



# Alabama State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## 2013-2014 Renewals and Continuing Education

All pharmacists, pharmacies, retail medical oxygen suppliers, and manufacturers/wholesalers/distributors are required to renew their license/permit and controlled substances permit this calendar year. Pharmacists will only need to provide the total number of continuing education (CE) hours completed in calendar years 2011 and 2012, but a post-audit review will be conducted. Pharmacists shall complete 15 hours of CE every year as a condition of licensure renewal. CE may be completed by either attendance or by a distance-based program, video, or by publication; however, a pharmacist must complete at least three hours of live CE through attendance at a course(s) each calendar year. A pharmacist may carry over and receive credit for 12 hours of CE in the succeeding calendar year. All licenses/permits become due on October 31 and shall become null and void on December 31.

## Attention – Prescribing Rules for Physician Assistants Have Changed

In 2009, a bill was passed, which allows the prescribing of controlled substances in Schedules III, IV, and V by a physician assistant (PA) that meets the requirements to hold a Qualified Alabama Controlled Substances Certificate (QACSC) by the Alabama Board of Medical Examiners. In addition to the QACSC the PA has to obtain a registration from the United States Drug Enforcement Administration (DEA) in order to prescribe controlled substances. Below are some of the prescribing protocols established by the Alabama Board of Medical Examiners:

1. The quantity of a controlled substance initially prescribed by a PA shall be **limited to a 30-day supply**, and **any refill must be authorized by the supervising physician**. The supervising physician must see the patient before authorizing a refill.
2. If a prescription for a controlled substance is initiated by the supervising physician, the PA may authorize **only one refill of a 30-day supply** of the medication.
3. A PA may make a verbal order for a controlled substance under the circumstances stated in the protocol.
4. A PA **cannot** be involved in the prescribing or authorizing of controlled substances for weight loss.

Some PAs have their own prescription pads. The prescriptions should have the following information: When prescribing legend drugs or controlled drugs a PA shall use a prescription form that includes all of the following: (a) the name, medical practice site address, and telephone number of the physician supervising the PA;

(b) the PA's name printed below or to the side of the physician's name; (c) the medical practice site address and telephone number of the PA, if different from the address of the supervising physician; (d) the PA's license number assigned by the Medical Board and the QACSC registration number, when a controlled substance is prescribed; (e) the words "Product Selection Permitted" printed on one side of the prescription form directly underneath a signature line; and (f) the words "dispense as written" printed on one side of the prescription form directly underneath a signature line.

You can verify if a PA has been issued a QACSC by the Board of Medical Examiners by visiting their Web address, [www.albme.org/licenseearch.html](http://www.albme.org/licenseearch.html).

## HIPAA Audits

The US Department of Health and Human Services Office for Civil Rights has recently issued Health Insurance Portability and Accountability Act (HIPAA) audit letters to a number of covered entities, including a **pharmacy**. A covered entity has only 10 days to provide the requested information. As such, proactive steps to prepare for the possibility of an audit are critical.

The failure to comply can create significant financial and administrative problems if a HIPAA violation is discovered. A recent example involves a surgery practice that failed to implement appropriate HIPAA policies and procedures, failed to document the training of its employees, failed to identify a security official and conduct a risk analysis, and failed to obtain business associate agreements with certain business associates. The practice ultimately accepted a \$100,000 penalty and agreed to institute a corrective action plan designed to bring it into full compliance with HIPAA's privacy and security rules.

Covered entities should be aware that there is far more to HIPAA than a privacy notice or written acknowledgment, and should do a thorough analysis of HIPAA's requirements and determine the extent to which they are in compliance, as well as potential security threats and vulnerabilities. Enforcement actions against covered entities and their business associates are expected to intensify as revisions to the HIPAA security and privacy rules are considered and implemented. It is therefore becoming increasingly important for covered entities and their business associates to analyze their compliance with HIPAA standards.

## DEA – Learn from the Mistakes of Others

On September 22, 2010, DEA issued an Order to Show Cause and Immediate Suspension of Registration to an Alabama doctor. The

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## **FDA Warned Medical Practices About Counterfeits in US and Risks to Patients**

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm), may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm).

### **Rethink the Vial**



*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 an 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).*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid pre-

scriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request Parents' Guide to Understanding Prescription Drug Abuse brochures for distribution to your patients, visit [www.SafeguardMyMeds.org](http://www.SafeguardMyMeds.org).

