



# Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## Clarification: February 2009 Newsletter – “Notice”

When your patient needs a refill but has no more left on the prescription, you cannot transmit a prescription to the prescriber. A pharmacist may call or send a fax if requested by the patient informing the prescriber that all refills have been dispensed and ask, if appropriate, to provide a **new** prescription.

This notice was intended to address the practice of adding refills to expired prescriptions. Once all refills have been exhausted or the six-month period for controlled substances, Schedules III through V, have run out, these prescriptions are null and void. No oral or written communication to the prescriber can breathe new life into them. Upon the request of the patient, the pharmacist can contact a prescriber to convey the message that the patient would like to continue on the therapy and provide information about the expired prescription in such a way that if approved, can be placed in the pharmacy records as a **new** prescription. The Alabama State Board of Pharmacy office apologizes for the confusion caused by the February 2009 notice.

## United States Pharmacopeia (USP) Chapter 797

The Alabama State Board of Pharmacy plans to support all pharmacy sites that do sterile compounding in their moves to become compliant with USP General Chapter 797 requirements. The Board is initiating a **nonpunitive** process of assessment and education. The Board sent out pharmacy permit renewals indicating that the pharmacy prepared sterile products and were sent a risk assessment form to define the compounding category(s) or risk level(s) of practice. Pharmacies compounding sterile products that did not receive a self-assessment should contact the Board at 205/981-4774 or request a letter at jaltsman@albop.com. A current copy of the USP or the USP <797> Guidebook is available at [www.usp.org/products/797Guidebook/](http://www.usp.org/products/797Guidebook/) for \$99 plus shipping.

## Compliance Tips

- 1. Can medication be returned to the pharmacy?**  
§34-23-70 (c) No licensed pharmacist or pharmacy operating within this state shall accept for refund purposes or otherwise any unused portion of any dispensed prescription.
- 2. A script is written for a combination drug no longer commercially available. Can a registered pharmacist dispense the ingredients separately?**  
§34-23-8 No person shall dispense or cause to be dispensed a different drug or brand of drug in lieu of that ordered or prescribed without the express permission in each case of the person ordering or prescribing such drug.
- 3. May prescriptions be organized and filed monthly, rather than numerically daily?**  
§34-23-70 (k) A prescription file or files shall be kept by every pharmacy for a period of not less than two years in which the original of every prescription compounded or dispensed shall be filed in the

order of compounding with number and date of dispensing placed on each prescription. Each pharmacy shall produce any prescription file whenever legally required to do so. Such prescription file shall at all times be open for inspection by the prescriber, the board of pharmacy or its inspectors.

§680-X-2-.05 In order to facilitate the inspection of records, each prescription on file must bear the initials of the person who compounded and/or dispensed it, as well as the number of the prescription and the date it was dispensed.

- 4. Does a PTCB technician change the technician staffing ratio?**  
§680-X-2-.14 (3) It is ruled by the Board of Pharmacy that three (3) technicians, one of which shall be certified through the Pharmacy Technician Certification Board (PTCB), on duty are sufficient in the prescription area of a retail pharmacy or an institutional pharmacy for each full time licensed pharmacist on duty.
- 5. May a pharmacist take patient information home and have a family member assist in organizing patient records for filing?**  
§680-X-2-.12 (4) The supervising pharmacist shall be responsible for the following: (c) Maintaining the security of the prescription department and its contents.

The Health Insurance Portability and Accountability Act of 1996 Privacy Rule establishes a pharmacy as a covered entity to provide federal protections for personal health information.

- 6. A physician writes for a branded drug and signs on the signature line, “dispense as written.” May a registered pharmacist dispense a generic drug at the patient’s request without physician approval? No.**

§34-23-8 (4) Every written prescription issued in this state by a licensed practitioner shall contain two signature lines. Under one signature line shall be printed clearly the words “dispense as written.” Under the other signature line shall be printed clearly the words “product selection permitted.” The practitioner shall communicate instructions to the pharmacist by signing on the appropriate line. The State Board of Pharmacy shall not promulgate any rule or regulation affecting the subject matter of this subdivision.

