

January 2015

News



# Arizona State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

1616 W Adams St, Suite 120 • Phoenix, AZ 85007 • Website: [www.azpharmacy.gov](http://www.azpharmacy.gov)  
E-mail: [chunter@azpharmacy.gov](mailto:chunter@azpharmacy.gov)

## **Naturopaths and Optometrists May Prescribe Hydrocodone Combination Products**

Effective in 2014, naturopathic physicians and many optometrists were granted prescriptive authority for hydrocodone prescription drug products by the Arizona State Legislature. The legislation was passed in anticipation of Drug Enforcement Administration rescheduling these combination products from Schedule III to Schedule II. You may reference the Arizona State Board of Pharmacy web page prescriber chart at <https://pharmacy.az.gov/sites/default/files/prescriptive%20authority%20chart%20%2810-27-2014%29.pdf>.

## **2014 Year in Review**

The year had been very busy and unfortunately, not as productive as hoped for. Renewals are still “held hostage” by the original International Business Machines Corporation (IBM) source code that was provided to the Board for no charge about 10 years ago. You all know the old saying: “*You get what you pay for.*” At that time, the Board was led to believe that its source code would be adopted by all 90/10 boards and kept up to date by IBM.

Needless to say, IBM was replaced as the Board’s primary vendor, and a new company with initials for a name – NIC – was put in charge of the code. Early on, NIC was successful in improving several functions of the program and as a result, renewals were fairly satisfactory for one year. The next few years were unremarkable, but the Board was not as efficient as hoped. No software changes were made and the Board got behind in the desired capabilities of the program. One change the Board hopes to make as soon as possible is to allow licensees and permittees to locate and print out their own credential (license or permit). This seemingly simple modification should alleviate the Board’s biggest bugaboo or glitch, which is emailing licenses and permits after payment of renewal fees.

This task may be accomplished with help from the National Association of Boards of Pharmacy® (NABP®). Talks are ongoing, and the Board will know before the next renewal period. Thank you for your patience in this area. The Board is painfully aware that renewals need to be streamlined and made significantly more user-friendly. The

Board is working with NABP on a replacement solution for its database and the entire renewal process.

## **2015 Budget**

Board staff has been working with analysts from the Governor’s Office of Strategic Planning & Budgeting as well as the Joint Legislative Budget Committee to develop a fair and equitable budget for the next two years. The Board’s critical needs are a part-time rule writer and competitive pay for comparable work in the private sector. It is important to note that the Board is about a year or more behind in performing its required reviews of all rules every five years. Controlled Substances Prescription Monitoring Program Director Dean Wright and Compliance Officer Sandy Sutcliffe have really been doing double duty keeping up with the rules revisions, but the task has become overwhelming since the compounding controversy and the accompanying statute and rule changes required to make sure the public safety is not negatively impacted.

## **2015 Legislation**

After preliminary discussion with legislative leaders, the Board has been convinced that this session is not a session that would receive any legislative proposals that would establish any new fees or even new fee categories. So do not be surprised if none are forthcoming. “*Maybe next year,*” a refrain familiar to all good Cubs fans, seems to be appropriate with regard to new fees as well. Needless to say, legislative priorities for the session center on new compounding language.

Revisions to United States Pharmacopeia Chapters <795>, <797>, and <800> need to be incorporated into statute, as well as several definitions of various facilities and practice standards. These include drug facilitators, third-party logistics providers, and more.

Pharmacies will be limited in the sense that no drug may be compounded unless it is prescribed for a specific patient, human or animal. Outsourcing facilities, a new permit type, will only be registered and regulated by the federal government, most likely a part of Food and Drug Administration. Stay tuned for new developments in this rapidly changing area. The topics are largely dictated by the ebb and flow in the aftermath of the New England Compounding Center tragedy, and it will be necessary that actions here are thoughtful and comprehensive, not simply “knee jerk” or quick reactions to a rapidly changing, complex area of pharmacy practice.



## DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at [www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances](http://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances).

## System-Based Causes of Vaccine Errors

 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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter ([www.ismp.org/sc?id=307](http://www.ismp.org/sc?id=307)), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

**Practice Recommendations.** Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

## FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that 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. Those 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 a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm).

## **PTCB Implements Changes to CE Requirements**

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at [www.ptcb.org](http://www.ptcb.org).

## **Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern**

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at [www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf](http://www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf). In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at [www.njconsumeraffairs.gov/press/05012013.pdf](http://www.njconsumeraffairs.gov/press/05012013.pdf).

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, [www.rxpatrol.com](http://www.rxpatrol.com), provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

## **Assured Brand Naproxen Tablets Recalled Due to Packaging Error**

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm).

