



Alabama State Board of Pharmacy

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Board Approves Both Sides of a Prescription

Pharmacies throughout the state have had experiences with pharmacy benefit manager auditors, and at times with Drug Enforcement Administration (DEA) personnel, charging that the pharmacy is wrong in recording prescription information on both the front and back of a prescription form. To clarify the Alabama State Board of Pharmacy position in this matter, a letter was sent to all registered community pharmacies in the state. The text of that letter is as follows.

The Board has received numerous questions about the legality of placing information on both the front and back of a paper prescription. There are an equal number of concerns expressed about pharmacies being penalized by various audit groups, for using both the back and front of the prescription. Often such penalties result in the loss of reimbursement, not because the pharmacy made a mistake in preparing and billing the prescription, but rather that they used the back of the prescription to enter information. As you are well aware, federal law, Title 21, 1306.22 mandates that any refill information be recorded on the back of the prescription. Obviously, precedent was set years ago for the use of the reverse side of the prescription form. During the June 17, 2015 meeting of the Alabama State Board of Pharmacy, Board member, Buddy Bunch proposed a discussion of this ongoing difficulty. After discussion of the concern, the Board voted unanimously to establish this policy:

Alabama pharmacies, may use both the front and back of a prescription, as well as any necessary, required or customary attachments to the prescription, to record information necessary for the correct and safe preparation, interpretation, dispensing, transferring or refilling of that prescription.

The Board offered a number of reasons for this decision:

- ◆ Often there is insufficient room on the front of the form to add information due to the extent of the prescription, or to the amount of information which needs to be added.
- ◆ At times prescribers enter multiple prescriptions on the front of one form.
- ◆ At times it might be possible to squeeze in additional information on the front, but the congestion increases the risk of error due to a misreading.

The Board encourages all pharmacists to use professional judgment when placing information on a prescription to assure others know to read information on the back and to prevent cluttering the front with data that can be misread. Thank you.

Clarification of DEA Prescription Position

The Board staff has received numerous questions about addresses on Schedule II prescriptions. The majority of the questions are regarding the interpretation of DEA law concerning what needs to be on a prescription for a Schedule II medication. Title 21 Code of Federal Regulations (CFR) §1306.05a states, **“All prescriptions for controlled substances shall**

be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.” A common question has been about the address; if the address is missing, may the pharmacy add the address and then fill the prescription? The Board and the DEA representative agreed that the pharmacy may ask the patient to fill in the address, or the person accepting the prescription may add the address. However, the address must be on the prescription by the time the prescription is presented to the pharmacy staff for filling. This means that the pharmacy may not fill the prescription and then place a label on the prescription form with the patient address included as printed information. The address must be entered on the prescription form **before** the filling process begins.

Another frequently asked question about DEA regulations regards what may be changed about a Schedule II prescription. At this time, much of the answer to that question is up to the individual state. The Board has stated that anything that may be changed on a Schedule III-IV prescription may be changed on a Schedule II prescription. Therefore, the pharmacist needs the permission of the prescriber, and with that permission, may change or add the patient address, the dosage form, drug strength, drug quantity, directions for use, or issue date. However, the pharmacist may not change the **“do not fill before date”** written on Schedule II prescriptions prepared in multiple form, with some to be filled at future dates.

Technicians Renew License This Fall

All pharmacy technician registrations expire December 31, 2015. Technician renewal for 2016-2017 will be **online only**. **Technicians may renew at www.albop.com** beginning in September 2015 through December 31, 2015. Please check the Board website for the available start date in September. To comply with recent Alabama legislation, citizenship documentation must be submitted prior to renewal. This will be a one-time submission. If you send the citizenship documentation any time beginning now, it will speed up the processing of your license when you do renew. Any technician with a number from T43757 or higher will not need to submit citizenship documentation. The Board began requesting citizenship documentation when it received original applications at license number T43757 and all licenses after that. If you have a technician number below this number, you will need to submit citizenship documentation. Visit the Board website for details about this submission.

All payments will be online. You may use MasterCard, Visa, or a single-use credit card that you have purchased. The technician fee will be \$62. If you are changing your name, send proof of the legal name change **before you register online**.

If you fail to renew your license by December 31, 2015, but continue to work as a technician in any way, you will be subject to late fees and discipline.

The Board is **not** asking for continuing education proof now.



Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox[®] was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at www.fda.gov/Drugs/DrugSafety/ucm443217.htm.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy[®] (NABP[®]) Verified-Accredited Wholesale Distributors[®] (VAWD[®]) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

 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 Alerts![®] 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.