## Technician Registrations Delinquent at Midnight December 31, 2009

The Board office will send postcard renewal notices to each technician. If you do not receive a renewal notice, it is most likely the Board does not have your current address. Go to the Board Web site, [www.albop.com](http://www.albop.com), and visit the section on forms, applications, and publications (select “Change of Status Request”) to submit your new address or employment change, then **renew online starting October 1, 2009**. If you have not completed the **yearly** Accreditation Council for Pharmacy Education (ACPE) or Board-approved continuing education (CE) requirements,

*Continued on page 4*



## Pharmaceutical Cargo Theft of Copaxone®

The Food and Drug Administration (FDA) Office of Criminal Investigations (OCI) reported that a shipment of approximately 14 pallets/994 cartons/5,962 packs of Copaxone® (glatiramer acetate) 20 mg, a non-controlled substance, was stolen during the week of April 13-17, 2009. The tractor trailer was recovered at a rest stop on the New Jersey Turnpike on April 20. Unfortunately the trailer was empty. Corporate security from Teva Pharmaceutical Industries Ltd recalled the remainder of lot #P53159, which has an expiration date of January 2011. If that particular product is found anywhere or offered for sale, it would be the stolen product.

Copaxone is a unique product and is used only to treat patients suffering from multiple sclerosis. If the product is not stored below 74° F and out of the sunlight, it becomes ineffective and may not be safe for use.

Immediately notify the FDA OCI if you are contacted by individuals offering to sell this product, if you have purchased this product, or if you know of anyone that may be involved with the theft and the distribution of this product.

Any information should be provided to Special Agent Gregg Goneconto or Special Agent Nancy Kennedy at OCI Headquarters (800/551-3989), or at [www.fda.gov/oci/contact.html](http://www.fda.gov/oci/contact.html).

## Failed Check System Leads to Pharmacist's No Contest Plea for Involuntary Manslaughter



*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](http://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 a 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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

A former Ohio pharmacist will plead no contest to involuntary manslaughter of a two-year-old child who died in 2006 as a result of a chemotherapy compounding error.<sup>1</sup> The pharmacy board revoked the pharmacist's license and, after

holding a criminal investigation, a grand jury indicted him on charges of reckless homicide and involuntary manslaughter. The pharmacist faces up to five years in prison.

Prosecutors hold the pharmacist responsible for the toddler's death because he oversaw the preparation of her chemotherapy. A pharmacy technician mistakenly prepared the infusion using too much 23.4% sodium chloride. The infusion was administered to the child, who died three days later.

Though we cannot shed more light on the root causes of the error, our experiences with analyzing other errors strongly suggest that underlying system vulnerabilities played a role. Compounding the solution from scratch is error prone. Communication failures between technicians and pharmacists, IV compounding-related failures, inadequate documentation of the exact products and amounts of additives, and other system issues have contributed to numerous fatal errors. ISMP has also received reports of compounding errors and subsequent failed double-checks due to adverse performance-shaping factors such as poor lighting, clutter, noise, and interruptions. In fact, in this particular case, news reports suggest that the pharmacist felt rushed, causing him to miss any flags that may have signaled an error.<sup>2</sup>

Without minimizing the loss of life in this case, we continue to be deeply concerned about the criminalization of human errors in health care. Safety experts including ISMP advocate for a fair and just path for individuals involved in adverse events, arguing that punishment simply because the patient was harmed does not serve the public interest. Its potential impact on patient safety is enormous, sending the wrong message to health care professionals about the importance of reporting and analyzing errors. All professionals are fallible human beings destined to make mistakes and drift away from safe behaviors as perceptions of risk fade when trying to do more in resource-strapped professions. When warranted, licensing boards can protect patients from reckless or incompetent actions of health care practitioners by limiting or revoking licenses.

While the law clearly allows for the criminal indictment of health care professionals who make harmful errors, the greater good is served by focusing on system issues that allow tragedies like this to happen. Focusing on the easy target, the pharmacist, makes us wonder whether any regulatory or accreditation agency is ensuring that all hospitals learn from this event and adjust their systems to prevent the same type of error. If not, the death of this little girl is a heartbreaking commentary on health care's inability to truly learn from mistakes so that they are not destined to repeat.

## References

1. McCarty J. *Eric Cropp, ex-pharmacist in case in which Emily Jerry died, is ready to plead no contest.* Cleve-



land Plain Dealer. April 19, 2009. Available at: [www.cleveland.com/news/plaindealer/index.ssf?/base/cuyahoga/1240129922221300.xml&coll=2](http://www.cleveland.com/news/plaindealer/index.ssf?/base/cuyahoga/1240129922221300.xml&coll=2).

