



Idaho State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Statute Changes, Effective July 1, 2009 Telepharmacy Across State Lines

Statute 54-1705 was amended to read, “(22) ‘Pharmacist’ means an individual licensed by this state to engage in the practice of pharmacy or a pharmacist licensed in another state who is registered by the board of pharmacy to engage in the practice of telepharmacy across state lines . . . (24) ‘Practice of telepharmacy’ means the provision of pharmaceutical care by registered or licensed pharmacies or pharmacists located within the United States jurisdictions through the use of telecommunications or other technologies to patients at distances that are located within the United States jurisdictions, as defined in the rules of the board. (25) ‘Practice of telepharmacy across state lines’ means the practice of telepharmacy when the patient is located within the state of Idaho and the pharmacist is located in a United States jurisdiction outside the state of Idaho, as defined in the rules of the board.”

The addition of statute 54-1723A allows for the registration of pharmacists to engage in the practice of telepharmacy across state lines provided that “[n]o pharmacist who is not licensed to practice pharmacy within the state of Idaho may engage in the practice . . . unless registered by the board.” In order to obtain such a registration, the applicant is required to “present to the board proof of licensure in another state and proof that such license is in good standing,” submit a written application, pay a fee, and sign a “statement attesting that the applicant will abide by the pharmacy laws and rules of the state of Idaho.” Pursuant to these changes, the Idaho State Board of Pharmacy is currently promulgating rules for the practice of telepharmacy across state lines.

Idaho Legend Drug Donation Act

Statutes 54-1762 through 54-1765 created an avenue for the donation of previously dispensed drugs to charitable entities. This act states that “[t]he board of pharmacy shall establish and implement a program through which legend drugs may be transferred from a donating entity that elects to participate in the program for the purpose of distribution to a charitable clinic’s or center’s pharmacy or to a qualifying charitable center or clinic acting in consultation with a pharmacist for donation to qualifying medically indigent patients.” The act does place restrictions on who can participate as a donating entity, limiting it to licensed pharmacies, hospitals, nursing homes, drug manufacturers, and wholesale distributors.

Participation in this program is entirely voluntary for the donating entity, as well as the receiving charitable center or clinic. The act does provide that “[a]ny entity that lawfully and voluntarily participates by donating, accepting, distributing or dispensing legend drugs under the

Idaho legend drug donation act shall be immune from liability for any civil action arising out of the provision of such action.” Additionally, “[a]ny person or entity lawfully donating, accepting, distributing or dispensing legend drugs under the Idaho legend drug donation act shall be exempt from the provisions of the Idaho wholesale drug distribution act . . .”

Interested parties should note that the act requires the Board of Pharmacy to “adopt rules necessary for the implementation and enforcement of the program established under the Idaho legend drug donation act and for the enforcement of board rules promulgated thereunder.” Promulgation of these rules requires 2010 legislative approval before the program can be implemented.

Idaho Wholesale Drug Distribution Act

The definition of “normal distribution channel” within statute 54-1752 (9) now includes the chain of custody for a prescription drug from a Food and Drug Administration (FDA)-approved manufacturer “directly or through its colicensed partner, third party logistics provider or manufacturer’s exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the [FDA] and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the [FDA].” As this form of wholesale distribution has not left the normal distribution channel, a pedigree is not required to be provided to the person who receives said prescription drug.

Side Effect Reporting Hotline

As of July 1, 2009, pharmacies are required by FDA to label prescription medications with a toll-free 1-800 number for consumers to report medication adverse events. The required labeling is referred to as the “side effects statement.” This statement may be distributed in one of five ways:

- ◆ On a sticker attached to the unit package, vial, or container of the drug product
- ◆ On a preprinted pharmacy prescription vial cap
- ◆ On a separate sheet of paper
- ◆ In consumer medication information
- ◆ In the appropriate FDA-approved medication guide that contains the side effects statement

New Licensure/Registration Forms

The Board office has been updating many of its licensure and registration forms and applications. Please discard any old forms

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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.

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. 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. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: 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.¹ 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.²

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.

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.

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.

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.

you may have and refer to the Web site at <http://bop.accessidaho.org> for the most current versions, including certified pharmacy technician and technician-in-training applications.

Reporting Theft or Loss of Controlled Substances to DEA

The Drug Enforcement Administration (DEA) Office of Diversion Control has updated the electronic version of DEA Form 106 to streamline data collection, reduce the burden of time on those reporting, and improve the accuracy of reported information. This form now uses the National Drug Code number to automatically populate the fields for product name, dosage form, strength, and package size. DEA hopes that improving this reporting process will “foster improved accountability of stolen or lost controlled substances.” This new form can be accessed at www.deadiversion.usdoj.gov, or by calling 202/307-4925 for any questions regarding this program.

Discipline: June 19, 2009 Board Meeting

D.G., RPh, violation of rule 184.04: failure to follow instructions; four hours continuing education (CE) and \$200 fine.

J.L., Pharmacy Technician, violation of rule 251.05.c: filling a prescription in a negligent or improper manner; two hours CE and \$50 fine.

W.M., RPh, violation of statute 54-1732(3)(f): obtaining a legend drug in a fraudulent manner; \$2,000 fine. Violation of statute 54-1733(3) and rule #184.10: filling an invalid prescription; additional \$2,000 fine.

S.B., Pharmacy Technician, registration revoked due to diversion.

D.B., RPh, violation of statutes 37-117(a) and 37-2734(a)(3): diversion and adulteration; license suspended for 10 years.

D.D., DMD, controlled substance registration revoked due to diversion.

Pharmacy Law CE Opportunities

- ◆ September 27, 2009, 11:30 AM - 12:30 PM – Idaho Society of Health-System Pharmacists Annual Fall Meeting in Sun Valley, ID.
- ◆ October 30, 2009, 10:45 AM - 11:45 AM – Idaho Health Care Conference in Pocatello, ID.

Notice to All Registrants and Applicants

The address, telephone, and other contact information you provide on applications for registration, licensure, and renewals is used to respond to Public Records Act requests. If you do not wish to have your home phone and address released to the public, you must use your current business contact information when completing these forms.

Validity of Prescription Drug Orders

Statute 54-1733(1)(a)(ii), entitled Validity of Prescription Drug Orders, states “A prescription drug order may also be received by a licensed pharmacist verbally from the practitioner, the practitioner’s agent or from a licensed practical nurse or licensed professional nurse **in** a health care facility for a patient or resident **in** such facility.” Because the hospice patient often resides at home rather than in a facility, this later provision of this statute does not currently grant hospice nurses the authority to transmit verbal drug orders. Should the practitioner consider the individual nurse his agent, as many practitioners working with hospice agencies do, this oral transmission would constitute a valid prescription drug order. If a pharmacist should question the relationship between any practitioner and their prospective agent, the pharmacist should verify the relationship with the practitioner directly.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy intern/externs, and pharmacy technicians registered by the Board. Please read them carefully. We encourage you to keep them filed in your pharmacy, preferably in your Idaho Pharmacy Law Book, for future reference.

Know a Pharmacist in trouble with drugs/alcohol or mental health problems?
 Please contact the Pharmacist Recovery Network for help.
www.SouthworthAssociates.net 800.386.1695
24 HOUR CONFIDENTIAL Toll free Crisis Line
866.460.9014

The *Idaho State Board of Pharmacy News* is published by the Idaho 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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