



Missouri Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Congratulations

The Missouri Board of Pharmacy would like to congratulate inspectors Sid Werges and George McConnell on their recent retirement. Sid and George were valuable resources for both the Board and licensees. The Board thanks them for their dedicated service to the citizens of Missouri.

The Board also welcomes the following new inspectors: Joe Dino (mid-Missouri region), Bennie Dean (St Louis region), and Lisa Thompson (southwest Missouri).

New Rule Changes

The Board recently revised/promulgated the following rules: **20 CSR 2220-2.017** (Non-Electronic Manual Prescription Records), **20 CSR 2220-2.018** (Prescription Requirements), **20 CSR 2220-2.080** (Electronic Prescription Records), and **20 CSR 2220-2.083** (Electronic Record-Keeping Systems).

The new rules will become effective on **August 30, 2013**, and are available online at <http://pr.mo.gov/pharmacists-rules-statutes.asp>. Some of the changes include (**this summary is not exhaustive**):

20 CSR 2220-2.017 (Non-Electronic Manual Prescription Records): Pharmacies that maintain manual prescription records are now required to document the identity of the pharmacist responsible for verifying the accuracy of prescription data on each original prescription **as well as** the pharmacist responsible for verifying the final product prior to dispensing, if different. If additional refills are added to a prescription, the method (eg, telephone) and source of authorization (ie, name of authorizing person) must be documented in the manual record or on the prescription hard copy.

20 CSR 2220-2.018 (Prescription Requirements): Current rule language has been updated to only reference prescription requirements. The rule also clarifies that prescriptions for animal use must include the animal's species and the owner's name to be valid for dispensing.

20 CSR 2220-2.080 (Electronic Prescription Records): Similar to the new rule for manual records, pharmacies

maintaining an electronic prescription record must document the identity of the pharmacist responsible for verifying the accuracy of prescription data on each original prescription **as well as** the pharmacist responsible for verifying the final product prior to dispensing, if different.

Additionally, the pharmacy must document the manner in which the prescription was received (ie, written, telephone, electronic, or faxed). For verbal, telephone, or electronic data transmission prescriptions, a hard copy representation of the prescription must be made and filed. If additional refills are added to a prescription, the method (eg, telephone) and source of authorization (ie, name of authorizing person) must be documented in the electronic record or on the prescription hard copy.

Significantly, the Board removed the requirement that a pharmacist maintain a bound logbook or separate file (also known as the pharmacist signature log) that is signed daily by the pharmacist to verify that prescription information entered into the electronic prescription record was accurately entered. Instead, the pharmacy's electronic prescription record must identify the pharmacist responsible for verifying the accuracy of prescription data on each original prescription.

Note: Licensees are still required by federal law to maintain a logbook or a signed printout for verifying controlled substance (CS) refill data. Specifically, the Drug Enforcement Administration (DEA) *Pharmacist's Manual* (2010) provides the following:

To meet the C.F.R. recordkeeping requirements, the pharmacy's electronic system must comply with the following guidelines:

1. If the system provides a hard copy printout of each day's controlled substance prescription refills, each pharmacist who refilled those prescriptions must verify his/her accuracy by signing and dating the printout as he/she would sign a check or legal document.
2. The printout must be provided to each pharmacy that uses the computer system within 72 hours

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.

ISMP Study on Targeted Mandatory Patient Counseling

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
 - ◇ fentanyl patches
 - ◇ hydrocodone with acetaminophen
 - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
 - ◇ warfarin
 - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
 - ◇ Humalog® (insulin lispro)
 - ◇ NovoLog® (insulin aspart)
 - ◇ Levemir® (insulin detemir)
 - ◇ Lantus® (insulin glargine)
 - ◇ Apidra® (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
 - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

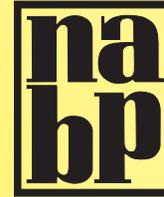
Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at www.ismp.org/AHRQ/default.asp?link=ha.

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter*, which may be accessed in the Publications section of www.nabp.net.

