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Item 2346 – New Rules Governing CE Go Into Effect January 1, 2018

The North Carolina Board of Pharmacy amended the rules governing continuing education (CE). **The amended rules go into effect January 1, 2018.** To assist pharmacists in planning for the changes, Board staff have assembled the following frequently asked questions (FAQs) guidance.

1. **I heard that the Board has changed its CE requirements. Is that true?**
   Yes, the Board has adopted changes to Rule 21 North Carolina Administrative Code (NCAC) 46.2201, which sets forth CE requirements for pharmacist license renewal.
2. **When do these changes go into effect?**
   The changes go into effect **January 1, 2018.**
3. **So, when I renew my license for 2018, what rule do I have to follow?**
   The current rule. Again, the changes to the CE rule do not go into effect until January 1, **2018.** So, when pharmacists begin renewing their licenses on November 1, 2017, those renewals will be governed by the current CE rule.
4. **What if I renew my license for 2018 during the "grace period" from January 1, 2018, to March 1, 2018?**
   That does not matter. All license renewals for 2018 will be governed by the **current** CE rule, even if you renew during the "grace period."
5. **So, I do not need to do anything different with my CE this year?**
   That is correct. The Board will roll out a new information technology system later in 2017, which will change the pharmacist CE interface. When that system goes live, Board staff will provide any necessary instructions. But rest assured, any CE that you enter into the system between now and then **will not be "lost."**
6. **Alright. Can you explain how the new rule that goes into effect January 1, 2018, will govern my license renewal for 2019?**
   a. **How many total hours of CE will I need to renew for 2019?**
      15. The total number of required CE hours has not changed.
   b. **How many "live" CE hours will I need to renew for 2019?**
      Five. This is a decrease from the eight hours of "live" CE required for renewal under the current rule.
   c. **What kinds of CE will count toward my renewal for 2019?**
      CE must fall into one of the following categories: (1) Accreditation Council for Pharmacy Education (ACPE)-accredited courses; (2) North Carolina Association of Pharmacists (NCAP)-accredited courses; or (3) precepting a student enrolled in the University of North Carolina Eshelman School of Pharmacy, the Campbell University College of Pharmacy and Health Sciences, the Wingate University School of Pharmacy, or the High Point University Fred Wilson School of Pharmacy for at least 160 hours as part of the school's academic program.
   d. **Will I have to enter all my CE course titles and accreditation numbers into the Board's website to renew for 2019?**
      No. You will have to attest that you have acquired all the CE necessary for renewal, and you will have to report the number of hours you received from ACPE courses, NCAP courses, and/or precepting. But you will not have to enter course titles and accreditation numbers.
   e. **Will I have to keep paper certificates for the CE that I earn for my 2019 renewal?**
      No. The new rule specifies that if an approved accreditor keeps an electronic database of all pharmacists granted CE, the pharmacist's record-keeping requirement is met. The CPE Monitor® system, provided through the collaborative efforts of the National Association of Boards of Pharmacy®, ACPE, and ACPE-accredited providers, maintains a database for all ACPE-accredited courses. NCAP will maintain a database of all pharmacists who receive CE credit from

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

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an NCAP-accredited course. The North Carolina-based schools of pharmacy maintain databases that track preceptor credit.

f. Will I be able to carry over surplus CE hours from year to year?

No. The five-hour carry-over option ends effective January 1, 2018. So, for 2019 renewal, you must make sure you obtain a full 15 hours of CE in calendar year 2018.

g. Will there be any exemptions from CE?

Only two: (1) members of the armed forces who are eligible for a waiver under Rule 21 NCAC 46.1613; and (2) pharmacists who resided the entire year in another state, did not practice pharmacy in North Carolina, and satisfied the state of residence's CE requirements for pharmacist licensure.

h. Will the Board audit more pharmacists for CE compliance?

Yes. But Board staff will provide reports to CPE Monitor, NCAP, and the North Carolina-based schools of pharmacy. Those reports will identify pharmacists selected for audit and the claimed CE hours accredited by the organization receiving the report. The organization will review the report and notify Board staff of any discrepancy. The Board will only contact a pharmacist selected for audit if that review identifies a discrepancy.

Item 2347 – Board Begins Mandatory Periodic Rule Review

In accordance with North Carolina General Statute (NCGS) §150B-21.3A and Rule 26 NCAC 05.0206, the Board has adopted initial determinations of its rules for purposes of completing the mandatory periodic rule review. The report of the Board's initial determinations is available at *www.ncbop.org/LawsRules/NCBOP_RULEMAKING_Report_on_Periodic_Rule_Review150B_21.3AFeb2017.pdf.*

The Board will be accepting public comments on the initial rule designations until the close of business on Monday, May 1, 2017. If you wish to submit a public comment about any of the proposed rule classifications, you may do so by either mailing a public comment to the attention of the Board's Executive Director, Jack W. "Jay" Campbell, by United States Postal Service or other delivery service to 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517, or by email to rulereview@ncbop.org.

"Public comment" is defined by NCGS §150B-21.3A(a)(5) as a written objection to all or part of a rule. Additionally, pursuant to NCGS §150B-21.3A(c)(2), in order for the North Carolina Rules Review Commission to determine whether the public comment has merit, the public comment must address the specific substance of the rule and address any of the standards of Commission review, as set forth in NCGS §150B-21.9(a).

Item 2348 – Dispensing Prescriptions Written by Veterinarians Does Not Require a DEA Number (for Non-Controlled Drugs) or an NPI

Several times over the past few weeks, Board staff have received calls from veterinarians who are frustrated that a pharmacy has refused to dispense an otherwise valid prescription because the veterinarian lacks a Drug Enforcement Administration (DEA) number or a National Provider Identifier (NPI) number.

A veterinarian (or, for that matter, any other health care provider) who writes a prescription for a drug that is not a controlled substance does not need a DEA number to do so. Nor does North Carolina law require a DEA number to appear on a prescription for a non-controlled substance. Historically, there had been some confusion on this latter point under North Carolina law, but that confusion was laid to rest in 2008, as detailed in the FAQs at *www.ncbop.org/faqs/Pharmacist/faq_DEANoOnNoncontrolledRX.htm.*

Veterinarians are **not eligible** to obtain an NPI number. In 2013, the Centers for Medicare and Medicaid Services clarified that veterinarians do not meet the regulatory definition of "health care provider" for purposes of obtaining an NPI. More information can be found at *https://nabp.pharmacy/veterinarians-not-eligible-for-npis-cms-clarifies.*

The Board appreciates, as always, pharmacists' efforts to ensure that prescriptions comply with all applicable laws and rules. But demanding a DEA number for a non-controlled substance prescription and/or an NPI number from a veterinarian who is not eligible to obtain one is not required by law. And doing so can pose a barrier to timely, effective treatment of veterinary patients.

Item 2349 – Statewide Naloxone Standing Order Updated

Pharmacies that participate in the statewide naloxone standing order are advised that the order was reissued by Kelly Kimple, MD, in January to ensure continuity between the departure of Randall Williams, MD – the previous state health director – and his eventual successor. There has been no change in the content of the standing order. The updated order may be found at *www.naloxonesaves.org/files/2017/01/2017-Naloxone-Standing-Order.pdf.*

Pharmacists are reminded that a great deal of information about naloxone dispensing may be found at *www.naloxonesaves.org.*

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