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# Arkansas State Board of Pharmacy

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## New Assistant Director and Chief Fiscal Officer

The Arkansas State Board of Pharmacy is pleased to announce the appointment of Trey Gardner, PharmD, to the position of "Assistant Director, State Board of Pharmacy." Trey graduated from the University of Arkansas for Medical Sciences (UAMS) College of Pharmacy where he has been on the faculty since 1998. He has served as the assistant dean at the college for the past two years. You can contact Trey at trey.gardner@mail.state.ar.us.

The Board also welcomes Margaret Lincourt, BFA, as chief fiscal officer. Margaret is a graduate of the University of Massachusetts, Amherst (1971). She has served as pathway coordinator for the external PharmD program at UAMS for the past 11 years. She served as both financial aid director and associate director at the Department of Higher Education for four years; and also worked as the assistant budget director at UAMS for two years. She has more than 15 years experience owning and operating a small business. You can contact Margaret at margaret.lincourt@mail.state.ar.us.

## FDA Compounding Policy Guide

The Food and Drug Administration (FDA) has issued a pharmacy compounding compliance guide entitled "Sec. 460.200 Pharmacy Compounding." This document provides guidance to drug compounders on how the FDA intends to address pharmacy compounding following the Supreme Court's decision declaring Section 503A of the Modernization Act of 1997 invalid in its entirety.

The compliance guide is being implemented immediately without prior public comment, under §21 CFR 10.115(G)(2) because of the Agency's urgent need to explain how, in light of the Supreme Court's decision, it will exercise its enforcement discretion in regard to compounded human drugs. However, the FDA has requested comments regarding the document and will consider revisions deemed by the FDA as appropriate.

The following specific activities are listed as criteria to consider enforcement action:

(1) compounding drugs in anticipation of receiving prescriptions, except in very limited quantities, in relation to the amounts of drugs compounded after receiving valid prescriptions
(2) compounding drugs that were withdrawn or removed from the market for safety reasons
(3) compounding finished drugs from bulk active ingredients that are not components of FDA-approved drugs, without an FDA-sanctioned investigational new drug (IND) application in accordance with 21 U.S.C. § 355(i) and 21 CFR 312
(4) receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility
(5) receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements
(6) using commercial scale manufacturing or testing equipment for compounding drug products
(7) compounding drugs for third parties who resell to individual patients, or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale
(8) compounding drug products that are commercially available in the marketplace, or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, the FDA will consider whether there is documentation of the medical need for the particular variation of the compound, for the particular patient.
(9) failing to operate in conformance with applicable state law regulating the practice of pharmacy

The entire compliance policy guide may be viewed at www.fda.gov.

## Importation of Canadian Drugs

The US Food and Drug Administration (FDA) has stated that the purchase and importation of drugs by US consumers is illegal. Various advertisements have appeared, which encourage consumers to take advantage of the economic savings obtained by illegally purchasing prescription medications from Canadian sources. The FDA states, "virtually all Canadian pharmacies that ship prescription drugs to consumers in the US violate US law because such drugs are generally unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. § 353(b)(2), and/or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)."

Although the FDA's personal importation policy does allow consumers to import small quantities of specific medications that are otherwise illegal, certain defined circumstances must exist. Under the personal importation policy, the FDA has per-

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mitted individuals and their physicians to bring into the US small amounts of FDA non-approved drugs for the compassionate treatment of life threatening diseases. Patients receiving such drugs are required to supply the name of the licensed physician in the US responsible for the patient's specific treatment.

However, a contributing factor to advertisements promoting personal importation of Canadian drugs may be the FDA guidance document, which describes the agency's "enforcement priorities." This document states that although unrestricted personal importation is illegal, the FDA will focus its limited enforcement resources on bulk commercial imports rather than on individual consumers. Irrespective of enforcement priorities, general importation of Canadian drugs by US consumers is illegal.

## *Arkansas Medicaid – Early Refill Concerns*

The Arkansas Medicaid Pharmacy Program has been reviewing claims data transmitted by pharmacists who override the Early Refill ProDUR alert. The Early Refill sets an alert for Arkansas Medicaid if the next date of service is sooner than 75% of the day's supply of previous fill date. For example, if a quantity of 62 tablets is entered for a 31-day supply, the prescription will set an Early Refill alert if the prescription is filled sooner than seven days early. The Early Refill alert will **only** set an alert against the previous fill **that was for the same strength drug**. Pharmacists should verify that they are transmitting the correct days supply at the time the claim is transmitted to avoid improper Early Refill alerts.

The Early Refill override allowed for Arkansas Medicaid is more liberal than many other state Medicaid agencies. Other states require the pharmacist to contact a Help Desk and provide justification in order to override the Early Refill alert. Arkansas pharmacists have been allowed to use their professional judgment to override the Early Refill alert without the necessity of contacting the Electronic Data Systems Help Desk for override assistance. For controlled drugs, this should be reserved for atypical cases, for example, where the same physician has increased the dose, as evidenced by the new prescription and directions compared to the previous prescription, or the pharmacist has verified the increased dose with the physician if the previous prescription was filled at another pharmacy.

The Arkansas Medicaid Pharmacy Program currently allows pharmacists to refill or fill the next prescription up to seven (7) days early for all classes of drugs without setting an alert, and yet **many controlled drugs are overridden more than 50% of the time to fill early** as shown by this brief list:

- Methylphenidate – overridden 54% of the time
- Oxycodone (OxyContin) – overridden 66% of the time
- Oxycodone/APAP – overridden 55% of the time
- Fentanyl (Duragesic) – overridden 54% of the time
- Morphine – overridden 77% of the time
- Detroamphetamine – overridden 62% of the time
- Hydrocodone – overridden 50% of the time

Due to excessive overrides, Arkansas Medicaid is considering disallowing early refills.

## *A Message from Arkansas Bureau of Standards*

In March 2001, Arkansas officially adopted the National Type Evaluation Program (NTEP) into statutory law. Consequently, state law requires (in accordance with the Certificate of Conformance) the owners of the Baker Universal Model 2000 and BU Model digital scales to display a sign that states: "For Prescription Weighing Only." Additionally, the **BU Model 2010** digital scale must display the following: "The counting feature is not legal for trade." These special application and restricted use markings are required to be attached on the front of the scales near the weight display.

Please advise your licensees of this notice, in order that they meet these requirements prior to a visit by a bureau investigator.



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