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Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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16.14. DSCSA Product Tracing Requirements

The Drug Supply Chain Security Act (DSCSA) was signed into law in November 2013. Over a 10-year period, specific systems are required to be put into place to identify, trace, and verify prescription drugs in addition to standardizing processes to detect and report suspect and illegitimate drugs. Food and Drug Administration (FDA) will be developing standards and publishing guidance documents as this Act is phased in over the next seven years.

Product tracing requirements, including transaction history, transaction information, and transaction statements, in paper or electronic form, are required to be kept when product is transferred between trading partners and/or dispensers. More detailed information may be found at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct.*

Section 582(d)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) states:

> [A] dispenser . . . prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a **specific patient need.** (emphasis added)

Section 581(19) of the FD&C Act defines "specific patient need" as the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. It further states that this term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

Simply stated, a pharmacy must provide product tracing requirements when transferring medication to another pharmacy unless it is for a specific patient.

From the Inspector's Desk

- **16.15. Selling "Office Stock" to Physicians:** Before selling prescription drugs to a practitioner's office for office stock or to another pharmacy, a pharmacy must have a drug supplier permit from the Oklahoma State Board of Pharmacy. The permit fee is $20 per year. A drug supplier's total annual sales may not exceed 5% of the total annual sales of the pharmacy.

  A practitioner wanting to order drugs may **not** write a prescription for "office use" or write a prescription for an employee to stock his or her office. The pharmacy (ie, drug supplier) must create an invoice with the following items: name and address of purchaser, drug description, quantity, price, and date of transaction. These invoice files must be maintained by the pharmacy. If a pharmacy chooses to run a mock prescription through their system for perpetual inventory purposes **only,** it must **not** be submitted to the prescription monitoring program.

  If a pharmacy or prescriber is wishing to purchase a Schedule II medication, the receiving party (ie, purchaser) must issue a Drug Enforcement Administration (DEA) Form 222 and the fulfilling pharmacy (ie, drug supplier) must complete Form 222 and send the appropriate copy to DEA. Keep in mind that all invoices must bear the name of the entity/prescriber licensed to purchase prescription drugs. It is prudent to ask for a copy of their license or go online to their licensing board and verify that their license is current.

  Pharmacy drug suppliers may **not** sell to wholesalers, repackagers, or manufacturers, but this does not prohibit the return of a drug from whom it was purchased. A pharmacy drug supplier may **not** sell a compounded product to another pharmacy for resale. However, it may sell a nonsterile compounded product to a practitioner for administration in the office, but **not** to be dispensed in the office and **not** for resale. Any nonsterile preparations sold to a practitioner must be labeled "for office use only – not for resale."
- **16.16. Live Continuing Education:** Since 2002, the Board has recommended, but not required, three hours of live continuing education (CE) each year. The Board feels that pharmacists who actively engage with their peers at live conferences are less isolated and are less likely to be disciplined. Pharmacists who attend live conferences also tend to garner a wealth of information during the breaks and become more knowledgeable of current problems in the profession. Although some webinars are considered live, the Board prefers seminars where the pharmacist is physically present and able to interact with other professionals. The Board does not accept webinars as live CE for pharmacists who have been disciplined and are required to complete live CE.
- **16.17. Compounded Irrigations – Sterile or Nonsterile?:** The Board has been asked if bladder irrigations and wound irrigation solutions such as tetracaine/epinephrine (adrenalin)/cocaine (TAC) or lidocaine/epinephrine/tetracaine (LET) solutions must be compounded under United States Pharmacopeia (USP) Chapter <797> standards.

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

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4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc.* 2014;89(8):1042-1051.
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6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch.* March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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Under current USP <797> standards, all irrigations for wounds must be sterile. Under proposed USP <797> standards, irrigations are only required to be sterile if they are used in an internal body cavity that does not communicate freely with the environment outside of the body. Therefore, under current USP <797> and proposed USP <797> standards, bladder irrigations definitely must be sterile. The bladder is an internal body cavity that "does not freely communicate with the environment outside of the body." So, **if the proposed USP <797> standards are adopted,** and the wound is left open, the irrigation would not be required to be sterile. If the wound is to be closed after irrigation, the irrigation needs to be sterile. **The question on the TAC/LET solution would fall under the "closed wound" category because of the stitches closing the wound. Therefore, it must be sterile regardless.**

