. See S.C. Code Ann. §40-43-86(L)(1) (providing that the pharmacist shall offer counseling to the patient or the "patient's agent"); see also S.C. Code Ann. §40-43-86(H)(6) (requiring the

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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patient or the "patient's agents" to consent to substitution of a drug).

Based on the above, the workgroup and the Board concluded that the South Carolina Pharmacy Practice Act clearly contemplates the delivery of a medication to a patient's agent. This may arise in the case of a relative picking up a prescription for an elderly family member or, as in the question presented, in the case of a patient of a free medical clinic who is unable to visit the pharmacy and designates the clinic as his or her agent to receive a prescription medication. Since the agent is an extension of the patient, the agent would not require a permit to receive and store the prescription medication. However, it is important to note that once a medication is dispensed, it may not be returned to the dispensing pharmacy (eg, in the case of a patient of a free medical clinic who did not pick up his or her prescription). Furthermore, if the patient's agent is an entity (such as a free clinic) that stores medications for administration pursuant to a permit issued by the Board, the dispensed patient-specific medication should be stored in an area separate from the area where the permitted medications are stored. Finally, while the Board has determined that this practice is allowed under the South Carolina Pharmacy Practice Act, the Board notes that this opinion is subject to any federal or state laws outside the jurisdiction of the Board and makes no representation as to whether this practice may be appropriate under said federal or state laws in certain circumstances.

USP Delays Implementation of General Chapter <800>

The United States Pharmacopeial Convention (USP) announced on September 29, 2017, that it will postpone the official implementation date of USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings to December 1, 2019. The goal is to have the official date of USP Chapter <800> align with the final version of USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. At this time, it is not mandated by statute that the Board enforce USP Chapter <800>. Additional information on USP Chapter <800> is available on the USP website at *www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.*

Executive Orders Regarding the Opioid Epidemic

On December 18, 2017, Governor Henry McMaster issued two executive orders regarding the opioid epidemic. Executive Order 2017-42 declares the opioid epidemic a statewide public health emergency in South Carolina, pursuant to S.C. Code Ann. §1-3-420, and establishes the Opioid Emergency Response Team, of which the Department of Labor, Licensing, & Regulation is a member. Executive Order 2017-43 requires the South Carolina Department of Health and Human Services (DHHS), the Governor's Cabinet agency responsible for administering Medicaid benefits in our state, to develop a policy restricting reimbursement to initial opioid prescriptions of no more than a five-day supply for acute and postoperative needs. Additionally, DHHS must develop a policy regarding opioid dosing thresholds and prepare recommendations for legislative changes to the Opioid Emergency Response Team. DHHS must develop and publish these policies on or before March 1, 2018.

The Opioid Emergency Response Team held its initial meeting on December 19, 2017. It was announced that the Public Employee Benefit Authority (PEBA), which provides insurance for public employees in South Carolina, will voluntarily adopt the five-day limitation on initial opioid prescriptions for acute and postoperative needs by March 1, 2018. Although other health insurance providers may adopt this reimbursement policy in the future, only PEBA and DHHS-administered programs will be impacted by this restriction as of the publication of this *Newsletter.* The intent of this restriction is to prevent the development of opioid addiction arising from an excessive prescription for acute and postoperative pain management needs.

These executive orders do **not** restrict the prescriptive authority of any provider authorized to prescribe CS in this state and do **not** impact prescriptions for the treatment of chronic pain. Further, these executive orders do **not** prohibit a provider from prescribing a refill of the initial five-day supply; however, providers should carefully evaluate whether non-opioid alternatives may better serve the patient's needs when considering a refill.

It is important to keep in mind that the five-day restriction on initial opioid prescriptions for acute and postoperative needs is consistent with the recommendations contained in the Revised Joint Pain Management Guidelines published in August 2017 by the South Carolina state boards of dentistry, medical examiners, nursing, and pharmacy, which adopted the Centers for Disease Control and Prevention's (CDC's) March 2016 Guideline for Prescribing Opioids for Chronic Pain, as tailored to comport with South Carolina law. A copy of the Revised Joint Pain Management Guidelines is available at *www.llr.sc.gov.*

Additional updates will be provided as the interdisciplinary Opioid Emergency Response Team advances its efforts to combat this public health emergency.

The Department of Labor, Licensing, & Regulation hosts the website *www.NaloxoneSavesSC.org,* where pharmacies that dispense naloxone via protocol can **choose** to register. **Registration is not mandatory** in order to dispense naloxone via protocol; however, registration does assist caregivers and those at risk for opiate overdose in

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locating this lifesaving medication. As of January 24, 2018, 254 South Carolina pharmacies have registered.

Additionally, South Carolina State Fire is partnering with the South Carolina Department of Health and Environmental Control's (DHEC's) Bureau of Emergency Medical Services to deliver Reducing Opioid Loss of Life (ROLL) training to the fire service in 2018. State Fire will meet with DHEC leadership to develop a program for direct delivery of live training and online training components through the South Carolina Fire Academy's learning management system. ROLL is currently being piloted with the Caromi and C&B Fire Departments in Berkeley County and countywide with the Clarendon County Fire Department.

South Carolina Health Alert Network Registration

The South Carolina Health Alert Network (SCHAN) is a web-based system that provides alerting and notification capability to health care workers throughout the state. It is used to notify health care providers of clusters, outbreaks, and other events of public health significance. SCHAN is also used to distribute health advisories and updates from the CDC. All public health/emergency personnel and first responders are invited to voluntarily register for the CodeRED system, which is used to distribute the health advisories and updates. Interested licensees may access the registration form by visiting *www.scdhec.gov/Health/FHPF/SCHANRegistration.* The form may be submitted electronically via the website, emailed to the Health Alert Network coordinator at SCHAN@dhec.sc.gov, or faxed to 803/898-0897.

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