



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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13.19. Reducing Errors

There are several low-cost methods that have the capability to significantly reduce prescription dispensing errors in your pharmacy. The Institute for Safe Medication Practices has published studies showing that two-thirds of dispensing errors might be eliminated by these low-tech ideas.

- ◆ 16% reduction in errors when pharmacists were given a high-intensity light and magnifying lens to use for reading prescriptions and labels, and for identifying medications.
- ◆ 24% fewer process errors occurred when the prescription was placed in a copy stand or copy holder alongside the computer screen rather than on the counter. This is probably due to the eyes' ability to compare the original prescription with entered data when the original prescription is placed in a left-to-right reading position.
- ◆ 27.8% reduction in process errors was observed when "product sleeves" were used for some drugs with a high risk of dispensing errors due to look-alike/sound-alike names or doses. For example, place Coumadin® 10 mg in a "product sleeve" or ziplock bag with a warning label to double-check the prescription to make sure it was 10 mg – not 1 mg – that was ordered. Another example might be Zyprexa®-Zyrtec®. Each pharmacy should choose its own drugs with the highest risk of errors.

The computer screen is your work site and should be uncluttered. Remove distractions such as pictures of family, vacations, the new car you are thinking about, and sticky-notes from around your computer screen to help keep your mind focused on the important dispensing tasks you are performing.

Even the type of background music can affect your ability to stay focused and task-oriented. Popular music with "sing-along lyrics" is often far more distracting than "elevator music" and may cause your mind to lose focus on the important dispensing checks you are doing.

Pharmacists-in-charge (PICs) should not just "accept things as they are" but should often reevaluate the dispensing areas of the pharmacy to ensure the safest work site possible to help eliminate dispensing errors.

There is a free three-hour continuing education (CE) course covering these topics on the Oklahoma State Board of Pharmacy's Web site under the "Continuing Education" section. See "Community Pharmacy Risk Assessment Tool."

From the Inspector's Desk

- ◆ **13.20. New Hydrocodone Law:** Effective November 1, 2013, prescriptions for any medication containing hydrocodone may not be refilled. This applies even if the prescription was written prior to November 1. Transfers are considered to be a refill of a preexisting prescription and are not allowed. Partial fills would be permitted (eg, a prescription is written for a quantity of 100 but the patient only wants to purchase 20 at a time). Documentation for partial fills would be required in accordance with OAC 475:30-1-12. Hydrocodone combination medications are still classified as Schedule III products and may be phoned in. Mid-level practitioners (nurse practitioners, physician assistants, etc) may continue to prescribe hydrocodone combination medications at this time.
- ◆ **13.21. Estratest and Estratest HS:** There are several generic brands of Estratest and Estratest HS that are considered Schedule III substances. The new manufacturers did not apply for exempt status from Drug Enforcement Administration. Until they have obtained an exemption, all prescriptions for those products must be treated as a controlled substance (CS). Furthermore, Donnatal® and associated generics that contain phenobarbital are not exempted from controlled status by the Oklahoma Bureau of Narcotics and Dangerous Drugs and must be treated as a CS.
- ◆ **13.22. Purchase from Licensed Entities Only:** Pharmacies and hospitals must confirm that all prescription drugs are purchased **only** from entities that are licensed by the Board. This can be easily verified on the Board's Web site. Pharmacies and hospitals must exercise due diligence in confirming the licensing of the businesses they purchase from and should review disciplinary actions involving such businesses.
- ◆ **13.23. Hospitals and Non-Patient-Specific Compound Medications:** Hospitals that purchase non-patient-

Continued on page 4



Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.

ISMP Study on Targeted Mandatory Patient Counseling

 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 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. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
 - ◇ fentanyl patches
 - ◇ hydrocodone with acetaminophen
 - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
 - ◇ warfarin
 - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
 - ◇ Humalog[®] (insulin lispro)
 - ◇ NovoLog[®] (insulin aspart)
 - ◇ Levemir[®] (insulin detemir)
 - ◇ Lantus[®] (insulin glargine)
 - ◇ Apidra[®] (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
 - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at www.ismp.org/AHRQ/default.asp?link=ha.

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,

Compliance News



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encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of www.nabp.net.

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancil-

lary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of www.nabp.net.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in NABPLAW® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. NABPLAW Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about NABPLAW Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at www.nabp.net/programs/member-services/nabplaw/.



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Don't Miss Out on Valuable CPE Credit.
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Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

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Continued from page 1

specific compounded medications must confirm that the state in which the compounding pharmacy resides allows non-patient-specific compounded medications to be sold by the compounding pharmacy. Most states do not allow this practice.