Disciplinary Actions

For more information, you may view hearing minutes at *http://ok.gov/pharmacy/Board/Minutes/index.html.*

16.18. February 24, 2016 Board Hearing

Teresa L. Hamilton, Technician #9484 – Case No. 1328: Found guilty on two counts including failing to notify the Board, in writing, within 10 days of change of employment and failing to comply with Board orders. **Revoked.**

Impaired Pharmacist #10822 – Case No. 1383: Must enter into and abide by a contract with Oklahoma Pharmacists Helping Pharmacists (OPHP). Agreed to guilt on five counts including incorrectly filling or misfilling a prescription; failing to maintain and have readily retrievable for five years an original prescription; failing to establish and maintain effective controls to prevent prescription errors; and failing to satisfactorily respond within 10 days to a warning notice. **Indefinite suspension. $3,000 fine.**

City Drug Store, #39-7498 – Case No. 1384: Neither admits nor denies guilt on six counts including failing to obtain a new license after change of name, ownership, and/or location; failing to report to the Board all changes in any information required for licensure; failing to take and send to the Board a controlled substance inventory within 10 days of change of owner or pharmacy manager; incorrectly filling or misfilling a prescription; and failing to establish and maintain effective controls to prevent prescription errors. **Suspension stayed and license placed on probation for five years until February 24, 2021. $5,000 fine.**

Amber Lowe, Technician #6254 – Case No. 1385: Found guilty on four counts including theft while working as a registrant; failing to establish and maintain effective controls against the diversion of prescription drugs; and possession of a controlled dangerous substance (CDS) without a valid prescription. **Revoked.**

Danielle Noyes, Technician #20757 – Case No. 1386: Found guilty on four counts including allowing someone other than a licensed pharmacist to certify a prescription and performing a duty that may not be performed by supportive personnel. **Revoked.**

Ryan Pryor, Technician #18463 – Case No. 1387: Agreed to guilt on five counts including theft while working as a registrant; conducting business in a registrant's capacity without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition; abusing alcohol or drugs, using an illegal substance or CDS, and/or testing positive for such substance or its metabolite; and possession of a CDS without a valid prescription. **Revoked.**

Victoria Rushing, Technician #19676 – Case No. 1388: Found guilty on five counts including furnishing false or fraudulent material in an application made to the Board; having an arrest, charge, plea of nolo contendere, or conviction, or deferred sentence for any misdemeanor or felony offense; and failing to be forthright and open in the provision of information to the Board in the application process. **Revoked.**

Darren York, Technician #14199 – Case No. 1389: Found guilty on five counts including theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

APS Pharmacy, #99-7398 – Case No. 1390: Agreed to guilt on four counts, neither admits nor denies guilt on eight counts, and does not dispute that the Board has found it violated one count. Counts include selling at retail, or offering for sale, dangerous drugs, medicines, chemicals, or poisons for the treatment of disease, excluding agricultural chemicals and drugs or accepting prescriptions for the same, without first procuring a license from the Board for the period of October 1, 2013, through May 31, 2015; failing, as a nonresident pharmacy, to make application and receive an annual nonresident pharmacy license at a fee set by the Board for the period of October 1, 2013, through May 31, 2015; entering into an arrangement whereby prescription orders are received, or prescriptions are delivered, at a place other than the pharmacy in which they are filled, compounded, or dispensed; compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product; failing to establish and maintain effective controls against the diversion of prescription drugs; filling a written prescription that was not signed by the practitioner; failing to ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized prescriber; dispensing a prescription drug knowing or should have known that the prescription was issued without a valid pre-existing patient-prescriber relationship; making or filing a report or record that the registrant knows or should have known to be false; and failing to follow Oklahoma pharmacy laws and regulations in the practice of pharmacy for the Oklahoma portion of the nonresident pharmacy's practice or operation; specifically, respondent submitted an application including a pharmacist-in-charge who was not currently licensed as a pharmacist in Florida and in Oklahoma. **License placed on probation for three years until February 24, 2019. $15,000 fine.**