### **Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports**

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at [www.abbott.com/vicodin-consumer-alert.htm](http://www.abbott.com/vicodin-consumer-alert.htm). Abbott advises that anyone who has the counterfeit ver-



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sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at [www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm](http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

## **PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits**

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at [www.safemedicines.org/resources-for-healthcare-professionals.html](http://www.safemedicines.org/resources-for-healthcare-professionals.html). Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

## **FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches**

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm). Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at [www.fda.gov/Drugs/DrugSafety/ucm300747.htm](http://www.fda.gov/Drugs/DrugSafety/ucm300747.htm). Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARE<sub>x</sub>E<sup>®</sup> Web site at [www.awarerx.org/informedSiteMap.php](http://www.awarerx.org/informedSiteMap.php).

## **Providers Asked to Advise Patients of Acetaminophen Safe Use Steps**

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWARE<sub>x</sub>E Web site at [www.awarerx.org/OTCMedUse.php](http://www.awarerx.org/OTCMedUse.php). The AWARE<sub>x</sub>E consumer protection program and the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) are part of the Acetaminophen Awareness Coalition.



**Pharmacists & Technicians:**  
Don't Miss Out on Valuable CPE Credit.  
Set Up Your NABP e-Profile and  
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.*

order alleged that while the doctor was authorized to prescribe Suboxone® and Subutex® “for maintenance or detoxification treatment pursuant to 21 U.S.C. 823 (g)(2),” he had “prescribed methadone to patients for the purpose of drug addiction treatment” without the registration required under 21 U.S.C. 823 (g)(1).

The order further alleged the doctor had prescribed both methadone and Suboxone to a number of patients whose charts show that he:

1. did not obtain a prior medical history
2. did not perform an initial physical exam
3. established little or no basis for the diagnoses
4. offered no other treatment other than prescribing controlled substances
5. continued to prescribe alprazolam to a patient after the patient file explicitly noted that the patient abused this drug

Furthermore, he:

1. post-dated prescriptions for Schedule II controlled substances
2. admitted to having issued a controlled substance prescription after he was served with the Immediate Suspension Order
3. improperly used his data-waiver number on prescriptions

The doctor requested a hearing and was placed on the docket of the agency’s administrative law judges. In January 2011, the administrative law judge recommended the doctor’s registration be revoked.

On March 16, 2012, an administrator with the Department of Justice, DEA, under the authority vested in her, ordered that the DEA Certificate of Registration, and identification number be, and they hereby are, revoked. It was further ordered that any application for renewal or modification of such registration be, and it hereby is, denied.

### **CPE Monitor Service**

With the electronic transmission of continuing pharmacy education (CPE) data now live, the National Association of Boards of Pharmacy® (NABP®) CPE Monitor™ service is fully operational. All Accreditation Council for Pharmacy Education (ACPE)-accredited providers will have until the end of 2012 to implement systems to transmit data to CPE Monitor.

As additional ACPE-accredited providers transition their systems, pharmacists and pharmacy technicians will be able to begin viewing their CPE contact hours online through their NABP e-Profile.

Pharmacists and technicians, visit *MyCPEmonitor.net* to set up your NABP e-Profile and to register for CPE Monitor. Failure to set up an e-Profile or inaccuracies in an e-Profile may result in unrecorded or mis-recorded CPE, with possible adverse consequences for licensees/registrants when renewing their licenses/registrations.

### **Recent Updates to the Board’s Web Site**

1. A link has now been added under “Forms, Apps, & Publications” for the state of Alabama’s Sales and Use Tax Division’s pharmaceutical pamphlet.
2. A link has now been added under “Forms, Apps, & Publications” to update or add a licensee’s/registrator’s e-mail address.
3. A link has now been added under “Forms, Apps, & Publications” for the Alabama State Board of Pharmacy’s “Non-Pharmacist Key Holder Designation Form.”
4. A link has now been added under “Continuing Education” listing all Board-approved certification programs for parenterals, consultants, and preceptors for 2012 with upcoming seminar events.

To view these recent updates, visit the Alabama State Board of Pharmacy’s Web site at [www.albop.com](http://www.albop.com).

### **Reminder**

Please notify the Board, in writing, of any change of address or employment.

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

Call the Alabama State Board of Pharmacy Wellness Program help-line at 205/981-2273. 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 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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