



# Arkansas State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Electronic Prescriptions Received Via Fax**

The Arkansas State Board of Pharmacy office has received a number of calls recently regarding electronically signed prescriptions. This is an issue that the Board has discussed several times over the last few years to share guidance with pharmacists licensed in Arkansas. The following is an excerpt from the December 2005 *Newsletter*:

During the October 2005 Meeting, Emdeon corporation, formerly WebMD, made a presentation to the Board highlighting electronic prescribing and security measures incorporated into the process of electronic prescribing to ensure valid electronic signatures for prescriptions. A topic of concern during this discussion was the fact that most pharmacies are not currently set up to receive electronic prescriptions directly to a computer in the pharmacy. Because of this, processing companies that transmit the electronic prescriptions to pharmacies must transmit the prescription to the fax machine in the pharmacy much like a computer generated request for refill authorizations which a computer faxes to a prescriber. At the end of this discussion, the Board decided that electronic prescriptions that are submitted by prescribers electronically and received in a pharmacy on a fax machine, are considered electronic prescriptions and do not require a handwritten signature. If there are any questions about the legitimacy of the prescription, it should be treated like a phoned-in prescription and the pharmacist must verify it with the prescriber. It is important to note that this process is only for **non**-controlled medications.

In the years since publishing this guidance to pharmacists, Board staff has continually received questions regarding electronic prescriptions for controlled substances (EPCS) related not only to electronic prescriptions received via fax but also regarding prescriptions received through e-prescribing or brought in by patients. It is interesting to summarize the progression of this over the last few years as most of the changes related to this subject have happened within the last year.

On March 31, 2010, Drug Enforcement Administration (DEA) published an Interim Final Rule with Request for Comment in the *Federal Register* entitled "Electronic Prescriptions for Controlled Substances" (Docket No. DEA-218, RIN 1117-AA61). The official rule may be viewed at <http://origin.www.gpo.gov/fdsys/pkg/FR-2010-03-31/pdf/2010-6687.pdf> as published in the *Federal Register*. The rule became effective June 1, 2010, and while it revised DEA regulations to provide practitioners with the option

of writing prescriptions for controlled substances electronically and also allows pharmacies to receive, dispense, and archive these electronic prescriptions, the requirements to participate in this process are quite onerous. These regulation changes added to existing federal rules related to controlled substances to provide practitioners with the ability to utilize technology to electronically transmit controlled substance prescriptions "while maintaining the closed system of controls on controlled substances." This is a key phrase in this process because the rule as published was 84 pages long and included several requirements that most pharmacists and prescribers have not fully examined. One major obstacle in all of this is that the rule requires any system that either transmits or receives EPCS to be "certified" as meeting the security and control standards set out in the EPCS rules. At the time of submission for publication of this *Newsletter*, DEA has not certified any transmitting or receiving system as meeting these criteria, therefore according to DEA regulations any electronically signed prescription for a controlled substance would not satisfy federal law requirements. Furthermore, DEA has no allowance for electronic signatures on controlled substances that are received via the pharmacy's fax machine or brought in by the patient.

So how do you handle EPCS that have been received or prescriptions for controlled substances with an electronic signature that are brought in by a patient? Basically we are stuck where we have been for some time in that a pharmacy/pharmacist that receives an electronically signed prescription for a controlled substance in Schedule III, IV, or V either by fax, e-prescribing, or hard copy may call the prescriber to verify the prescription and then treat it as a verbal order. The Board of Pharmacy is well aware that many hospitals, clinics, administrators, and prescribers have affirmed to pharmacies that they are legally transmitting EPCS but according to federal regulatory requirements this cannot be correct. This is an issue that many pharmacists have tried to explain to prescribers and is often identified as one of the most confusing and frustrating subjects of daily practice for pharmacists.

The Board suggests that pharmacists visit the DEA's Electronic Prescriptions for Controlled Substances site at [www.deadiversion.usdoj.gov/ecommm/e\\_rx/index.html](http://www.deadiversion.usdoj.gov/ecommm/e_rx/index.html). This site includes a brief description of the EPCS rule and has useful links to the rule itself as well as question and answer sections for pharmacies and for prescribers. Here are a couple of the most frequently asked questions to the Board's office that are answered by DEA in this section.

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## **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 at [www.federalregister.gov/articles/2010/10/06/2010-25136/role-of-authorized-agents-in-communicating-controlled-substance-prescriptions-to-pharmacies](http://www.federalregister.gov/articles/2010/10/06/2010-25136/role-of-authorized-agents-in-communicating-controlled-substance-prescriptions-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](http://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/nabp-recommends-boards-of-pharmacy-prohibit-use-of-acetaminophen-abbreviation/](http://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 non-profit 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 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](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).*

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](http://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](mailto: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](http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

## **Survey of Pharmacy Law's 60<sup>th</sup> Edition Now Available!**

Celebrating its 60<sup>th</sup> 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](http://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](mailto:custserv@nabp.net).

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**Q. When can a practitioner start issuing electronic prescriptions for controlled substances?**

A. A practitioner will be able to issue electronic controlled substance prescriptions only when the electronic prescription or electronic health record (EHR) application the practitioner is using complies with the requirements in the interim final rule.

**Q. When can a pharmacy start processing electronic prescriptions for controlled substances?**

A. A pharmacy will be able to process electronic controlled substance prescriptions only when the pharmacy application the pharmacy is using complies with the requirements in the interim final rule.

**Q. As a practitioner, until I have received an audit/certification report from my application provider indicating that the application meets DEA's requirements, how can I use my electronic prescription application or EHR application to write controlled substances prescriptions?**

A. Nothing in this rule prevents a practitioner or a practitioner's agent from using an existing electronic prescription or EHR application that does not comply with the interim final rule to prepare and print a controlled substance prescription, so that EHR and other electronic prescribing functionality may be used. Until the application is compliant with the final rule, however, the practitioner will have to print the prescription for manual signature. Such prescriptions are paper prescriptions and subject to the existing requirements for paper prescriptions.

**Q. As a pharmacy, until I have received an audit/certification report from my application provider indicating that the application meets DEA's requirements, how can I use my pharmacy application to process controlled substances prescriptions?**

A. A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third-party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. The pharmacy may continue to use its pharmacy application to store and process information from paper or oral controlled substances prescriptions it receives, but the paper records must be retained.

## Technician Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacy technician permit renewals in October. These permit renewal reminders are sent directly to pharmacy technicians at their address of record and it should be noted that technician permits that were not renewed expired on December 31, 2010. The Arkansas State Board of Pharmacy allows a grace period until March 31 on permits. However, there is a \$20 penalty on technician permit renewal if not renewed by February 1, a \$40 penalty if not before March 1, and if a permit is not renewed by April 1, then the permit is void. The Board strongly encourages you to use the Board's Web site to renew technician permits via the Internet as it will speed up the renewal process for your technicians and it will also reduce the turnaround time for technicians to receive their new permits. This is also the only way that the Board can accept credit card payments for renewal of these permits.

## Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter*.

Arkansas Pharmacy Support Group Help Line

870/636-0923

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