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111 Village St • Birmingham, AL 35242 • Tel: 205/981-2280 • Fax: 205/981-2330

New Regulation for Partial Filling of Schedule II Prescriptions

There has been a change in federal law regarding partial filling of Schedule II controlled substances (CS). The Comprehensive Addiction and Recovery Act (CARA) of 2016 passed the United States Senate and was signed into law on July 22, 2016. CARA allows pharmacists to partially fill Schedule II CS. According to CARA, a prescription may be partially filled if it is not prohibited by state law; it is written and filled according to state and federal law; the partial fill is requested by the patient or prescribing practitioner; and the total quantity dispensed does not exceed the quantity prescribed. Remaining portions of partially filled prescriptions must be filled within 30 days of the original prescription date.

Senator Elizabeth Warren (D-MA) recently sent a survey about CARA to the governors of all 50 states, and the Alabama State Board of Pharmacy office was asked to respond. The Board responded that it has agreed to support CARA and would notify pharmacists in Alabama. On the survey, the Board noted concerns about billing for partial fills, tracking inventory, and potential diversion. There is no single specified way to fill or bill prescriptions under the CARA update. Prior partial filling was limited by Drug Enforcement Administration (DEA) code.

DEA Title 21 Code of Federal Regulations Section 1306.13 notes:

> The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

This DEA regulation is unchanged; however, it is superseded by the new CARA law.

Forwarding Controlled Drug Prescriptions

The Board has researched, read regulations, and made phone calls on the topic of forwarding controlled drug prescriptions to provide Alabama pharmacists with the most recent answers to the questions about what forms of prescriptions may be transferred and how that may be accomplished. This is what the Board knows concretely:

1. **Any controlled drug prescription,** including prescriptions for Schedule II drugs that are sent to a pharmacy via e-prescribing, may be forwarded to any other pharmacy if done through the use of an e-prescribing system. Until now, the understanding has been that a Schedule II prescription could only be forwarded using e-prescribing to another pharmacy that shared the same computer system. That is no longer the case.

   According to Loren Miller, DEA's associate section chief of the Liaison and Policy Section of the agency's Diversion Control Division, "As posted in the preambles of the [notice of proposed rulemaking] and the [interim final rule], an unfilled original [electronic prescription for controlled substances] can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances."
2. The question that remains is about forwarding Schedule III-V drugs.
   a. If the pharmacy receives an e-prescribed Schedule III-V CS, the prescription may be forwarded from one DEA-registered retail pharmacy to another DEA-registered retail pharmacy if done through e-prescribing.

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.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

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b. If there is a need to transfer a **refill** of a Schedule III-V prescription, that could be done through e-prescribing or by phone.

c. If a patient brings in a handwritten prescription for a Schedule III-V CS, the prescription could be filled or the paper copy returned to the patient to take to another pharmacy.

d. **This is the question remaining:** If a new Schedule III-V prescription is received as a **fax** or a phone call, could the pharmacist transfer that prescription to another pharmacy by phone? The Board has not been able to locate a firm answer to that question. Therefore, at this time, the Board must state that the pharmacist may not transfer by phone a new Schedule III-V prescription received by **fax** or phone.

Technician Renewal

This is the year for renewal of technician registration. If a technician plans to work after the end of December 2017, he or she will need to reregister with the Board. The place to reregister can be found on the Board's website. The Board's office receives a large volume of renewals toward the end of December, and the Board cannot promise that it will be able to process all last-minute renewal forms. If you know a technician, please encourage him or her to complete his or her renewal.

Renewals for Manufacturers, Wholesalers, Repackagers, Third-Party Logistics Providers, and Third-Party Distributors

This fall is also the renewal period for all pharmacy businesses including manufacturers, wholesalers, repackagers, third-party logistics providers, and third-party distributors. According to the law that took effect this past summer, all such businesses must renew annually. Renewal fees are the same as they were last year; none of them have changed. Renewal will be in paper format this year, since many people complained of difficulties last year. The forms may be downloaded from the Board's website.

Newsletter Goes Electronic

The Board's February 2016 *Newsletter* was the last printed issue. Going forward, all future Board *Newsletters* will be provided as a downloadable pdf posted on the Board's website. Licensees may sign up for a free email alert to receive a reminder whenever a new issue of the *Newsletter* becomes available. To sign up for the email alert, visit the Board's contact page in the Boards of Pharmacy section of the National Association of Boards of Pharmacy® website at *www.nabp.pharmacy* and click the subscribe link. The Board is undertaking this effort to deliver updates as timely as possible and make the information more easily accessible.

Reminder

Please notify the Board, in writing, of any change of address or employment by visiting its website, *www.albop.com;* click on "My Profile" to log in and update the appropriate information.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help line at 251/866-5585 or email bopwellness@gmail.com. All calls and emails are confidential.

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Susan Alverson, PharmD, RPh, Secretary - State News Editor

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