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter*; accessible in the Publications section of www.nabp.net. NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABPLAW**[®] Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABPLAW** Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABPLAW** Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at www.nabp.net/programs/member-services/nabplaw/.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor[®] into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

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

of the date on which the refill was dispensed. The printout must be verified and signed by each pharmacist who dispensed the refills.

3. In lieu of such a printout, the pharmacy must maintain a bound logbook or a separate file in which each pharmacist involved in the day's dispensing signs a statement, verifying that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. [See also 21 CFR 1305.22(f)(3)]

20 CSR 2220-2.083 (Electronic Record-Keeping Systems): This rule allows pharmacies that have an electronic record keeping system (ERS) to maintain digitized images of a prescription in lieu of maintaining a prescription hard copy. An ERS is defined in the rule as a system that provides "input, storage, processing, communications, output and control functions for digitized images of original prescriptions."

To qualify, an ERS must be able to capture "an exact digitized image" of the actual prescription, including the reverse side of the prescription, if applicable. Simply transferring or electronically recording prescription data is insufficient.

Significantly, **an electronic prescription record is different from an ERS.** Pharmacies that do not have an ERS that is able to capture an exact digitized image and meet the definition of the rule must still maintain a prescription hard copy as required by 20 CSR 2220-2.018 and 20 CSR 2220-2.080. **Additionally, CS prescriptions must still be maintained as required by applicable state and federal law.**

Digitized prescription images in an ERS must be readily retrievable and capable of being provided or reviewed immediately or within two hours of a request from the Board or a Board inspector. To prevent loss, digitized images in the ERS must be stored, copied, or saved onto secure storage media on a regular basis. Pharmacies with an ERS must maintain a written policy and procedure manual that includes policies and procedures for reviewing compliance.

The information provided above is not exhaustive and does not include all rule changes. Licensees should review the new/revised rules in their entirety to ensure compliance.

Webinars Now Available Online

Stay informed; watch the following on-demand Webinars on the Board's [Web site](#).*

- ◆ Developing a Patient Safety Culture in Pharmacy Practice
- ◆ Effective Patient Counseling
- ◆ BNDD 2013 Regulatory Update (**will be posted after August 8**)
- ◆ Board of Pharmacy 2013 Regulatory Update (**will be posted after August 15**)

*Webinar replays are not eligible for continuing education credit.

Pharmacy/Drug Distributor Renewals

Pharmacy and drug distributor renewals will be mailed in the beginning of August to the official **mailing address** designated with the Board. Changes in address, location, ownership, or the pharmacist-in-charge (PIC) cannot be done online or on your renewal application. Instead, a separate application must be submitted to the Board along with the appropriate fee. All pharmacy and drug distributor permits, licenses, or registrations must be renewed **before October 31, 2013**. Prevent delays; renew early!

New Disciplinary Actions

Pharmacists

Barashick, Mark W., #2006021583 – Wellington, FL. Public Censure. Dispensed unauthorized prescriptions for family member, and misbranding. Section 338.055.2(6), (13), and (15), RSMo.

Bosworth, John M., #043331 – Plattsburg, MO. Public Censure. As PIC, he and pharmacy staff failed to sign written protocols prior to giving immunizations, and failed to submit notifications of intent to the Board. Section 338.055.2(5), (6), (13), and (15), RSMo.

Brust, Daniel A., #2003019258 – Little Rock, AR. Voluntary surrender of license, and cannot reapply for seven (7) years. Admitted to diversion of controlled and non-controlled substances from employer; misbranding by unauthorized dispensing; while PIC, failed to implement effective security controls to prevent diversion of CS; illegally obtaining, holding, and dispensing CS; and record keeping violations including unauthorized modifications to prescriptions. Section 338.055.2(4), (5), (6), (13), and (15), RSMo.

Campanella, Angela A., #043404 – Hillsboro, MO. Revoked and cannot reapply for seven (7) years. Violation of discipline regarding failure to renew license, failure to submit to urine testing, tested positive for ethanol, failure to complete a chemical dependency evaluation, and failure to submit chemical dependency counselor/program for Board approval. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Dryden, Steven W., #041231 – Raymore, MO. Probation for five (5) years. Alcohol and CS abuse, misappropriation of CS. Section 338.055.2(1), (6), (13), (15), and (17), RSMo.

