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North Carolina Board of Pharmacy News

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Item 2358 – Licenses, Registrations, and Permits Not Renewed Are Now Expired; 60-Day Grace Period Has Commenced

By operation of law, all licenses, registrations, and permits that the North Carolina Board of Pharmacy issues expire on December 31 each year. All licenses, registrations, and permits not renewed for 2018 have therefore expired. North Carolina law, however, provides a 60-day "grace period" during which expired licenses, registrations, and permits may be renewed without penalty. That grace period has begun. If you have not renewed your license, registration, or permit for 2018 – and you wish to do so – please take immediate action.

As pharmacists know, the Board has transitioned to a new online licensing system. From this point forward, all renewals, new applications, forms, and updates will be submitted and managed through a single online portal, the Gateway: *https://portal.ncbop.org.* Instructions on creating a profile and renewing a license, registration, or permit may be found on the Board's website, *www.ncbop.org.*

Item 2359 – Board Remembers Nellie Taylor Jones

Our dear friend Nellie Taylor Jones passed away on November 17, 2017. Nellie was the Board's receptionist from 2011 to 2016 – and she was so much more than that. Nellie lived a life of compassion, service, and inspiration to others. Anyone who called the Board office or visited during Nellie's tenure was greeted with a warm smile and a kind welcome. We were amazed every day by her strength, her love of others, her contagious laughter and sense of humor, and her beautiful, positive spirit. We were fortunate to have her for a short while, and we are grateful to her family for sharing her with us for those five years. We miss her terribly. Nellie's obituary may be viewed at *www.ellisdjones.com/obituary/nellie-jones.*

Item 2360 – Boardroom Dedicated to Executive Director Emeritus David R. Work

At its November 2017 meeting, the Board dedicated the boardroom to Executive Director Emeritus David R. Work. Board members and staff are especially grateful to David's daughters – Dana Ward, Amy Needham, and Susan Launiau – for entrusting the Board with a number of David's awards, which are now on display outside the Work Boardroom. Thank you to friends, family, former Board members, and former Board staff who came to enjoy the presentation and reminisce about David. Many stories of David's years at the Board were told – and a few of them were actually true! David would have enjoyed the event immensely.

Item 2361 – Reminder: CE Rule Changes Became Effective on January 1, 2018

As pharmacists popped the bubbly and broke into "Auld Lang Syne" this New Year's Eve, they were not only welcoming a new year, but also new rules governing continuing education (CE). The CE rule amendments are the most comprehensive issued by the Board in some years, changing the number of live hours required, the types of CE that satisfy license renewal requirements, exceptions to the CE requirement, as well as the process of reporting CE for renewal. As pharmacists plan their CE year, start by reviewing the following frequently asked questions (FAQs): *http://ncbop.org/faqs/Pharmacist/CEFAQChangesEff010118.pdf.*

Item 2362 – Board Statement on Implementation of USP Chapter <800>

In light of questions to Board members concerning the implementation of United States Pharmacopeia (USP) Chapter <800>, which sets standards for hazardous drug handling by health care personnel, as well as USP's announcement on Friday, September 29, 2017, concerning

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National Pharmacy Compliance News

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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 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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the chapter's effective date, the Board has issued the following statement:

> North Carolina pharmacists are likely aware that on Friday, September 29, 2017 the United States Pharmacopeia ("USP") announced that it is postponing the effective date of General Chapter <800> to December 1, 2019. USP stated that the purpose of the postponement is to "align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797>." More information here: http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare?platform=hootsuite[.]
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> As compounding pharmacists know, federal law – via the Drug Quality and Security Act – requires that a compounding pharmacy comply with USP chapters <795> and <797>. Likewise, Board of Pharmacy Rule 21 NCAC 46.2801 requires that a compounding pharmacy: (1) "comply with the standards established by United States Pharmacopeia chapter <795>, including all United States Pharmacopeia chapters and standards incorporated into chapter <795> by reference and including all subsequent amendments and editions of the same"; and (2) "comply with the standards established by United States Pharmacopeia chapter <797>, including all United States Pharmacopeia chapters and standards incorporated into chapter <797> by reference and including all subsequent amendments and editions of the same . . . ."
>
> Accordingly, if and when USP chapter <800> is expressly incorporated into USP chapter <795> or <797>, it will govern compounding activities under both federal and state law. Pharmacists with an interest in this issue are advised to direct comments to USP as appropriate – www.usp.org[.]
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> North Carolina pharmacies who are licensed in other states should confer with those states' boards of pharmacies concerning USP <800> enforcement.

Item 2363 – Board Files Fiscal Year 2016-17 Annual Report

North Carolina law requires the Board to file an annual report with various state agencies, legislative committees, and executive officers. The Board's most recent report, filed October 31, 2017, may be found at *www.ncbop.org/about/AnnualReport2016_17.pdf.*

The report compiles various statistics on licensees, registrants, and permittees, as well as disciplinary statistics and highlights of various Board activities, including rulemaking.

Item 2364 – Reminder: Board Guidance to Pharmacists on Implementation of the STOP Act

As pharmacists know, the North Carolina General Assembly has passed, and Governor Roy Cooper has signed into law, the Strengthen Opioid Misuse Prevention ("STOP") Act. The STOP Act is an effort to combat the opioid abuse and misuse epidemic. The STOP Act makes numerous changes to the laws governing controlled substance (CS) prescribing, CS dispensing, and the North Carolina Controlled Substance Reporting ystem. Various sections of the STOP Act become effective at differing times.

Board staff continue to receive a number of inquiries on the STOP Act, and pharmacists in need of guidance are encouraged to call or otherwise contact Board staff. There is also a comprehensive FAQ document that goes through the STOP Act's provisions as they relate to the practice of pharmacy in some detail, which may be found at *www.ncbop.org/PDF/GuidanceImplementationSTOPACTJuly2017.pdf.*

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