February 2011 News



Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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2011 Fifty-Year Pharmacists

The Alabama State Board of Pharmacy recognizes and takes great pride in congratulating the 50-year milestone of pharmacists licensed in Alabama. This is an outstanding career accomplishment in the pharmacy profession and service contribution to their communities.

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Inspector George T. Grubbs Retires

After 26 plus years with the Board of Pharmacy, Inspector George T. Grubbs retired effective December 31, 2010. Mr Grubbs has represented the Board with dignity, knowledge, and compassion. In 2008, he was presented the Lester E. Hosto Inspector Distinguished Service Award from the National Association of Boards of Pharmacy® (NABP®) because

of commendable service in protecting the public health as an inspector and noteworthy contributions to NABP.

Are You Sure You Entered the Right Prescriber on That Prescription Record?

The Department of Public Health's Prescription Drug Monitoring Program (PDMP) includes various practitioner licensing agencies such as the Board of Medical Examiners. These agencies review the data submitted by pharmacies dispensing controlled substance prescriptions to ensure that prescribers are complying with certain restrictions placed on prescriptive authority. Some of the recent findings include:

- ♦ The prescriber recorded by the dispensing pharmacy passed away some time ago.
- ◆ The prescriber recorded by the dispensing pharmacy lost his or her Drug Enforcement Administration (DEA) registration some time ago.
- ♦ The inability by the dispensing pharmacy to read a prescriber's name and using a name and DEA number that is contained in the patient's profile.

Board Rule 680-X-2-.12, Supervising Pharmacist, currently holds the supervising pharmacist accountable for the proper maintenance of all prescription records.

Prescription Drug Monitoring Program

Effective February 1, 2011, the PDMP will require dispensers to report controlled substances data utilizing the most recent version of the American Society for Automation in Pharmacy (ASAP) 2007, 4.1. For technical questions on how to report data utilizing the ASAP 2007, 4.1., please consult your software vendor. In addition, you may contact the PDMP technical support desk at 1-800/225-6998 (option 8) or pdm-info@hidinc.com.

Board Members/Drug Inspectors for 2011

continued on page 4

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Compand can only be ascertained by examini

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 practitionersigned 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 at www.federalregister.gov/articles/2010/10/06/2010-25136/roleof-authorized-agents-in-communicating-controlled-substanceprescriptions-to-pharmacies.

FDA and NABP Partner to Help Prevent Acetaminophen Toxicity

In partnership with the National Association of Boards of Pharmacy® (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 https://www.nabp-net/news/nabp-recommends-boards-of-pharmacy-prohibit-use-of-acetaminophen-abbreviation/.

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

Compliance News

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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.

Iowa Tracks Group Using Fraudulent CS Prescriptions

The Iowa Department of Public Safety seeks assistance in tracking a group of individuals using fraudulent prescriptions to obtain CS. Specifically, four unidentified individuals have obtained oxycodone using fraudulent prescriptions at a number of pharmacies in Iowa. Similar cases have occurred in Missouri, and it is believed that the same group of people is involved. The subjects are reported to have used multiple aliases, to be in their 20s or 30s, and to have paid in cash. They have also been reported to use crutches when dropping off and picking up prescriptions. The fraudulent prescriptions were on legitimate prescription paper with valid prescriber names, but the addresses on them had been computer generated. Similar cases or relevant information can be reported to Criminal Intelligence Analyst Crystal Munson at the Mid-Iowa Narcotics Enforcement Task Force by calling 515/270-8233, extension 119, or by e-mailing crystal.munson@ polkcountyiowa.gov.

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.

Survey of Pharmacy Law's 60th Edition 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.

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Board of Pharmacy Meeting Dates for 2011

January 18-19	July 19-20
February 22-23	August 16-17
March 22-23	September 20-21
April 19-20	October 18-19
May 17-18	November 15-16
June 14-15	December 13-14

^{*}Please note: Administrative hearings are held on the first meeting date and business meetings are held on the second.

DEA Plans Second National Prescription Drug Take-Back Day

DEA is planning a second National Prescription Drug Take-Back Day to take place Saturday, April 30, 2011. The first National Prescription Drug Take-Back Day on Saturday, September 25, 2010, saw participation from 3,000 state and local law enforcement agencies and collected approximately 242,000 pounds of medications. Additional information is available on the DEA Web site.

NABP Uncovers More Rogue Internet Drug Outlets Operating in Conflict with Pharmacy Laws and Practice Standards

As of January 7, 2011, NABP has uncovered 7,134 Internet drug outlets operating in conflict with pharmacy laws

and practice standards. A full listing of both Recommended and Not Recommended sites is available online at their Web site at www.nabp.net/programs/consumer-protection/buying-medicine-online.

Continuing Education Approval

Effective January 1, 2011, the Alabama State Board of Pharmacy will no longer approve continuing education programs on a case by case basis. Only programs approved by the Accreditation Council for Pharmacy Education can be used to satisfy the requirements of the Board. This action was taken at the Board of Pharmacy meeting on September 22, 2010.

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.

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