March 2011

# Wyoming State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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*http://pharmacyboard.state.wy.us*

## Midwives Licensure Act

The Wyoming legislature enacted Chapter 46 or 33-46-101 through 33-46-108 in 2010, and it was signed into law by Governor Dave Freudenthal. This act establishes a board of midwifery and the requirements to become a licensed midwife in Wyoming. Licensing begins July 1, 2011. Part of the requirements include "[Providing] the [midwifery] board with evidence of successful completion of board approved courses in the treatment of respiratory distress in newborns, pharmacology, the treatment of shock, intravenous therapy and suturing specific to midwives." The act further provides for board rules to include "Defin[ing] a protocol for the use of those drugs approved by the board for administration to mothers and babies. The protocol shall include amounts and methods of obtaining, storing and disposing of approved drugs, indications and contraindications for usage, dosage, route of administration and duration of treatment."

Emergency rules have been proposed. Of interest to the practice of pharmacy in Wyoming is the Medication Formulary and the fact that the **formulary drugs can be obtained through a retail pharmacy,** in minimal quantities for office use. Formulary drugs can also be obtained by "A person or entity that is licensed as a Wholesale Distributor by the Wyoming State Board of Pharmacy." Section 5 of the proposed rules states:

> During the practice of midwifery a licensed midwife may obtain and administer the following drugs described in the midwifery formulary, according to the protocol outlined in Appendix B, describing the indication for use, dosage, route of administration and duration of treatment. The Medication Formulary is restricted to the following:
>
> (a) Oxygen;
>
> (b) Oxytocin as a postpartum antihemorrhagic agent;
>
> (c) Misoprostol as a postpartum antihemorrhagic agent;
>
> (d) Methylergonovine as a postpartum antihemorrhagic agent;
>
> (e) Injectable local anesthetic for the repair of lacerations which are no more extensive than second degree;
>
> (f) Antibiotics for group b streptococcus prophylaxis consistent with the guidelines set forth in Prevention of Perinatal Group B Streptococcal Disease, published by the Centers for Disease Control and Prevention;
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> (g) Epinephrine administered via a metered dose auto-injector;
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> (h) Intravenous fluids for stabilization of the woman;
>
> (i) Rho (D) immune globulin;
>
> (j) Vitamin K1 (phytonadione);
>
> (k) Eye prophylactics to the baby;
>
> (l) Sterile H2O Papules

More information can be obtained by calling 307/777-3628 or by reviewing the entire act at *http://legisweb.state.wy.us/statutes/titles/Title33/T33Ch46.htm.*

## Notice of Public Hearing for Wyoming State Board of Pharmacy Rules Revisions

A public hearing will be held on April 15, 2011, at 951 North Poplar Room 114, Casper, WY, beginning at 1:00 PM. Proposed revised rules are available at the Wyoming State Board of Pharmacy Web site at *http://pharmacyboard.state.wy.us*. The Wyoming Pharmacy Act Rules and Regulations are being revised in Chapter 2 (General Practice of Pharmacy Regulations), Chapter 3 (Pharmacy Internship Regulations), and Chapter 14 (Telepharmacy). Chapter 5 (Poison Regulations) and Chapter 7 (Computer Regulations) are proposed for deletion. The Wyoming Controlled Substance Act Rules and Regulations are being revised in Chapter 3 (Fees for Registration and Re-Registration), Chapter 4 (Records and Inventories of Registrants), Chapter 6 (Issuing, Filling, and Filing of Prescriptions), and Chapter 8 (Prescription Drug Monitoring Program). Comments can be mailed to Wyoming State Board of Pharmacy, 1712 Carey Avenue Suite 200, Cheyenne, WY 82002 or e-mailed to BOP@wyo.gov until 5 PM on April 14, 2011. Telephone comments will not be accepted and oral comments can be made in person at the hearing.

## New 'Tamper-Resistant' OxyContin from Purdue Pharma L.P.

*By Jessica Fonseca, PharmD Candidate*

Over the summer and into early fall, pharmacies may have noticed that there was a slight hardship in receiving OxyContin® products. This was likely due to the fact that Purdue Pharma, L.P., the manufacturers of the drug, had ceased production of their old product and had begun to produce their new formulation, which was approved by Food and Drug Administration (FDA) in April 2010.

