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North Carolina Board of Pharmacy News

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Item 2371 – Board Mourns the Passing of Stan Haywood

"Some men are born for the public. Nature by fitting them for the service of the human race on a broad scale, has stamped them with the evidences of her destination and their duty." Thomas Jefferson

No one exemplified Thomas Jefferson's observation better than Stan Haywood. The North Carolina Board of Pharmacy lost Stan on May 22, 2018. Stan was serving his third term as a Board member and was the first Board member to have ever served his statutorily allowed two consecutive terms, sit out a term, and then be chosen again by the state's pharmacists to resume a post as guardian of the public health.

The trust and confidence that the pharmacists of this state placed in Stan demonstrated that he was, above all things, a servant leader throughout his life. Stan's commitments to his family, his church, scouting, Randolph County (through long service as a member of the school board and as a county commissioner), and the state were deep and abiding. Those commitments were matched by a sense of humility and self-deprecation that proved Stan's focus ever remained on service to others, not service to self.

Stan also possessed the rare gifts of having a mind open to positions utterly different than his own and an ability to disagree on policy matters in a respectful way.

The Board proudly established the L. Stanley Haywood Recovery Fund in April 2018 and endowed it with $1.1 million to provide financial support to qualifying pharmacists and pharmacy personnel in need of substance abuse assessment, treatment, and monitoring services. Stan championed proactive measures to stem the opioid public health crisis, and the Board is grateful that Stan was able to see this transformative program through to completion.

Even as Stan fought serious illness over the past year, he demonstrated daily the ability to draw sustenance from faith and family. The Board loved Stan. The Board mourns his loss. And the Board is thankful beyond measure for his service, his inspiration, and his example. The Board's love extends to his wife, Hope, and his sons, Drew, Jon, and Mark.

Item 2372 – Pharmacists Cautioned on Proper Filing of Practical Pharmacy Experience Affidavits

Each spring sees an influx of Practical Pharmacy Experience Affidavits submitted by graduating pharmacy students. Under North Carolina law, a pharmacist must obtain 1,500 hours of practical pharmacy experience as a condition of licensure (Board Rule 21 North Carolina Administrative Code 46.1503(a)). For North Carolina licensure, the Board deems the 1,500-hour requirement to be satisfied by completion of an accredited doctor of pharmacy program as certified by the school (ibid).

Some states, however, require licensure applicants to demonstrate practical pharmacy experience obtained **outside** of the doctor of pharmacy curriculum. Whether the applicant obtained some or all of that practical experience in North Carolina, the Board must certify the experience. To certify that experience, the applicant must provide one or more Practical Pharmacy Experience Affidavits, which can be found at *www.ncbop.org/Forms%20and%20Applications%20-%20Pharmacists/PracticalPhcyExperienceAffidavit.pdf.*

It is **critical** to note that the pharmacist submitting the affidavit is stating, under oath, that he or she is a North Carolina-licensed pharmacist in good standing and that the "applicant will have my **immediate and personal supervision** and can render no pharmaceutical services except when under my immediate and personal supervision . . ." (emphasis added). In other words, the pharmacist submitting the affidavit is **not** simply confirming that an applicant worked a number of hours in a pharmacy with various pharmacists but, rather, that the applicant

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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.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation*. Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- receiving email alerts when CPE cycle deadlines are approaching;
- viewing all transcripts and individual courses and generating simplified, automated reports;
- searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists' Learning Assistance Network); and
- accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically

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obtained a number of hours of practical experience under the "immediate and personal supervision" of the pharmacist. This may, of course, require the applicant to obtain affidavits from several pharmacists who provided "immediate and personal supervision."

Any pharmacist or license applicant with questions about the Practical Pharmacy Experience Affidavit should contact Stacie Mason at smason@ncbop.org or 919/246-1050.

Item 2373 – Confusion, Frustration Continue on DEA's Position Regarding the Transfer of 'On File' CS Prescriptions

Pharmacists continue to call Board staff with understandable confusion on whether and how "on file" controlled substance (CS) prescriptions that were never filled may be transferred. To recap:

In April 2017, word began swirling that Drug Enforcement Administration (DEA) viewed transfers of "on file" CS as not allowed. On July 7, 2017, Loren Miller, associate section chief, Liaison and Policy Section, Diversion Control Division, DEA, sent an email to Carmen Catizone, executive director of the National Association of Boards of Pharmacy®, setting forth DEA's view on the matter.

In that email (which can be found at *www.ncbop.org/PDF/LMillerDEAGuidanceTransferofOnFileCSPrescriptions.pdf*), Mr Miller states the view that Title 21 Code of Federal Regulations (CFR) 1306.25 allows a pharmacy, "once it has filled an original prescription for a controlled substance in Schedule III-V," to "transfer the original prescription information to another DEA registered pharmacy for the purposes of allowing that second pharmacy to then dispense any remaining valid refills . . ." Mr Miller further stated that "an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered pharmacy."

Mr Miller then stated that, based on "the preamble" of an "interim final rule," it is DEA's "policy" that an electronic prescription for a CS of any Schedule may be "forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy" even if that prescription had not been filled.

To say that DEA's positions in this matter create a mess is a gross understatement. First, while Mr Miller's reading of Title 21 CFR 1306.25 is textually plausible, it represents a departure from decades of standard pharmacy practice, and there has been no suggestion from DEA or anyone else that the standard practice of transferring "on file" but unfilled (as opposed to once-filled) CS prescriptions has caused or materially contributed to CS abuse or misuse. Second, neither Mr Miller's email nor any language in the preamble he references contains so much as a hint as to what an appropriate mechanism for "forwarding" (and documenting the forwarding of) an unfilled electronic CS prescription would be. Third, Mr Miller's email does not explain why "forwarding" an unfilled electronic CS prescription is substantively different than transferring an unfilled CS prescription, whether electronic, verbal, or written. Fourth, DEA's position creates not only an incentive, but a practical necessity for patients seeking to change their pharmacy of choice to obtain duplicate CS prescriptions from their caregiver. Interpretations and policies that guarantee duplicate prescriptions for CS in multiple pharmacies hardly seem consistent with the Controlled Substances Act's purpose to create a controlled, closed distribution system and minimize CS abuse and misuse.

All that said, however, DEA has shown no inclination to reconsider or clarify these positions. Where does that leave us?

(1) Though "forwarding" of unfilled electronic CS prescriptions is available by "policy," the lack of any guidance from DEA on how a "forwarding" should occur and be documented means that most pharmacies and pharmacists are reluctant to entertain the practice. And who can blame them?

(2) For unfilled verbal prescriptions for Schedule III-V CS, DEA's position means that there is no mechanism for moving them from one pharmacy to another.

(3) For unfilled paper prescriptions for Schedule III-V CS, a pharmacy could return the original to the patient to physically carry to another pharmacy. Board staff understand completely the practical problems of this approach.

Some pharmacists have inquired why Board staff, the Board, or the North Carolina Legislature have taken this position. As the above makes clear, none of the three are to blame. The present state of affairs is attributable solely and entirely to DEA. Board staff will, of course, update pharmacists if DEA sees reason and backs away from these positions. Until then, send your cards, letters, and calls to DEA.

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