- ♦ **13.24. Sale of Prescription Medication to an Out-of-State Patient or Entity:** Pharmacies may not sell prescription drugs to wholesalers (returning a product that was purchased from a wholesaler to the wholesaler for credit is considered a “return,” not a “sale”). The sale of any prescription medication to an out-of-state patient or entity almost always requires that the pharmacy be licensed with the state into which they are shipping. State boards are actively prosecuting those in violation of this regulation.
- ♦ **13.25. CSOS Personal Certificates:** Controlled Substance Ordering System (CSOS) personal certificates are issued to individuals, and passwords are not to be shared with any other persons. This is a violation of federal law.
- ♦ **13.26. Inhalant Solutions:** Inhalant solutions are considered to be sterile drug products and must be compounded as such under applicable sterile compounding regulations and rules. All compounders should closely review and be very familiar with the compounding rules that apply to their pharmacy practice.
- ♦ **13.27. Change of PIC Notice:** Please remember to notify the Board when there is a change of PIC. A controlled dangerous substances (CDS) inventory needs to be taken and sent to the Board within 10 days of a PIC change.

Disciplinary Actions

For more information, you may view hearing minutes at www.pharmacy.ok.gov.

13.28. April 11, 2013 Board Hearing

Shannon Monteggia, Technician #17249 – Case No.

1160: Did not contest one violation of failure to obtain a pharmacy technician permit prior to performing pharmacy technician duties in a pharmacy. **Permit placed on probation for ninety (90) days and must attend a law seminar in 2013.** (Agreed Order)

Jason Lee O’Neal, DPh, #14970 – Case No. 1161: Did

not contest one violation of failure to supervise pharmacy employees. **Fine of \$500, must attend law seminar in addition to the required 15 hours of CE in 2013 and 2014, and all CE for 2013 and 2014 must be live.** (Agreed Order)

Ben Blackburn, DPh, #12179 – Case No. 1162: Did not

contest two violations of failure to supervise pharmacy employees. **Fine of \$500, must attend law seminar in addition to the required 15 hours of CE in 2013 and 2014, and all CE for 2013 and 2014 must be live.** (Agreed Order)

Walgreens No. 02361, #2-4841 – Case No. 1163: Did not

contest two violations including failure to maintain effective controls against misfills and failure to supervise pharmacy employees. **Fine: \$6,000.** (Agreed Order)

Ashley Howard, Technician #16063 – Case No. 1164:

Admitted guilt on four violations including theft of CDS and possession of a CDS without a prescription resulting

in the loss of over 4,200 doses of CDS to the pharmacy where she worked. **Revoked.** (Agreed Order)

Timothy Osborn, Technician #16150 – Case No. 1165:

Found guilty on five violations including theft of CDS and possession of a CDS without a prescription. **Revoked.**

Dana Thompson, Technician #14550 – Case No. 1166:

Admitted guilt on four violations including theft of CDS and possession of a CDS without a prescription. **Revoked.** (Agreed Order)

Anthony Owens, DPh, #10513 – Case No. 1167: Admitted

guilt on five violations including failure to report disciplinary action in another state, using an illegal CS, and falsifying information on a pharmacist renewal. **Indefinite suspension.** (Agreed Order)

Mercy Hospital Tishomingo, Inc, #61-6202 – Case No.

1168: Neither admitted nor denied guilt on three violations including failure to be licensed, to obtain a license in a timely manner after a change of ownership, and failure to have a PIC. **Fine: \$9,000.** (Agreed Order)

Wal-Mart Pharmacy No. 10-2804, #1-4460 – Case No.

1169: Neither admitted nor denied guilt on three violations including failure to maintain effective controls against diversion resulting in the loss of 9,788 doses of hydrocodone products. **Fine: \$9,000.** (Agreed Order)

Norman Regional Hospital Pharmacy, #7-523 – Case No.

1170: Admitted guilt on five violations including failure to provide effective controls against theft and diversion of CS and failure to maintain adequate records resulting in the loss of over 4,200 doses of CDS. **Fine: \$6,000.** (Agreed Order)

13.29. May 15, 2013 Board Hearing

Doug Sisemore, DPh, #9159 – Case No. 1156: Admitted

guilt on 10 violations while acting as PIC of Reliable Pharmacy including failure to establish and maintain effective controls against the diversion of prescription drugs and failing as pharmacy manager to be responsible for all aspects of the pharmacy operation including the proper record keeping system for drugs. **Probation for five (5) years and \$10,000 fine. Must attend a law seminar in addition to the required 15 hours of CE in 2013 and 2014 and all CE during the calendar years of 2013, 2014, and 2015 must be live CE.** (Agreed Order)

Reliable Discount Pharmacy, Inc, #1-3893 – Case No.

