



North Carolina Board of Pharmacy

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Item 2350 – Board of Pharmacy Executive Director Emeritus David R. Work Passes Away

David R. Work, who served as the North Carolina Board of Pharmacy's executive director from 1976 to 2006, passed away on Saturday, April 22, 2017. David is remembered, and will be forever remembered, as one of the giants of North Carolina pharmacy. His tenure as executive director saw enormous growth in the profession of pharmacy and seismic changes in the regulatory landscape. David navigated these changes expertly and, under his steady hand, the North Carolina Board emerged as, and remains, a progressive force for the advancement of the profession and protection of the public.

David's influence ranged far beyond North Carolina. His years of service to the National Association of Boards of Pharmacy® (NABP®), including his time as president, allowed him to help craft the future of the profession at the national and international level.

Anyone who knew David will remember him as full of joy for life, possessed of a rapierlike wit, ever ready with his camera, and a constant source of sound advice. The Board members and staff, past and present, will miss him terribly.

The French philosopher Paul Valéry said, "A great man is one who leaves others at a loss after he is gone." With David's passing, we are all at a loss.

Item 2351 – New Board Rule Requires Pharmacists, Technicians, Pharmacies, and DME Facilities to Obtain an NABP e-Profile ID Number

New Board Rule .1615 (21 North Carolina Administrative Code 46.1615) requires all pharmacists, technicians, pharmacies, and durable medical equipment (DME) facilities to obtain and report an NABP e-Profile ID number. This requirement will make it easier for Board staff to access and track information on continuing pharmacy education (CPE) fulfillment, pharmacy and DME facility inspections, and out-of-state disciplinary actions.

Most pharmacists should already have an e-Profile ID number, as one is required to obtain credit for Accreditation Council for Pharmacy Education (ACPE)-accredited CPE coursework. All Pharmacy Technician Certification Board-certified technicians also have an e-Profile ID number, which was assigned at the time of certification.

All pharmacists and pharmacy technicians (whether registered or certified) should follow the instructions below to obtain (or recover) an e-Profile ID number, which you will need to complete the license or registration renewal process for 2018. Note that there is no cost to obtain an e-Profile ID number.

Board staff are working with NABP staff to determine the most efficient method for pharmacies and DME facilities to obtain an e-Profile ID number. More information will follow from Board staff on this process.

Instructions for Obtaining an NABP e-Profile ID Number for Pharmacists and Technicians

To create your NABP e-Profile and receive an e-Profile ID number, please follow these instructions:

1. Please visit <https://store.nabp.net>.
2. Click on "Create an e-Profile" button to begin the registration process.
3. Read and accept the NABP e-Profile Terms of Service. At the bottom of this page, click the box that reads "By clicking this box I confirm my acceptance and agreement with these Terms of Service" and click the "Continue" button.
4. When asked "What product or service do you need today?" select "CPE Monitor," a collaborative service from NABP, ACPE, and ACPE providers that allows you to track your CPE credit, and again click the "Continue" button.
5. Fill out all the fields marked with an asterisk (*) on the "Personal Information" page (Step One); please be sure to fill in the information completely and accurately. After filling out all the required fields, click "Continue."

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations

 *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.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

6. The next page is “Contact Information” (Step Two). Again, fill out the requested information and click “Continue.”
7. Confirm your contact details by clicking “Continue” once more.
8. At the “Security Information” page (Step Three), select the security questions of your preference and answer them accordingly. After answering three security questions, click “Continue” to proceed to the next page.
9. After completing the three steps mentioned above – personal, contact, and security information – you will see your NABP e-Profile ID number in the upper right-hand corner underneath your name. **In addition, your NABP e-Profile ID will be sent to you in a separate email; be sure to check your spam/junk folder if you do not receive this email in your inbox.**
10. Lastly, on the left-hand side column, click “CPE Monitor” to complete the final steps of your registration. You will be prompted to select your profession and enter your professional credential(s). To fully activate CPE Monitor[®], provide at least one license, registration, or certification number, if applicable.

Please note that if the system cannot match key identifying information between your new user registration and a previous registration, you will be instructed to research the necessary frequently asked questions (FAQs) found in the CPE Monitor FAQs under the section titled “NABP e-Profile Assistance,” or you may contact NABP Customer Service for further instructions on what is needed to complete the new user registration. To quickly access the CPE Monitor section of the NABP website, you can use the web address MyCPEMonitor.net.

Note: If you already have an NABP e-Profile ID but misplaced the number, you may do a quick search by clicking on the My e-Profile ID Quick Search button that is on the NABP e-Profile login page, which is accessible via <https://store.nabp.net>.

Item 2352 – Advertisements and Sales Pitches to North Carolina Residents and Employers Concerning Importation of ‘Canadian’ Prescription Drugs

Board staff have become aware of an uptick in advertisements and sales pitches to North Carolina residents and employers encouraging the purchase of prescription drugs from “Canadian” pharmacies. The public is reminded that federal law prohibits the importation of prescription drugs from foreign countries, except by the original manufacturer, and even then, only for emergency purposes. Moreover, the advertised “pharmacies” (which are often not pharmacies and are “Canadian” only insofar as the name includes “Canada” and the website displays a red maple leaf) are not licensed and overseen by the Board – and cannot be. Finally, importing drugs from “Canadian” or other foreign “pharmacies” is highly dangerous. These outfits are often purveyors of counterfeit, adulterated, and dangerous products. Patients can be, and have been, seriously harmed by them.

A 2003 position paper from NABP, available at www.ncbop.org/PDF/NABPImportationofPrescriptionDrugs_March2003.pdf, outlines the public health and safety dangers of importing prescription drugs from foreign countries. So, too, does information for consumers from Food and Drug Administration (FDA), available at <https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143561.htm>.

Consumers are sometimes told by “Canadian” or other foreign pharmacies that FDA generally allows the importation of a “personal supply” of prescription drugs. This is not true. FDA’s information for consumers discusses that, in rare circumstances, FDA will exercise discretion to refrain from action against an illegal importation. Those rare circumstances are when an “effective treatment may not be available domestically,” the patient’s own doctor works with FDA to obtain the treatment not available domestically, and “there is no known commercialization or promotion to [United States] residents by those involved in the distribution of the product.” As FDA makes clear, importation pursuant to promotions and/or because the medication is “cheaper – even though a drug with the same name is approved for sale in the United States” does not fall into that set of rare circumstances.

Again, the importation of prescription drugs from foreign countries (Canada or anywhere else outside the US) is illegal, and it is dangerous. Additional information for pharmacists and consumers concerning the dangers of online prescription drug purchases – whether from domestic or foreign sources – and how to avoid them may be found at <https://nabp.pharmacy/initiatives/dot-pharmacy/buying-medicine-online>. And, as always, consumers or pharmacists with questions are encouraged to call Board staff for guidance.

Item 2353 – Board Issues Updated Guidance on the Sale of Hemp-Derived Products

The North Carolina Industrial Hemp Commission has issued rules that govern “industrial hemp products.” As a result, the Board has updated its *Guidance to North Carolina Pharmacies on the Sale of Products Derived From Hemp*. This updated guidance, available at www.ncbop.org/PDF/RevisedHempProductGuidanceDocument051617.pdf, replaces the guidance document issued on March 30, 2017.

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