Although Purdue's decision to alter the formula was multifaceted, two reasons were likely the largest contributing factors. First, Purdue Pharma had marketed the product in 1995 when it was first released to the market through advertisements that this drug would have a lower abuse potential due to its controlled release mechanism. After being scrutinized by FDA, Purdue was required to revise their marketing strategy and to pay large amounts in fines. This situation may have motivated Purdue Pharma in their quest for a tamper-resistant form of OxyContin. Second, OxyContin has rapidly become one of the most abused drugs in America. In fact, the number of prescription drug abusers has surpassed the number of abusers of cocaine, heroin, hallucinogens, and inhalants combined.

This medication, which may be essential to patients with legitimate chronic pain has rapidly become a source of entertainment and income

*continued on page 4*

## Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new NABP CPE Monitor Program, a collaborative effort between the National Association of Boards of Pharmacy® (NABP®), the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in fall 2011. In addition, the program will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. Plus, beginning in early April, as an extra benefit, pharmacists and technicians may enter detailed career information relating to education or work history, which may streamline license transfer processing. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification soon after March 10, 2011 to ensure their e-Profile is properly set up. In fall 2011, the e-Profile ID will be required to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Registrants will then be known in the ACPE provider's system by two additional identifiers: their month and day of birth (mmdd) and NABP e-Profile ID. Please note that CPE Monitor does not currently track CPE from non-ACPE accredited providers. This feature will be added in Phase 2 of the CPE Monitor Program, and, until then, pharmacists and technicians will need to submit non-ACPE accredited CPE directly to their board of pharmacy when required to do so.

After March 10, pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at *www.nabp.net/pharmacists*. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at *www.nabp.net/technicians*. Or visit *www.MyCPEmonitor.net* for more information.

## DEA Policy Statement on Role of Agents in Communicating CS Prescriptions

Drug Enforcement Administration (DEA) issued a statement of policy that clarifies the proper role of a duly authorized agent of a DEA-registered individual practitioner in communicating controlled substance (CS) prescription information to a pharmacy. The statement, published October 6, 2010, in the *Federal Register,* reminds health care providers that a prescription for a CS medication must be issued by a DEA-registered practitioner acting in the usual course of professional practice. Such a practitioner may authorize an agent to "perform a limited role in communicating such prescriptions to a pharmacy in order to make the prescription process more efficient," and the guidance emphasizes that medical determinations to prescribe CS medications may be made by the practitioner only.

The specific circumstances in which an agent may assist in communicating prescription information to a pharmacy are detailed and include:

- An authorized agent may prepare the prescription, based on the instructions of the prescribing practitioner, for the signature of that DEA-registered practitioner.
- For a Schedule III-V drug, an authorized agent may transmit a practitioner-signed prescription to a pharmacy via facsimile, or may communicate the prescription orally to a pharmacy on behalf of the practitioner.
- An authorized agent may transmit by facsimile a practitioner-signed Schedule II prescription for a patient in a hospice or long-term care facility (LTCF) on behalf of the practitioner.

The guidance also makes clear that generally, Schedule II prescriptions may not be transmitted by facsimile and that hospice and LTCFs are exceptions. Further, Schedule II prescriptions may only be communicated orally by the DEA-registered practitioner and only in emergency situations. DEA stresses that the practitioner should decide who may act as his or her authorized agent and advises that such designation be established in writing. An example written agreement is included in the policy statement, along with additional guidance related to designating an authorized agent. DEA also notes that as electronic prescribing for CS is implemented and its use increases, the role of the agent in communicating CS prescriptions will likely be reduced over time. The DEA policy statement is available on the *Federal Register* Web site.

## The ISMP Ambulatory Care Action Agenda: Learn from Others' Mistakes

*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.*

No news is **not** good news when it comes to patient safety. Each organization needs to accurately assess how susceptible its systems

are to the errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative.

A great way to utilize the ISMP Medication Safety Alert!® Community/Ambulatory Care Edition is by using the Ambulatory Care Action Agenda*. Three times a year, selected items are prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors previously reported to the ISMP Medication Errors Reporting Program (MERP). The agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition during the preceding four months. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired.

