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Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

It's Time to Renew Your Pharmacist License

Pharmacist renewal notices were mailed out in July to all pharmacists licensed with the Ohio State Board of Pharmacy who are eligible for renewal. If you have not received your renewal notice yet, you need to check with the Board office to find out what you need to do to renew your license. If your license is not renewed by September 15, 2009, you may not continue to practice as a pharmacist in Ohio until you do get it renewed.

The process for renewal is the same as last year. We are providing an online renewal process and that is the method we will expect the majority of pharmacists to utilize. Instructions for renewing your identification card online were included with the renewal notices. Please follow the instructions carefully and you should have no problems. If you do run into problems or have concerns, please call the Board office. If you do not have Internet access or cannot renew online for some other reason, you will need to contact the Board office in writing (fax or e-mail are also accepted) and request a paper renewal form. Unless we hear from you, we will expect you to renew online.

There are several advantages to both pharmacists and the Board when the online renewal is utilized. You must use a credit card to renew, so you will have proof that payment was made. It should take less time than the paper forms did, and there will be no delays in the Board receiving the renewal due to the postal service. The advantages to the Board will come in reduced personnel time to sort through all that paper, less filing time and problems, and much faster reporting and license printing.

Again, you need to renew your license by September 15, 2009, if you plan to continue practicing pharmacy in Ohio after that date. If you do not wish to renew your license, please notify the Board immediately.

Technician Rules Effective

On June 21, 2009, three rules dealing with pharmacy technicians became effective. They are rules 4729-4-01 (definitions), 4729-4-03 (qualified pharmacy technician training program), and rule 4729-4-04 (criminal records check for qualified pharmacy technicians). The last rule, 4729-4-02 (board approved examination for qualified pharmacy technicians) was adjusted by the Board in June due to comments received and it was then refiled. It is anticipated that the Board will have made rule 4729-4-02 effective by the time this *Newsletter* is published. All of the rules that are effective should be included in the listing of all of our Administrative Code rules on the Board's Web site.

Any employers who wish to prepare and administer their own examinations should note that it will be necessary to have those examinations approved by the Board **before** they may be used. Instructions for submission of employer-based examinations will be posted on the Web site. Please submit a complete package containing all the items listed on the Web site to avoid delays. Since we anticipate that we will have to review many examinations, it may take a period of time for us to get through them all. The earlier you can submit the examinations, the better, but please be patient.

Zoster Vaccine Approved

Also on June 21, 2009, revised rules 4729-5-36 (course requirements in the administration of immunizations) and 4729-5-37 (protocols for the administration of immunizations) and new rule 4729-5-38 (immunization administration) became effective.

During the last legislative session, the law relating to pharmacists administering injections (§4729.41 ORC) was changed to allow the Board of Pharmacy to add drugs to the list of approved vaccines by rule. We have to do this in consultation with the State Medical Board of Ohio, but it is no longer necessary to ask the legislature to change the law every time a new drug needs to be added.

The first drug that the Board was requested to add was zoster vaccine. After consulting with the Medical Board on the proposed wording for the new rule, the Board was able to add this product to the list of immunizations that may be administered by a pharmacist.

After receiving proper training for zoster vaccine administration as outlined in rule 4729-5-36 and after obtaining a signed protocol pursuant to rule 4729-5-37, a pharmacist may now administer zoster vaccine to patients. Unlike the other approved products, however, zoster vaccine has some additional requirements to be met. The new rule reads as follows:

4729-5-38 Immunization administration:

In addition to the immunizations and medications listed in section 4729.41 of the Revised Code and pursuant to the requirements noted in section 4729.41 of the Revised Code and rules 4729-5-36 and 4729-5-37 of the Administrative Code, a pharmacist may administer the zoster vaccine according to the following requirements:

(A) The pharmacist must receive a patient specific prescription prior to administration of the drug;

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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 74º 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 compounder-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.

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(B) The vaccine must be administered within thirty days of the issuance of the prescription;

(C) The patient must meet the age criteria specified in the F.D.A. approved labeling; and

(D) The pharmacist must be able to document meeting the training criteria required by rule 4729-5-36.

As the rule states, a pharmacist must receive a prescription before administering zoster vaccine and then the vaccine administration must occur within 30 days from the date the prescription was written. If the drug is not administered within the 30-day window, the pharmacist must receive new authorization from the prescriber before administering the vaccine (ie, a new prescription or, at least, a verbal authorization to proceed, properly noted on the original prescription). The drug may not be administered to anyone under the age of 60 at this time, although that may change in the future, based on the Food and Drug Administration (FDA) labeling.

OARRS Weekly Reporting

Also effective on June 21, 2009, was rule 4729-37-07 (frequency requirements for submitting drug database information). This rule was discussed in some detail in the May issue of this *Newsletter*, but now that the rule is effective, a reminder is being issued.

By now, everyone should be reporting directly to the Ohio Automated Rx Reporting System (OARRS) program instead of through the outside agency that was used previously. That began on July 1, 2009. In addition, beginning September 1, 2009, everyone must begin reporting their dispensing information to OARRS on a weekly basis instead of twice a month. Paragraphs B and C of rule 4729-37-07 are reprinted below and outline the requirements:

(B) Starting on September 1, 2009, all drug dispensing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code shall be submitted at least weekly. The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than eight days after the date of the dispensing.

(C) If a pharmacy has no drug dispensing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code, the pharmacy shall submit a "Zero Report" during the regular reporting cycle.

If anyone has problems complying with this requirement, please discuss them with the OARRS program staff as soon as possible. As mentioned in the May *Newsletter*, the combination of reporting dispensing information directly to OARRS and reporting on a weekly basis should improve the timeliness of the data available to pharmacists and physicians. In addition, the weekly reporting is required by federal law if the OARRS program is to continue receiving federal grants. Again, as noted in the May issue, anyone wishing to report more often than once a week (eg, daily) may do so. Please consult with the OARRS technical staff for any assistance needed with your reporting process.

Disciplinary Actions

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, *www.dental.ohio.gov*

State Medical Board – 614/466-3934, *www.med.ohio.gov*

State Nursing Board – 614/466-3947, *www.nursing.ohio.gov*

State Optometry Board – 614/466-5115, *www.optometry.ohio.gov*

State Pharmacy Board – 614/466-4143, *www.pharmacy.ohio.gov*

State Veterinary Medical Board – 614/644-5281, *www.ovmlb.ohio.gov*

Drug Enforcement Administration – 1-800/882-9539, *www.deadiversion.usdoj.gov*

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