1156: Admitted guilt on nine violations including failure to properly maintain the required inventories and records of CDS. **Fine: \$10,000.** (Agreed Order)

Cindy Hudgins, Technician #13646 – Case No. 1171:

Admitted guilt on three violations including theft of CDS and possession of a CDS without a prescription which resulted in the loss of 1,097 doses of Schedule II CDS and 217,154 doses of Schedule III CDS to the pharmacy where she worked. **Revoked.** (Agreed Order)

Sooner Pharmacy, Inc, of Tishomingo, #61-3493 – Case

No. 1172: Admitted guilt on 445 violations including failure to provide effective controls and procedures to guard against theft and diversion of CDS resulting in the loss of 1,097 doses of Schedule II CDS and 217,154 doses

Continued on page 5

Continued from page 4

of Schedule III CDS. **Probation for five (5) years and \$40,000 fine.** (Agreed Order)

Michael Roy LaFevers, DPh, #9728 – Case No. 1173: Admitted guilt on 447 violations while acting as PIC of Sooner Pharmacy including failure as pharmacy manager to establish and maintain effective controls and procedures to guard against theft and diversion of CDS resulting in the loss of 1,097 doses of Schedule II CDS and 217,154 doses of Schedule III CDS. **Probation for five (5) years and \$15,000 fine. Must attend a law seminar in addition to the required 15 hours of CE in 2013 and 2014 and all CE must be live while on probation.** (Agreed Order)

CVS/Pharmacy No. 08312, #26-5406 – Case No. 1174: Admitted guilt on two violations including failure to keep adequate records regarding 1,887 doses of controlled drug substances. **Fine: \$3,000.** (Agreed Order)

Brandon Maples, DPh, #13275 – Case No. 1175: Admitted guilt on nine violations including administering drugs that were not dispensed on orders from a prescribing practitioner. **Indefinite suspension.** (Agreed Order)

Red Cross Drug, #47-4751 – Case No. 1176: Admitted guilt on 16 violations including failure to assign correct beyond-use dates for sterile compounded drugs. **Probation for five (5) years and \$20,000 fine. Parenteral permit is suspended indefinitely.** (Agreed Order)

Larry Kirkpatrick, DPh, #7942 – Case No. 1177: Admitted guilt on eight violations while acting as PIC of Red Cross Drug including failure to assure compliance with sterile compounding rules. **Probation for five (5) years and \$1,000 fine. Must attend a law seminar in addition to the required 15 hours of CE in 2013 and 2014 and all CE must be live while on probation.** (Agreed Order)

Vivien L. Grose, DPh, #11361 – Case No. 1178: Admitted guilt on 34 violations while employed by Red Cross Drug including failure to assign correct beyond-use dates for sterile compounded drugs, and failure to assure compliance with sterile compounding rules. **Probation for five (5) years and \$2,000 fine. Must attend a law seminar in addition to the required 15 hours of CE in 2013 and 2014 and all CE must be live while on probation.** (Agreed Order)

Ashley Weathers, Technician #2075 – Case No. 1179: Admitted guilt on five violations including theft of personal prescriptions and failure to notify the Board of address change. **Revoked.** (Agreed Order)

Allen Community Pharmacy, #23-5285 – Case No. 1180: Admitted guilt on nine violations including filling or refilling prescriptions for dangerous drugs without authorization of a practitioner and failure to establish and maintain effective controls against the diversion of drugs. **Probation for five (5) years and \$20,000 fine.** (Agreed Order)

David Campbell, DPh, #12885 – Case No. 1181: Admitted guilt on five violations while acting as PIC of Allen Community Pharmacy including failure to ensure that prescription drugs are issued “by an authorized practitioner” and failure to establish and maintain effective controls against diversion of drugs. **Probation for five (5) years and \$10,000 fine. Must attend a law seminar in addition to the required 15 hours of CE in 2013 and 2014 and all CE must be live while on probation.** (Agreed Order)

Clay Haisten, DPh, #11522 – Case No. 1182: Admitted guilt on 138 violations while acting as PIC of The Pharmacy of Pocola including knowingly billing or charging “for a brand when a generic or compounded product is dispensed,” submitting fraudulent billing to a third-party payer of prescription drugs, and compounding drug products that are commercially available. **Fined \$15,000 and remains on probation until October 3, 2017. Must attend a law seminar in addition to the required 15 hours of CE in 2013 and 2014 and all CE must be live while on probation.** (Agreed Order)

The Pharmacy of Pocola, #19-4449 – Case No. 1183: Admitted guilt on 137 violations including submitting fraudulent billing, and compounding drug products that are commercially available. **Probation for five (5) years and \$15,000 fine.** (Agreed Order)

Calendar Notes

The Board will be closed Thursday, **July 4**, for Independence Day and Monday, **September 2**, for Labor Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the October Newsletter.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext. 5773. All calls are confidential.

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Page 5 – July 2013

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