Claremore Compounding Center, Inc, #29-4671 – Case No. 1391: Agreed to guilt on five counts including failing to have a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy, including the establishment of policies and procedures for the safekeeping of pharmaceuticals and the proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs; failing to establish and maintain effective controls against the diversion of prescription drugs; distributing Schedule I or II controlled substances without using either a DEA Form 222 or its electronic equivalent; and compounding a drug product not compounded for an identified individual patient pursuant to a practitioner prescription. **License placed on probation for six months until August 24, 2016. $3,000 fine.**

Darren Hightower, DPh #13228 – Case No. 1392: Agreed to guilt on five counts including failing as pharmacy manager to be responsible for all aspects of the operation related to the practice of pharmacy, including the establishment of policies and procedures for the safekeeping of pharmaceuticals and

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the proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs; failing to establish and maintain effective controls against the diversion of prescription drugs; distributing Schedule I or II controlled substances without using either a DEA Form 222 or its electronic equivalent; and compounding a drug product not compounded for an identified individual patient pursuant to a practitioner prescription. **$1,500 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar year of 2016. All 15 hours of required CE that respondent must have to renew his license shall be live during the calendar year of 2016.**

Mary Hurley Hospital, #74-4833 – Case No. 1393: Agreed to guilt on 27 counts including failing to establish and maintain effective controls against the diversion of prescription drugs; failing to record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser; and failing to maintain on a current basis a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of. **License placed on probation for five years until February 24, 2021. $10,000 fine.**

Larry Pope, DPh #9733 – Case No. 1394: Agreed to guilt on 18 counts including failing to establish and maintain effective controls against the diversion of prescription drugs and failing to conduct business at all times in conformity with all federal, state, and municipal laws. **$1,000 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar years of 2016 and 2017. All 15 hours of required CE that respondent must have to renew his license shall be live during the calendar years of 2016 and 2017. At least four hours shall be about drug diversion prevention.**

16.19. April 6, 2016 Board Hearing

RX Shoppe, Inc, #45-7418 – Case No. 1395: Agreed to guilt on four counts including failing to have a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy, including the establishment of policies and procedures for the safekeeping of pharmaceuticals and the proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs; failing to establish and maintain effective controls against the diversion of prescription drugs; and distributing Schedule II controlled substances without using either a DEA Form 222 or its electronic equivalent. **License placed on probation for one year until April 6, 2017. $6,000 fine.**

Teresa Kay Butler, DPh #12107 – Case No. 1396: Agreed to guilt on four counts including failing to have a pharmacy manager who is responsible for all aspects of the operation related to the practice of pharmacy, including the establishment of policies and procedures for the safekeeping of pharmaceuticals and the proper record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs; failing to establish and maintain effective controls against the diversion of prescription drugs; and distributing Schedule II controlled substances without using either a DEA Form 222 or its electronic equivalent. **$3,000 fine. Respondent shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar years of 2016 and 2017. All 15 hours of required CE that respondent must have to renew her license shall be live during the calendar years of 2016 and 2017.**

Angela Roebuck, Technician #15464 – Case No. 1397: Agreed to guilt on four counts including theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

Macy Haworth, Technician #19039 – Case No. 1398: Agreed to guilt on four counts including theft while working as a registrant; possession of a CDS without a valid prescription; and unlawfully distributing, dispensing, transporting with intent to distribute or dispense, or possessing with intent to manufacture, distribute, or dispense a CDS. **Revoked.**

Melanie Hudson, Technician #19224 – Case No. 1399: Found guilty on three counts including theft while working as a registrant and possession of a CDS without a valid prescription. **Revoked.**

CVS/Pharmacy No. 06009, #1-5380 – Case No. 1402: Agreed to guilt on five counts including failing to establish and maintain effective controls against the diversion of prescription drugs; failing to notify the Board immediately by certified mail of the separation of employment of any pharmacist, pharmacy intern, or pharmacy technician for any suspected or confirmed drug- or pharmacy-related violation; failing to supervise all employees as they relate to the practice of pharmacy; failing to implement and follow a written drug diversion detection and prevention policy; and failing to notify the Board, in writing, within 10 days of the employment termination of a pharmacy technician. **$12,000 fine.**

Calendar Notes

The Board will meet on **August 3, 2016.** The Board will be closed Monday, **September 5** 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. 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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