September 2018

Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Illegal for Health Insurance to Limit Selection of Pharmacy

At the Alabama Pharmacist Association meeting this year, the Alabama State Board of Pharmacy was asked about any state law that addresses limiting where a prescription may be filled. This is addressed in Title 27 of the Alabama Insurance Code.

Insurance Code §27-45-3 states:

> No health insurance policy or employee benefit plan which is delivered, renewed, issued for delivery, or otherwise contracted for in this state shall:
>
> (1) Prevent any person who is a party to or beneficiary of any such health insurance policy or employee benefit plan from selecting the pharmacy or pharmacist of his choice to furnish the pharmaceutical services, including without limitation, prescription drugs, offered by said policy or plan or interfere with said selection provided the pharmacy or pharmacist is licensed to furnish such pharmaceutical services in this state; or
>
> (2) Deny any pharmacy or pharmacist the right to participate as a contracting provider for such policy or plan provided the pharmacist is licensed to furnish pharmaceutical services, including without limitation, prescription drugs offered by said policy or plan.

Insurance Code §27-45-4 states:

> Any provision in a health insurance policy or employee benefit plan which is delivered, renewed, issued for delivery, or otherwise contracted for in this state which is contrary to this article shall to the extent of such conflict be void.

Insurance Code §27-45-6 states:

> It shall be unlawful for any insurer or any person to provide any health insurance policy or employee benefit plan providing for pharmaceutical services, including without limitation, prescription drugs, that does not conform to the provisions of this article.

Time for All Permit Holders to Renew

That time has rolled around once again: renewal of your license or permit. Renewals will be completed online for all businesses and people this year, except technicians. The Board will begin taking renewals Wednesday, September 5, 2018. Payments must be made using a credit card unless other arrangements have been made. The Board law states that renewals should be completed by October 31, although there is a grace period that extends to December 31. In essence, that means your renewal must be finished by December 31, 2018. The Board is asking you, however, **please do not wait until the end of December to renew.**

December 31 is a Monday this year, and it is also New Year's Eve. If you do not have a renewed permit on January 1, 2019, you may not legally work. Renew early and avoid the rush during the last two weeks of December. Please note that there is also a change in fees for manufacturers, wholesalers, third-party logistic providers, private label distributors, outsourcing facilities, and repackagers.

New Rule About Drug Takebacks

A few years ago, the governor directed the Board to develop guidelines for the return of drugs, including controlled drugs, to pharmacies. Although the Board had some general concepts on this topic, its members voted at the last Board meeting to mimic the federal guidelines for drug takebacks. It seemed there would be a problem if pharmacies had to abide by two different sets of regulations.

The notice of the submission of the new rule is in the August 2018 issue of *Alabama Administrative Monthly*. The public hearing regarding the new rule is scheduled for September 19, 2018, during the regular Board meeting.

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National Pharmacy Compliance News

September 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.

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 Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It 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 plan 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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The Board will be taking public comments regarding the new rule from August 1 until September 15, 2018.

The new rule will state:

BOARD RULE 680-X-2-.42

Requirements for Return and Destruction of Drugs by Pharmacies

1. This Rule shall apply only to the collection and disposal of prescription drugs by pharmacies returned or received from an ultimate user or a person entitled to dispose of prescription drugs.
2. An ultimate user is a person who has obtained and who possesses the controlled substance for his own use or for the use of a member of his/her household or an animal owned by him/her or a member of his/her household.
3. A person entitled to dispose of prescription drugs is one entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in possession of prescription drugs (hereinafter referred to as Other Person(s)).
4. Any pharmacy which intends to receive, collect and dispose of controlled substances from an ultimate use(s) or Other Person(s) shall comply with the applicable provisions of any existing rule or regulation or any amendment or revision thereto adopted pursuant to the Secure and Responsible Drug Disposal Act of 2010. Each such pharmacy shall submit to the Board the necessary authorization to be a collector issued by the DEA within ten (10) days of the receipt thereof. ln the event any such pharmacy ceases activities as a collector the Board shall be notified in the same manner as required by the applicable Federal rule or regulation.
5. Any pharmacy who also intends to receive, collect and dispose of non-controlled prescription drugs from ultimate user(s) or from Other Person(s) shall also comply with the same requirements relating to controlled substances with the exception of any requirement for authorization from the DEA. Each such pharmacy shall notify the Board at the same time of the submission of the Authorization referenced in Paragraph 3 above as well as the notification at the same time if such pharmacy ceases activities as a collector referenced in Paragraph 3 above.

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