2. McCoy K, Brady E. *Rx for Errors: Drug error killed their little girl*. USA Today. February 25, 2008. Available at: [www.usatoday.com/money/industries/health/2008-02-24-emily\\_N.htm](http://www.usatoday.com/money/industries/health/2008-02-24-emily_N.htm).

## **NABP Wins ASAE's 2009 Associations Advance America Award of Excellence**

In recognition of its efforts for educating patients on the potential dangers of buying medications online and empowering patients to make informed choices through its Internet Drug Outlet Identification program, the National Association of Boards of Pharmacy® (NABP®) recently received the 2009 Associations Advance America (AAA) Award from the American Society of Association Executives (ASAE) and the Center for Association Leadership in Washington, DC.

Launched in May 2008, the Internet Drug Outlet Identification program reviews and monitors Web sites selling prescription medications and distinguishes those sites that do and do not meet state and federal laws and/or NABP patient safety and pharmacy practice standards. Internet drug outlets that appear to be operating in conflict with program criteria, such as dispensing drugs that are unapproved and potentially counterfeit, frequently without a valid prescription, pose a significant risk to the public health. Such findings underscore the importance of this project and other efforts to contain the Web-based distribution of prescription drugs within the appropriate legal and regulatory framework.

"NABP is honored to have been selected for this prestigious award for our efforts to bring about positive change," says NABP President Gary A. Schnabel, RN, RPh. "This program represents a strong demonstration of our commitment to the NABP mission of assisting the state boards of pharmacy in protecting the public health."

NABP is one of only 21 organizations nationally to receive an award of excellence in the first round of ASAE's 2009 AAA Award program, an award that recognizes associations that propel America forward with innovative projects in education, skills training, standards setting, business and social innovation, knowledge creation, citizenship, and community service.

## **Consumer Directed Questions and Answers about FDA's Initiative Against Contaminated Weight-Loss Products**

FDA has developed questions and answers to help consumers, health care practitioners, and the general public understand FDA's actions regarding weight-loss products contaminated with various prescription drugs and chemicals.

Many of these products are marketed as dietary supplements. Unfortunately, FDA cannot test and identify all weight-loss products on the market that have potentially harmful contaminants in order to ensure their safety. FDA laboratory tests have revealed the presence of sibutramine, fenproporex, fluoxetine, bumetanide, furosemide, phenytoin, rimonabant, cetilistat, and phenolphthalein in weight-loss products being sold over-the-counter. Enforcement actions and consumer advisories for unapproved products only cover a small fraction of the potentially hazardous weight-loss products marketed to consumers on the Internet and at some retail establishments.

Pharmacists can advise patients to help protect themselves from harm by consulting with their health care professional before taking dietary supplements to treat obesity or other diseases. Patients should be advised of the following signs of health fraud:

- ◆ Promises of an "easy" fix for problems like excess weight, hair loss, or impotency
- ◆ Claims such as "scientific breakthrough," "miraculous cure," "secret ingredient," and "ancient remedy"
- ◆ Impressive-sounding terms, such as "hunger stimulation point" and "thermogenesis" for a weight-loss product
- ◆ Claims that the product is safe because it is "natural"
- ◆ Undocumented case histories or personal testimonials by consumers or doctors claiming amazing results
- ◆ Promises of no-risk, money-back guarantees

More information is available on the FDA Web site at [www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm136187.htm).

## **Jury Trial Set for Doctor Charged with Bringing Misbranded Foreign Cancer Drugs into US**

A jury trial to hear the case of *USA v. Vinod Chandrashekm Patwardhan, MD* was set to begin on April 21, 2009, in the US District Court for the Central District of California. Patwardhan, an Upland, CA doctor who specialized in treating cancer patients, was arrested in August 2008 by federal authorities after being charged with introducing foreign misbranded drugs into interstate commerce. These drugs reportedly were sometimes diluted when they were administered to his patients, according to a news release issued by Thomas P. O'Brien, US attorney for the Central District of California, on the day of the arrest. The charge of delivering misbranded drugs into interstate commerce with the intent to defraud or mislead carries a penalty of up to three years in federal prison.

