‘Therapeutic Substitution’ by Pharmacists in Arizona Is Not Permissible Unless Acting Under a Specific Formulary Authorized by an Appropriately Designated Committee of Medical Staff

The Arizona State Board of Pharmacy office has been receiving inquiries regarding “therapeutic substitution” by long-term care facilities (LTCF) and assisted living facilities in Arizona. The definition of the term therapeutic substitution for the purpose of this Newsletter article is:

Therapeutic substitution is defined as pharmacist dispensing of a drug that is therapeutically equivalent to but chemically different from the drug prescribed by a physician or other authorized prescriber. Although usually of the same pharmacologic class, drugs appropriate for therapeutic substitution may differ in chemistry or pharmacokinetic properties, and may possess different mechanism of action, adverse-reaction, toxicity, and drug interaction profiles. In most cases, the substituted drugs have close similarity in efficacy and safety profiles.

A pharmacist contemplating such a therapeutic substitution pursuant to a request from a LTCF or assisted living facility would be wise to review the Arizona Pharmacy Act and Board Rules, available at www.azpharmacy.gov/rules_and_statutes/default.asp.

The term is not defined in the act or the rules and there are no statutes or rules authorizing it. The practice is therefore not permissible in Arizona unless occurring in hospitals or health maintenance organizations (HMOs) authorized by a committee of the hospital or HMO medical staff at this time.

The reasons for the prohibition are many, but center on the fact that lacking a specific formulary approved by an authorized committee of medical staff, the practice is essentially independent prescribing by the pharmacist, which is not authorized in Arizona. If the Board, interested stakeholders, or the legislature desire to expand the practice of therapeutic substitution beyond that described above the following should be considered:

a. Therapeutic substitution may be appropriate in institutional and ambulatory settings that have a functioning formulary system and Pharmacy and Therapeutics Committee or equivalent drug use policy setting bodies.

b. Therapeutic substitution, as defined herein, may be executed by pharmacists when prescribers have been advised of the policy set forth by the appropriately authorized committee or its equivalent. Prescribers should be notified within a reasonable time frame through written, oral, or electronic communication. Use of technology to aid in managing the therapeutic substitution policy is highly desirable.

c. The professional staff including prescribers and pharmacists should be educated regarding the policies, procedures, objectives, and rationale for therapeutic substitution.

d. The policies should include provisions for disclosure of therapeutic substitution policies to patients as appropriate to the setting in which therapeutic substitution will occur.

e. Therapeutic substitution policies should include a mechanism that permits exceptions to the policy and procedures when necessary and/or appropriate.

New Board Member

William H. Francis, MBA, RPh, a 1979 graduate of the University of Arizona College of Pharmacy, was appointed to the Board by Governor Jan Brewer on March 16, 2012, to a five-year term. Mr Francis is currently the director of pharmacy for the University of Arizona Health Plans (UAHP) and responsible for the development and oversight of the UAHP pharmacy programs, including clinical pharmacy support for medical management, Pharmacy and Therapeutics Committee, prior authorization guideline development, budget development and cost management, delegation oversight of external vendors, regulatory compliance and accreditation requirements, and management and partnering with other internal departments to fulfill the UAHP mission. Mr Francis also serves on the Legislative Committee of the Academy of Managed Care Pharmacy. He has an extensive background as a community pharmacist in Arizona, including stints at Eckerd Drug and Fry’s pharmacies.

Physician Assistant Prescribing

Chapter 26, Arizona Revised Statutes §32-2532 (B), requires that all prescription orders issued by a physician assistant (PA) shall contain the name, address, and telephone number of the supervising physician. A PA shall issue prescription orders for controlled substances under the PA’s own Drug Enforcement Administration registration number.

When a pharmacist is presented a noncompliant prescription, one that is missing some or all of the required information, especially if it is late on a Saturday night or early on Sunday morning, a pharmacist must utilize professional judgment before determining to dispense the prescription or not dispense it. If the medication is for an acute illness, a pharmacist may elect to fill the prescription and obtain the missing information from the Arizona Medical Board’s “Doctor Search” Web page at the link www.azmd.gov/GLSPages/DoctorSearch.aspx or from the PA later. This practice decision needs to be consistent with providing good pharmaceutical care by the pharmacist, a health care provider.

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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, 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 sending warning letters are available on the FDA Web site at 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. 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.

Recently, ISMP has been receiving many reports from consumers who report the pharmacy “shorted them” on a variety of opioid prescriptions. 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.

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. Abbott advises that anyone who has the counterfeit ver-
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. 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. Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARxE® Web site at 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 AWARxE® Web site at www.awarerx.org/OTCMedUse.php. The AWARxE consumer protection program and the National Association of Boards of Pharmacy® (NABP®) 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 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.
If there is potential harm to the patient by dispensing the prescription without first obtaining the required information, in the pharmacist’s opinion, then the prescription should not be filled.

It is not the responsibility of the pharmacist to “enforce” the PA statute but it would be prudent for the pharmacy’s ancillary staff to inform the Medical Board of the PA’s noncompliance as soon as practicable.

Lastly, please note that the Medical Board Web page function is called “Doctor Search” when in fact the function provides lookup information for medical doctors, doctors of osteopathy, and PAs. As we all know a PA is not a doctor, but the term has been used for this function by the Medical Board Web page since its inception at least 15 years ago. All prescription labels should have the correct title of the actual prescriber on the label, not the general term “doctor” or “Dr” when the prescriber is not a doctor, but a mid-level practitioner such as a PA or nurse practitioner.

**Notice**

Arizona House of Representatives Bill Number 2263 passed the legislature, was signed by the governor, and becomes effective January 1, 2013. The bill requires retailers to track the sales of listed methamphetamine precursors electronically with certain exceptions. Retailers in Arizona will be receiving further information from the Board of Pharmacy and Appriss Inc, the vendor providing the system for reporting, over the next few months. You may contact Appriss at AZNPLEx@appriss.com or 855/506-7359 for more information.

**Disciplinary Actions**

**Pharmacists**


Duncan, William (S014750) – Suspension of license for six months, effective December 20, 2011; followed by five-year probation; Pharmacists Assisting Pharmacists of Arizona contract; cannot serve as preceptor or pharmacist-in-charge while suspended or on probation; 400 hours of community service. Effective March 16, 2012.


Weston, Robert (S014326) – $1,000 civil penalty and six additional hours of continuing education credits due within 90 days. Effective March 15, 2012.

**Pharmacies**

Holiday Rx (Y005095) – Consent Agreement for one-year probation; within 30 days of consent’s effective date, must establish and implement a compliance program, to be approved by the Arizona State Board of Pharmacy and the monitor. Effective March 21, 2012.

**Disciplinary Updates and Other Actions – Other Boards**

**Arizona Medical Board (MDs)**

Benitez, Marie (MD 30014) – Non-Disciplinary – Consent Agreement for Practice Limitation – Physician’s practice is limited in that she shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective May 21, 2012.

Eisenberg, James W. (MD 40512) – Consent Agreement for Degree of Censure and Practice Restriction – Respondent is prohibited from prescribing, administering, or dispensing any controlled substances for a period of five years. Effective April 4, 2012.

Hinson, Christopher S. (MD 44464) – License surrendered to the Board. Effective April 4, 2012.

Holden, Paul K. (MD 43170) – Non-Disciplinary – Interim Consent Agreement for Practice Limitation – Physician’s practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective May 23, 2012.


Shotton, Rodney K. (MD 11139) – Non-Disciplinary – Consent Agreement for Practice Limitation – Physician’s practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective May 14, 2012.

Slaski, Andrzej (AKA Slaski, