



# Kansas State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Pharmacists Peer Review Network Gets a New Name

For many years, the Committee on Impaired Pharmacy Practice (CIPP) has assisted pharmacists grappling with drug, alcohol, and mental health issues. The program was known simply as CIPP, after the committee that provides the oversight. Encouraged by the success of the program, the committee believes that the time has come to select a name that focuses on the ultimate goal – the recovery of the individual as a professional. The program will now be known as KsPRN, the Kansas Pharmacist Recovery Network.

The term **pharmacist recovery network** is widely used in similar programs across the country, and offers instant recognition among medical professionals. The KsPRN program is authorized by Kansas peer review statutes and is administered by the Kansas Pharmacists Association. The program has been underwritten by a grant from pharmacist fees under a contract with the Kansas State Board of Pharmacy. It offers a way for pharmacists and pharmacy interns to anonymously refer themselves or other pharmacy professionals who have issues that might endanger the public. It has some advantages for a truly impaired pharmacist by providing an avenue of rehabilitation, monitoring, and treatment. Participation in the program is confidential in most cases. The names of participants are not revealed to the licensing board as long as participants comply with their agreements with KsPRN. In addition to overseeing these anonymous participants, KsPRN also monitors compliance of pharmacy professionals that have been referred to them directly by the Board of Pharmacy.

If you know of a pharmacist or pharmacy student dealing with alcoholism, drug use/abuse, dependency, or other health issues, please make a call. Pharmacists, pharmacy students, and their family members can contact the KsPRN at **785/217-7091**. For more information, visit [www.ksrx.org](http://www.ksrx.org) under the link for “Resources.”

## Have You Set Up Your NABP e-Profile?

CPE Monitor™, a collaborative effort between the National Association of Boards of Pharmacy® (NABP®) and the Accreditation Council for Pharmacy Education (ACPE), offers pharmacists and pharmacy technicians a convenient method to electronically track their completed continuing pharmacy education (CPE) credits from ACPE-accredited providers.

To benefit from CPE Monitor, pharmacists and pharmacy technicians should take the following actions:

- ◆ Set up an NABP e-Profile, obtain your NABP e-Profile ID, and register for CPE Monitor.
- ◆ Provide your NABP e-Profile ID and your date of birth (MMDD) to an ACPE-accredited provider when registering for CPE or submitting a request for credit. Note: some providers are still in the process of transitioning their systems to CPE Monitor.

The data will then be transmitted from the ACPE-accredited providers to ACPE and then to NABP, ensuring that CPE credit is officially verified. Once information is received by NABP, pharmacists can log in to access information about their completed CPE, and monitor their progress in acquiring the three continuing education units required by Kansas Pharmacy Practice Regulations. Please visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile.

## Changes to a C-II Prescription

Drug Enforcement Administration (DEA) issued a policy letter that states that pharmacists are instructed to adhere to state regulations or policy regarding changes that a pharmacist may make to a Schedule II prescription after oral consultation with the prescriber.

The Kansas State Board of Pharmacy has determined that it is in the best interest of the patient to permit a pharmacist to add the date if it is not indicated, and change

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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-



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.*

the drug strength, quantity, and directions for use. The pharmacist may also add the patient's address, the prescriber's DEA number, and select a dosage form if one is not indicated. The pharmacist should document with his or her initials the time and date that the prescriber or prescriber's agent was contacted. Remind the prescriber to document the changes in the patient's chart.

### **SB 134 Electronic Prescribing**

In 2010 DEA published its interim final rule on electronic prescriptions for controlled substances (EPCS). Since that time software vendors have been working to make sure that the prescribers and pharmacy software are compliant with the new rule as it relates to controlled substances.

SB 134 was passed in the 2012 Legislative Session. It put the same directives in Kansas law as that required by the DEA's rule. SB 134 did not place any new requirements on prescribers or pharmacies. The technical requirements of the DEA rule were very extensive so it has taken the software vendors a lot of time to get compliant. For instance, before a prescriber can send a "legal" EPCS to the pharmacy its software vendor must have provided the prescriber a certificate that shows the software vendor passed a third-party audit. It is called a third-party audit or certificate.

The third-party auditors are companies such as **Price Waterhouse Coopers, NetSPI, KPMG, Deloitte, Chief Security, Brightline, BDO, or Assurance Concepts**. This list is not all inclusive, but these companies understand what DEA is requiring.

As of press time there are several software vendors who have completed the third-party audit and have provided certificates to their prescribers. Those vendors are **DrFirst, NewCrop, NextGen, and RxNT** for prescribers. Pharmacy software vendors who have completed the third-party audit are **Cerner Etreby, Rite Aid, SUPERVALU, and Walgreens**. To find out whether your software vendor has fulfilled the audit task, ask them for documentation of the audit. DEA requires that the software vendor give the prescribers and pharmacies a copy of the certificate upon request. If you are a prescriber you will need to show a copy of the certificate to the pharmacy so that they can see that you are eligible to send EPCS. If the prescriber does not have a certificate yet the pharmacy will be required to verify the electronic prescription. This is required by federal and state law so prescribers need to understand that if their vendor has not provided them with a certificate then they are not eligible to send an EPCS.

Electronic signatures are permitted for non-controlled substance prescriptions. If the prescription is for a controlled substance the signature can be electronically generated only if the prescriber's software vendor has provided the third-party audit or certificate. Otherwise, all EPCS need to be signed manually by the physician.

The law states that the prescriber is responsible for prescriptions that come out of his or her office. If the transmission is generated by someone other than the prescriber the Kansas law requires a first and last name of the prescriber's agent. This applies to all prescriptions, not just controlled substances. If agents do not want to give their last name they need to let their prescriber know that they cannot be his or her agent. If the transmission line is blank the pharmacy may assume that the prescriber is transmitting the prescription. The pharmacy is not required to contact the prescriber to see whether the transmission was completed correctly. That responsibility lies with the prescriber since he or she is responsible for everything that comes from his or her office.

If the prescriber is a mid-level practitioner the electronic prescription shall state the name and address of the supervising physician. This is required under the Nurse Practice Act and the Healing Arts Act. There will be no exceptions for electronic prescribing. If the mid-level practitioner cannot complete the transmission with this information then he or she needs to continue using hard-copy prescriptions that contain this information.

SB 134 did not make any changes to the law. It merely reiterated 21 CFR §1311.100 *et seq.* The Board of Pharmacy would encourage everyone to review the federal law so that they can fully understand how to be compliant with the electronic prescribing regulations.