**do not wait!** Renew and make sure to complete the **yearly** three (3) hours of CE, one (1) hour of which should be live CE by December 31, 2009. View the Board's Web site for a list of live CE events throughout the state. Renew online at the same cost as mail-in. Renewal fees are payable using Visa, American Express, MasterCard, Discover, and debit cards. If you renew online you will receive your registration in the mail. Failure to renew your registration and to engage in any activity requiring a registration after the renewal date is subject to late fees and discipline.

**Free Board "Law Seminar"**

**Place:** Leslie S. Wright Center, Samford University

**Date:** October 25, 2009

**Time:** 12:30 PM seating, Program 1 - 4 PM, **Seating Limited to 1,500**

**Registration:** Preregistration online at [www.albop.com](http://www.albop.com)

All pharmacists, technicians, and interns are encouraged to attend this motivating teaching seminar.

**680-X-2-.36 Continuing Education for Pharmacists**

Alabama pharmacists are required to complete 15 hours of ACPE or Board-approved CE every year as a condition of licensure renewal. The 2007-2008 CE audit review consisted of 255 (5%) licensed Alabama pharmacists. (**2007 Compliance:** 79.2%, **2008 Compliance:** 89.8%)

The Board requested pharmacists deficient in hours to double the deficiency hours within three months and those hours will not count toward the 2009-2010 CE requirement. Failure to provide proof of the additional required hours within the specified time would result in a disciplinary appearance before the Board.

**The Ryan Haight Act**

Not surprisingly, due to widespread abuse of the Internet by physicians, pharmacists, pharmacies, and patients for the purpose of unlawfully obtaining controlled substances, the United States Congress intervened by the passage of the Ryan Haight Act. The act was passed in part to aid law enforcement and regulators in trying to combat the illegal diversion of controlled substances. This article shall briefly summarize the important mandates of this act.

The official name of the legislation is the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, which was signed by President George W. Bush on October 15, 2008. Pursuant to the act, the Drug Enforcement Administration (DEA) has promulgated an interim final rule that amends the regulations for the Controlled Substances Act and the Controlled Substances Import and Export Act by adding requirements to prevent the illegal distribution and dispensing of controlled substances by Internet sites that sell or facilitate the sale of controlled drugs for non-legitimate, ie, non-medical, purposes. While information about the act has been widely disseminated, while the full text of the act is available at various Web sites, and while you may have become familiar with the act through your employment or membership in professional associations or organizations, you are encouraged to read the act and be intimately familiar with its provisions if you or your pharmacy are in any way in-

volved in any facet of dispensing controlled substances via the Internet. Having said that, this article is primarily directed to the requirements of the above-referenced rule promulgated by DEA.

The significant requirements of the rule are as follows:

1. A valid prescription. Since in almost all cases there is not an in-person examination by a physician of the individual receiving controlled substances through various Internet resources, the rule includes a new definition of valid prescription, which requires at least one in-person medical evaluation of the patient before a prescription can be authorized. (This was already the position of the Alabama Board of Medical Examiners.) Additionally, and always, the prescription must be issued for a legitimate medical purpose.
2. Online pharmacies must disclose contact information for the pharmacy and prescribers affiliated with the pharmacy's Web site.
3. A mandated declaration on the online pharmacy Web site.
4. An online pharmacy must provide notification to DEA and the appropriate state board of pharmacy of its intent to operate as an online pharmacy.
5. The imposition of reporting requirements.
6. New criminal penalties for violating the act.

Most of the provisions of the interim rule became effective on April 13, 2009. The rule does contain eligibility requirements for an exemption.

As pharmacists, you can only dispense pursuant to a valid prescription. Understanding this law and any applicable rules will provide you with important information and hopefully prevent your involvement in what is now prohibited conduct.

*Author: James S. Ward, Esq, Board Attorney*

**Special Notice About the Newsletter**

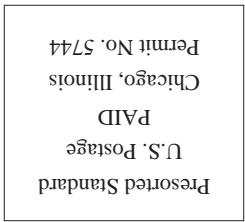
The *Alabama State Board of Pharmacy Newsletter* is considered an official method of notification by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully.

**Do You Know a Pharmacist or Technician Who Needs Help?**

Call the Committee on Rehabilitating Impaired Pharmacists help line at the voicemail of Steve Moore at 205/975-8548. All calls are confidential.

The *Alabama State Board of Pharmacy News* is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary 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 the Foundation or the Board unless expressly so stated.

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