## **Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations**

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at [www.fda.gov/Safety/Recalls/ucm412431.htm](http://www.fda.gov/Safety/Recalls/ucm412431.htm).

## **Disciplinary Actions and Updates**

### **Pharmacists**

**Brauner, Lyle (S013725)** – One year probation; \$5,000 fine; compounding training course. If fine is paid and course is completed within 180 days, licensee may request early termination of probation. Effective October 23, 2014.

**Carranza, Robert (S015967)** – Probation terminated. Effective December 10, 2014.

**Cavanagh, Jacqueline (S014907)** – Six-month probation; \$3,000 fine; compounding training course. If fine is paid and course is completed before end of probation, probation terminates. Probation terminated. Effective December 10, 2014.

**Dahlk, Paul (S007308)** – Probation terminated. Effective December 10, 2014.

**Du Preez (Hogan), Elizabeth (S015072)** – Probation terminated. Effective December 10, 2014.

**Markus, John (S010719)** – Probation terminated. Effective December 10, 2014.

**Smith, Kenneth (S009235)** – Request to reinstate license granted upon completion of Pharmacist Assessment for Remediation Evaluation® and Multistate Pharmacy Jurisprudence Examination® (MPJE®) exams; probation will be imposed. Effective December 10, 2014.

**Soraya, Soheila (S009159)** – \$5,000 fine; MPJE; one random, unannounced inspection within one year of effective date. Effective December 10, 2014.

### **Interns**

**Gerber, Colin (I011780; Was T036006)** – Five-year probation; Pharmacists Assisting Pharmacists of Arizona contract; 400 hours community service. Effective December 10, 2014.

### **Technicians**

**Leon, Brittany (T038790)** – Revoked. Effective December 10, 2014.

**Tomkins, John (T037424)** – Revoked. Effective December 10, 2014.

### **Permits**

**PharMerica (Y002939)** – Subject to two random, unannounced inspections within one year of effective date. Effective October 24, 2014.

**Phoenix Children's Hospital Outpatient Pharmacy (Y001644)** – Two-year probation; \$5,000 fine; two random, unannounced inspections within one year of effective date. Effective December 10, 2014.

**Rx Formulations (Y003586)** – Two-year stayed suspension; \$3,000 fine; and passing two random, unannounced inspections within one year of effective date. Effective October 24, 2014.

### **Other**

**Simon, Carol (No License # Issued)** – Application for licensure denied based on revocation from California State Board of Pharmacy. Effective December 10, 2014.

## **Disciplinary Actions and Updates – Other Health Boards**

### **Arizona Medical Board (MDs)**

**Manuel Abrante, MD #22262** – *Interim Consent Agreement for Practice Restriction*. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona

until he applies to the Board and receives permission to do so. Effective October 10, 2014.

**Alaaeldin Babiker, MD #28043** – *Order for Decree of Censure, Probation, and Practice Restriction and Consent to the Same*. Interim order for summary suspension dated December 18, 2013, is vacated. Respondent is issued a Decree of Censure. Respondent is also placed on probation for five years subject to specific terms and conditions. Respondent is restricted from prescribing controlled substances (CS) and the issuance of marijuana certifications. Upon successful completion of Board ordered continuing medical education, respondent may petition the Board to lift this practice restriction. Effective October 3, 2014.

**Susan B. Fleming, MD #14840** – *Interim Consent Agreement for Practice Restriction*. Respondent is prohibited from prescribing, administering, or dispensing CS, effective November 20, 2014, until she applies to the Board and receives permission to do so. This prohibition does not apply to any prescription written prior to November 20, 2014, that is presented to a pharmacy after that date. Effective November 20, 2014.

**Simon Isaac, MD #46865** – *Interim Consent Agreement for Practice Limitation and Assessment (Non-Disciplinary)*. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and receives its affirmative permission to do so. Respondent may not apply for relief from this interim consent agreement until he has completed a current health assessment and the Board is in receipt of the assessment report and recommendations. Effective September 12, 2014.

**Michael Eugene James, MD #24537** – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License*. Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications or injections of any kind. Effective October 3, 2014.

**Phillip T. Rajadas, MD #43411** – *Order of Revocation*. Respondent's license is **revoked**. Effective November 7, 2014.

**Kathleen McHugh Strohmeyer, MD #44670** – *Interim Consent Agreement for Practice Restriction*. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until she applies to the Board and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement until she has completed a Physician Health Program assessment and any recommendations that arise as a result of the assessment including evaluation and treatment. Effective September 12, 2014.

---

Page 4 – January 2015

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Hal Wand, MBA, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor  
& Executive Editor

Deborah Zak - Communications Manager

---