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North Carolina Board of Pharmacy News

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Item 2374 – The Board Selects Ashley Duggins to Fill Open Central District Seat

The North Carolina Board of Pharmacy members have selected Ashley Duggins to fill the central district seat for a term to conclude on April 30, 2020. Dr Duggins is a 2002 graduate of the University of North Carolina Eshelman School of Pharmacy. She owns and operates Prevo Drug in Asheboro, NC. Dr Duggins' many professional and community memberships and activities show a deep commitment to public service. The Board members and staff welcome Dr Duggins.

The Board members and staff also thank all of the candidates who applied to fill the central district seat. Coming from a broad spectrum of practice backgrounds and experience, all were impressive. They are: Ismail Badjie, Jay Brown, Duke Calfas, Wes Cowell, Nicole Eastman, Jeff Eudy, Sam Forrester, Jennifer Funkhouser, Catherine Huemmer, Abdul Kader, Max Reece, Scott Romesburg, Angela Smith, Richard Sterling, Greg Vassie, Tim Weber, and Doug Yoch.

Item 2375 – Education for Pharmacists on Mitigating the Effects of the Opioid Misuse and Abuse Crisis; a Focus of Regional Workshops Hosted by NCAP

In November 2017, the Board agreed to provide financial support to the North Carolina Association of Pharmacists (NCAP) to subsidize a series of educational programs to address opioid misuse and addiction. The first of several planned regional workshops took place at NCAP's annual convention, September 21-22, 2018, in Winston-Salem, NC.

Following the convention, NCAP will host a series of regional advanced opioid workshops for pharmacists. These workshops will educate pharmacists on pain management topics and best practices; harm reduction topics and service concepts; use of screening, brief intervention, and referral to treatment, also known as SBIRT; and fundamentals of medication-assisted treatment. More information on the regional workshops can be found at *www.ncbop.org/CE/NCAPOpioidWorkshopsFall2018.pdf.*

Item 2376 – Reminder: Opioid Public Service Announcement Campaign Ads Available for Download

Pharmacists are reminded that the Board produced a series of public service announcements (PSAs) concerning the opioid crisis. The PSAs feature Joseph "Joe" Adams, a pharmacist and past president of the National Association of Boards of Pharmacy® (NABP®), sharing his deeply personal story of losing his son to an opioid overdose in 2014. These ads emphasize the importance of obtaining help and the critical role pharmacists can play.

The ads come in 30-second, 60-second, and six-minute versions, and are available for download here. Board members and staff welcome and encourage pharmacists using these ads to educate their patients and communities about proper medication use and the dangers of opioid abuse.

Other resources for pharmacists and the public can be found on the NABP AWAR$_X$E® Prescription Drug Safety web page at *https://nabp.pharmacy/initiatives/awarxe.*

Item 2377 – Reminder: CE Requirements for 2019 Renewals

Pharmacists are reminded that amended Board rules governing continuing education (CE) for licensure renewal went into effect on January 1, 2018. Those changes were detailed in the October 2017 *Newsletter,* in listserv emails to all pharmacists, and in a document of frequently asked questions found at *www.ncbop.org/faqs/Pharmacist/faq_ContEducation.htm.*

Key things to remember:

- The total CE requirement remains 15 hours, with five hours being "live" CE.
- The allowable categories of CE are **only** the following:

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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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Accreditation Council for Pharmacy Education-accredited courses; NCAP-accredited courses; and precepting a student enrolled at UNC Eshelman School of Pharmacy, Campbell University College of Pharmacy and Health Sciences, Wingate University School of Pharmacy, or High Point University Fred Wilson School of Pharmacy for at least 160 hours **as part of the school's academic program.**

- Pharmacists will not have to enter CE course titles and accreditation numbers as part of the renewal process. Pharmacists will, however, have to attest that they have met the CE requirement and attest which types of CE the pharmacist attained to satisfy the requirement.

Pharmacists with questions about the CE requirements for the 2019 renewal are encouraged to contact a member of the Boards licensing staff at 919/246-1050.

Item 2378 – Board Hosts 2018 NABP/ AACP District 3 Meeting in Asheville

The Board hosted the 2018 NABP/AACP District 3 Meeting at the Renaissance Hotel in Asheville, NC. Board members and staff from the Alabama, Florida, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee boards of pharmacy gathered for education, networking, and policy discussion.

This meeting also included representatives from most of the schools and colleges of pharmacy in the District 3 states, providing opportunity for dialogue and networking among educators and regulators.

The Board thanks Campbell University College of Pharmacy and Health Sciences for acting as the host school for the meeting, and in particular, Board president (and Campbell faculty member) Andy Bowman and Dean Michael Adams for their guidance, support, and contributions to a successful conference.

The Board thanks NABP staff, particularly Carmen Catizone, Dana Oberman, and Jenein Gaston, for their programming support and expertise.

The Board also gives special recognition to Cindy Parham, the investigations and inspections coordinator, who also serves as secretary/treasurer of NABP District 3. Cindy played the central role in planning and executing the conference. Without her expertise and efficiency, neither this District 3 meeting nor any other would be a success.

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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