The Action Agenda is presented in a format that allows community practice sites to document their medication safety activities, which is important for internal quality improvement efforts but also important for any external accrediting or regulatory organizations. Each pharmacy practice site should convene a staff meeting to discuss each item in the Action Agenda. The staff should ask themselves, "Can this error occur at our site?" If the answer is "yes," the ISMP recommendations for prevention should be reviewed for applicability at that specific site. If the recommendations are germane to the practice site, the columns on the Action Agenda indicating "Organization Assessment" and "Action required/Assignment" should be completed and a reasonable time set for completion. The staff should reconvene in three months time to determine if the proposed recommendation strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial meeting.

According to the 2011 *Survey of Pharmacy Law,* published by NABP, at least 19 states regulate, require, or recommend a continuous quality improvement (CQI) program to monitor and prevent quality related events. The purpose of the CQI program is to detect, document, and assess prescription errors in order to determine the cause, develop an appropriate response, and prevent future errors. Utilization of the Action Agenda to review externally reported errors combined with review and analysis of internally reported events constitutes a feasible and effective CQI program.

*The Action Agenda is available at no charge on the ISMP Web site, *www.ismp.org/Tools/communitySafetyProgram.asp.*

## FDA and NABP Partner to Help Prevent Acetaminophen Toxicity

In partnership with NABP, and as part of its Safe Use Initiative, Food and Drug Administration (FDA) encourages pharmacies to stop using the abbreviation APAP and to spell out the drug name, acetaminophen, in effort to help patients avoid acetaminophen toxicity. As explained in an FDA drug safety notice, liver injury due to acetaminophen overdose is a serious public health problem, and by spelling out the drug name on prescription labels, pharmacies are enabling patients to know when their medication contains the drug. Patients can then compare their prescription and over-the-counter medications to determine whether both contain acetaminophen and avoid taking two medicines containing the drug. The FDA drug safety notice provides more information and is available at *www.fda.gov/Drugs/DrugSafety/ucm230396.htm.*

In July 2010, NABP recommended that the state boards of pharmacy prohibit the use of the abbreviation APAP on prescription labels, and require that acetaminophen be spelled out. In situations where the board is unable to mandate such a provision, NABP recommended that the boards strongly encourage practitioners to follow this guideline. More information is available on the NABP Web site at *www.nabp.net/news/.*

## Stolen Carbatrol, Adderall XR Surfacing in Supply Chain

Shire, along with FDA, alerts pharmacists and distributors that certain lots of Carbatrol® that were stolen on October 17, 2008, have been found in the supply chain as expired returns. The stolen shipment also contained Adderall XR®. The manufacturer warns that more stolen product may still be on the market and that stolen Carbatrol and Adderall XR should not be used or sold because the safety and effectiveness of the product could have been compromised by improper storage and handling or tampering while outside of the legitimate supply chain. The following products and lot numbers are affected:

- Adderall XR 15 mg, Lot No: A38146A, Expiration Date: 02/29/2012
- Carbatrol 200 mg, Lot No: A40918A, Expiration Date: 04/30/2010
- Carbatrol 200 mg, Lot No: A40919A, Expiration Date: 04/30/2010
- Carbatrol 200 mg, Lot No: A41575A, Expiration Date: 05/31/2010

These lots of Carbatrol and Adderall XR were stolen while in transit from Shire's manufacturing facility in North Carolina to Shire Distribution Center in Kentucky. FDA seeks assistance and asks that any information regarding the stolen Carbatrol or Adderall XR, including suspicious or unsolicited offers for these products, be reported by contacting FDA's Office of Criminal Investigations (OCI) at 800/551-3989, or by visiting the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

## 2011 Survey of Pharmacy Law Now Available

Celebrating its 60th edition as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2011 *Survey of Pharmacy Law* is now available.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 18, Drug Control Regulations, asks whether or not states have CS or drugs of concern scheduled differently than the federal Controlled Substances Act.

Updates for the 2011 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of CS in Sections 26 and 27.