Garton, Rebecca A., #2001029146 – Greenwood, MO. Public Censure. As PIC, allowed pharmacist to work while license was suspended. Section 338.055.2(5) and (6), RSMo.

Hart, Joyce B., #028925 – West Plains, MO. Public Censure. Administered vaccinations prior to signing a written protocol and prior to submitting a notification of intent to the Board. Section 338.055.2(5), (6), (13), and (15), RSMo.

Hooper, Edward T., #1999141092 – Jackson, TN. Voluntary Surrender of License. Discipline in another state

regarding addiction to alcohol and/or other drugs. Section 338.055.2(1), (8), (13), (15), and (17), RSMo.

Ikona, Lucy B., #044854 – Kansas City, MO. Public Censure. As PIC, administered vaccines without a signed protocol. Section 338.055.2(5), (6), (13), and (15), RSMo.

Jarvis, Michael J., #2000172885 – O’Fallon, MO. Probation for two (2) years. As PIC, failed to obtain DEA and Bureau of Narcotics and Dangerous Drugs registrations prior to dispensing CS; pharmacy operated as a shared services pharmacy without a Class J permit; record keeping violations; and improper destruction of CS. Section 338.055.2(5), (6), (13), and (15), RSMo.

Nippes, Jeffrey K., #029418 – Rogersville, MO. Revoked, cannot reapply for seven (7) years. Impaired pharmacist; misappropriated CS from employer for personal consumption; pled guilty to one count of theft/stealing. Section 338.055.2(1), (2), (5), (13), (15), and (17), RSMo.

Patel, Amil K., #2011030565 – Brookfield, WI. Public Censure. Administered vaccinations without a signed protocol, submitted notification of intent to administer immunizations after he immunized. Section 338.055.2(5), (6), (13), and (15), RSMo.

Ramlatchman, Leonard V., #040626 – St Joseph, MO. Public Censure. Failed to sign written protocol prior to giving immunizations, and failed to submit notification of intent to the Board. Section 338.055.2(5), (6), (13), and (15), RSMo.

Satterfield, Ronald D., #041385 – Kansas City, MO. Probation for five (5) years. Dispensed legend and CS prescriptions to himself without valid prescriptions, early refills, and misbranding. Section 338.055.2(5), (13), (15), and (17), RSMo.

Shaffer, Kasey D., #2009021424 – Wappapello, MO. Public Censure. As PIC, loss of CS; failed to maintain adequate security to deter theft of drugs by personnel; failed to confirm technician’s licensure status and unknowingly granted access to CS stock without securing necessary waivers; and unable to maintain accurate CS records. Section 338.055.2(5), (6), (13), and (15), RSMo.

Pharmacies

Grove Pharmacy, #2008014865 – Springfield, MO. Public Censure. Loss of CS due to diversion by technician, failed to maintain adequate security over CS inventory. Section 338.055.2(5), (6), (13), and (15), RSMo.

PharMerica, #2013019681 – Louisville, KY. Probation for three (3) years. Disciplinary action in another state regarding diversion of CS and failure to provide proper oversight to prevent diversion. Section 338.055.2(8), RSMo.

Walgreen Drug Store, #002851 – St Louis, MO. Probation for three (3) years. Theft of CS by technician, failure to maintain security over inventory of CS. Section 338.055.2(6), (13), and (15), RSMo.

Walgreens #07551, #2003014789 – St Joseph, MO. Public Censure. Pharmacy staff administered vaccines prior to signing immunization protocols and prior to submitting notifications of intent to the Board. Section 338.055.2(6) and (15), RSMo.

Walgreens #09713, #2006000615 – Jefferson City, MO. Public Censure. Staff pharmacist administered vaccines prior to signing an immunization protocol and prior to submitting notification of intent to the Board. Section 338.055.2(6) and (15), RSMo.

Drug Distributor

Animal Health International, Inc – Salina, KS. Probation for two (2) years. Shipped legend drugs without being licensed to do so. Section 338.055.2(6), RSMo.

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