April 2018

North Carolina Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Item 2365 – North Carolina CSRS Now Connected to PMP InterConnect

The North Carolina Controlled Substance Reporting System (CSRS) is now connected to PMP InterConnect®, a program developed by the National Association of Boards of Pharmacy® (NABP®) to allow data sharing among states' prescription monitoring programs (PMPs). More information on this announcement is available at *www.ncnn.com/edit-news/10195-more-money-going-to-fight-opioids.*

This enhancement provides a significant new resource for pharmacists exercising their professional judgment when dispensing controlled substances. North Carolina Department of Health and Human Services (DHHS) staff advise that pharmacists may access data from other states by selecting the "Multiple State Query" link on the left-hand side of the CSRS query page on the system's website. A menu of available states will appear in the "Disclosing States" field. Some states (including Virginia) are already accessible. Other states will be added in the near future. Pharmacists with questions about the data sharing features are encouraged to contact Alex Asbun of DHHS' Drug Control Unit, who directly administers CSRS, at alex.asbun@dhhs.nc.gov or 919/733-1765.

On the subject of CSRS, pharmacists are reminded of their obligations under the Strengthen Opioid Misuse Prevention ("STOP") Act to incorporate CSRS review into their opioid dispensing process when certain "red flags" are evident. Comprehensive guidance on the STOP Act is available at *www.ncbop.org/PDF/GuidanceImplementationSTOPACTJuly2017.pdf.*

Item 2366 – Board Launches Public Service Announcement Campaign Concerning the Opioid Crisis

Beginning February 8, 2018, the North Carolina Board of Pharmacy launched an opioid public service announcement campaign on television stations in the Wilmington and Greenville, NC areas and on social media platforms. The advertisements feature Joe Adams, a pharmacist and past president of 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 that pharmacists can play.

The ads come in 30-second, 60-second, and six-minute versions and are available for download from the Board website. 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.

The Board thanks Third Wheel Media of Chapel Hill, NC, and NABP for their tremendous efforts on this issue. Pharmacists will note that texting "abuse" to 555888, as instructed in the ads, will result in a reply text that provides a link to an NABP-created and hosted page containing resources for pharmacists to share with patients and their communities. That page may be accessed directly at *https://nabp.pharmacy/homepage/prescription-drug-safety.*

These ads are the first phase of a multimedia campaign. Board staff will continue to keep pharmacists updated as the campaign progresses.

Item 2367 – Updated Board Guidance to Consumers on Safe Disposal of Unwanted or Unneeded Medications

Board staff often receive questions concerning safe medication disposal. An updated Board document provides guidance on safe disposal methods, as well as links to helpful resources. It may be found at *www.ncbop.org/faqs/SafeDisposalofMedicationsFeb2018.pdf.* Pharmacists are welcome and encouraged to download this guide to distribute to patients.

The Board thanks Vera Reinstein of Alliance Behavioral Healthcare and Nidhi Gandhi of the Wingate

continued on page 4

National Pharmacy Compliance News

April 2018

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 Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

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 at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

continued from page 1

University School of Pharmacy for leading the effort to create this guidance leaflet.

Item 2368 – Reminder: CE Rule Changes Became Effective on January 1, 2018

As of the date of this *Newsletter,* we are one-fourth of the way through 2018. Pharmacists are again reminded that the Board amended the rules governing continuing education (CE) for pharmacist license renewal, which became effective on January 1, 2018. The CE rule amendments change the number of live hours required, streamline the types of CE that satisfy license renewal requirements, reduce exceptions to the CE requirement, as well as make changes to the process of reporting CE for renewal. As pharmacists continue to plan their CE year, please review the following frequently asked questions: *http://ncbop.org/faqs/Pharmacist/CEFAQChangesEff010118.pdf.*

Item 2369 – Pharmacist-Managers Reminded of Their Obligation With Respect to Pharmacy Technician Hires and Registration Applications

In recent months, Board staff have seen an increase in the number of pharmacy technician applications in which the applicant's significant criminal history is not disclosed. Certainly, not every criminal conviction disqualifies a pharmacy technician applicant. But a failure to fully disclose criminal history can – and often does – result in denial of the registration for applicants who have "made false representations or withheld material information in connection with registering as a pharmacy technician" (North Carolina General Statute (NCGS) 90-85.15A(d)(1)). Not infrequently, a withheld (or, for that matter, a disclosed) criminal history includes matters that are disqualifying in and of themselves or strongly suggest other grounds for disqualification. See NCGS 90-85.15A(d)(2): "Been found guilty of or plead guilty or nolo contendere to a felony involving the use or distribution of drugs."; and NCGS 90-85.15A(d)(3): "Indulged in the use of drugs to an extent that renders the pharmacy technician unfit to assist a pharmacist in preparing and dispensing prescription medications."

Pharmacist-managers "[accept] responsibility for the operation of a pharmacy in conformance with all statutes and rules pertinent to the practice of pharmacy and distribution of drugs . . ." (Board Rule 21 North Carolina Administrative Code 46.1317(27)). Accordingly, pharmacist-managers must take reasonable steps to ensure that pharmacy technician applicants are qualified for registration. That includes taking reasonable steps to ensure that applicants make truthful and complete disclosures on their registration applications and that applicants do not have disqualifying criminal histories. Such steps are, of course, also part of a prudent hiring process, generally.

Item 2370 – Closing of License, Registration, and Permit Renewal Period

March 1, 2018, was the final day to renew your pharmacist license, dispensing physician assistant/nurse practitioner registration, dispensing physician registration, or technician registration for the current year. Any license or registration that was **not** renewed by March 1 became inactive. North Carolina law prohibits the practice of pharmacy without a current license or registration.

Likewise, March 1, 2018, was the final day to renew a pharmacy or durable medical equipment (DME) permit. From March 1 through March 31, pharmacy and DME permits could be renewed with a late penalty. As of the date of this *Newsletter,* that window has closed and any pharmacy permit or DME permit not renewed is now closed.

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