The *Survey* can be purchased online for $195 by visiting the Publications section of the NABP Web site at *www.nabp.net/publications.* All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

*continued from page 1*

for many people on the street. Not only does the drug provide a euphoric high, it also can provide a large profit when sold. The average retail price for these tablets range from $1 to $14 per pill depending on the strength but may be sold for 50 cents to $1 per milligram on the street allowing the dealer to make a significant profit rapidly. Ideally, all drug companies would be concerned with diversion of their products and would act to prevent it; however, the elimination of such diversion would also perhaps remove some fear from the prescribers, leaving them free to treat legitimate pain with these strong narcotics.

Having seen the new product, many may ask, how is it different? Subtle as the appearance changes may be, the chemical compound has changed tremendously. Beginning with the appearance, the defining factor for dealers and junkies, the obvious difference is that the old OxyContin were imprinted with an "OC" on one side while the new formulation is imprinted with an "OP." The "OP" is slightly thicker as well and there is no coating which can simply be "bathed" off as the new formulation is made of a specialized polymer instead. This new polymer is resistant to crushing, grinding, and milling; in fact, even hitting it with a hammer will only change the shape of the tablet rather than allowing a higher dose of drug to be released at once. When hydrated, the pill, or any fraction of the pill will form into a gelatinous mass rather than dissolving into a liquid. This polymer essentially prevents all administration routes other than ingestion. Because the pill does not fractionate into small enough particles, it cannot be snorted or chewed. If one does attempt to snort the fractions it may clog the nostril and result in "stringy goo" as the mucus membrane is moist and hydrates the particles in the nostril (as one such blogger discovered after receiving the new formulation). If attempting to inject the drug intravenously, liquid is added which in turn makes the product so thick and gelatinous that it cannot even be drawn into a needle.

Although no studies have yet been done and thus, no statements may yet be made, by the uproar in the streets and online forums, it appears that the chemical engineers at Purdue have successfully made a tamper-resistant product which could potentially decrease the abuse potential of such medications. Clearly a problem exists with diversion of such Schedule II substances as is seen in community pharmacies through drug seekers and doctor shoppers on a daily basis. Encouragement is renewed through the innovation of companies such as Purdue Pharma but it is unwise to assume that such an invention could, alone, cease all diversion, misuse, and abuse. As a pharmacist, a duty exists to practice prudently, a part of which may encompass assistance in the prevention of diversion.

## *Early Refills (Part 2)*

When a pharmacist reviews the patient record and has a question about overutilization the question has been asked, "What is a reasonable time frame to refill a prescription with refills authorized?" Some third-party payors will allow an early refill if 85% of the time has passed that the prescription amount should cover. Some pharmacies have made a policy of 90% of the time. For example, a refill for a prescription for hydrocodone/acetaminophen that should last 30 days might be refilled without question on day 26 or 27 (if refills were prescribed). Each pharmacist should use professional judgment and should document when they have contacted the prescriber. Communication with the patient and prescriber is important. Restricting the authorized refill to the actual last date may not be in the best interest of the patient if they are traveling or have planned ahead. If the patient continuously has a reason for the early refill request, the notes in the profile should alert the next pharmacist to get a prescription drug monitoring program report (for controlled substances) and/or call the prescriber. Many prescribers are using pain contracts and will put a note on the prescription to not refill before a certain time. The Wyoming Medicaid Lock-In program restricts a patient to one pharmacy to assist in monitoring and compliance. The patient's pain may not be relieved or they may be noncompliant with dosing. Whatever the reason, the pharmacist should communicate and **document** his or her notes and actions.

## *Suggestions to Name the Wyoming Prescription Drug Monitoring Program*

Ideas to name the Wyoming Prescription Drug Monitoring Program are being sought. Several states have developed an acronym such as KASPER (Kentucky All Schedule Prescription Electronic Reporting) or SCRIPTS (South Carolina Reporting and Identification Prescription Tracking System). The Board will consider names and possible acronyms at future meetings. Suggestions can be sent to BOP@wyo.gov or mailed to Wyoming State Board of Pharmacy, 1712 Carey Avenue Suite 200, Cheyenne, WY 82002.



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