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit www.ismp.org/communityRx/tools/ambulatoryhighalert.asp. ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat



muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- ◆ In “NDC Directory,” pharmacists demonstrate how to use this quick, easy, online resource.
- ◆ In “FAERS,” pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications’ drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- ◆ MUCINEX FAST-MAX Night-Time Cold & Flu;
- ◆ MUCINEX FAST-MAX Cold & Sinus;
- ◆ MUCINEX FAST-MAX Severe Congestion & Cough; and
- ◆ MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for

safe disposal, is available on the FDA website at www.fda.gov/Safety/Recalls/ucm444028.htm.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACCP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACCP website, www.aacp.org.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2,4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The “Orange Notice” warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at www.interpol.int/News-and-media/News/2015/N2015-050.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, “Pathways to Safer Opioid Use,” also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at <http://health.gov/hcq/training.asp#pathways>.

What May and May Not Be Compounded

There seems to be a continuing discussion about what may and may not be compounded by 503A and 503B pharmacies. Easy-to-read descriptions of the requirements can be found in *Guidance Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, and for 503B facilities, information may be found in *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance*.

Following are the Board's interpretations.

Drug products that may not be compounded or used in compounds: A drug product that appears on a list published by the Secretary in the *Federal Register* of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. This regulation may be found in the documents mentioned above or in Title 21 CFR 216.24.

Samples of drugs in these categories are: benzocaine otic (unapproved); benzocaine and antipyrine otic (unapproved); benzocaine, antipyrine, and zinc acetate otic (unapproved); benzocaine, chloroxylenol, and hydrocortisone otic (unapproved); chloroxylenol and pramoxine otic (unapproved); chloroxylenol, pramoxine, and hydrocortisone otic; cisapride; chloral hydrate (efficacy not reviewed by Drug Efficacy Study Implementation); DHEA (except by manufacturer as orphan drug for bone density); domperidone; ergotamine; estriol; human growth hormone (Food and Drug Administration (FDA) and DEA alerts); pergolide; pilocarpine hydrochloride solution (some brands); pregnenolone; and testosterone not to be prescribed for low levels due to aging (FDA alert).

Do not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. 503B facilities may make copies if drug is on the FDA shortage list (503A and 503B documents): albuterol inhalation; anastrozole; budesonide; Cialis®; clotrimazole; human chorionic gonadotropin injection; GHRP-2, GHRP-6; 5-fluorouracil products; ipratropium inhalation; itraconazole; mitomycin for irrigation; oxytocin; pilocarpine ophthalmic; progesterone; sodium chloride injectable unless on FDA shortage list and a 503B facility; steroid injections that are not on the shortage list and open to 503B facilities; Suboxone®; tamoxifen injectable; testosterone injection; thyroid tablets (plus do not have studies about therapeutic equivalence); and Viagra®.

This list contains a few of the products that the Board sees compounded and that the Board will limit. If a product is presently approved for manufacture in this country, it may not be copied in a compounded form. A slight adjustment in strength or addition of an add-on ingredient that is not needed for the product to be clinically effective is not justification for copying the product.

There are some special products that have been the subject of FDA warnings. These include anesthetic creams containing multiple topical anesthetic drugs and that have been implicated in patient deaths. FDA has also issued recent warnings about otic products that are not approved and may not be compounded.

Hazardous Products. For compounding with hazardous products that are on the National Institute for Occupational Safety and Health Hazardous Drug List, Occupational Safety and Health Administration (OSHA) states: **“Compounding should also occur in a [biological safety cabinet]. A gown and gloves should be worn.”** (OSHA Technical Manual: Section VI: Chapter 2, *Section VI: Chapter 2 Controlling Occupational Exposure to Hazardous Drugs*).

Electronic Prescriptions for Schedule II-V

On March 31, 2010, DEA published in the *Federal Register* an Interim Final Rule on Electronic Prescriptions for Controlled Substances. This rule, which became effective June 1, 2010, permits pharmacies to receive, dispense, and archive DEA-qualified Schedule II-V electronic prescriptions. Title 21 CFR Part 1311 details Pharmacy Responsibilities (1311.200) and Pharmacy Application Requirements (1311.205). The **electronic prescription application** used by a pharmacy to receive electronic prescriptions must conform to the DEA guidelines set forth in Title 21 CFR Part 1311.120. Most pharmacy applications are already capable of the requirements determined necessary to successfully import, store, display, and verify Schedule II-V prescriptions. The pharmacy application's help desk should be able to provide the documentation necessary to confirm the ability to legally receive and fill controlled substances. Electronic prescription applications used by practitioners must also conform to the guidelines set forth in this publication. If practitioner and pharmacy applications are compatible and adequate, then scheduled prescriptions should populate in the pharmacy queue at the time of the electronic prescription submission. In the *Pharmacist's Manual*, Section IX, DEA states, “When a prescription is received electronically, the prescription and all required annotations must be stored electronically.” An electronic prescription's “original” copy is the digital image transmitted through the pharmacy's application. The application should be able to virtually store the prescription and retrieve the digital image if needed for purposes such as an inspection or audit.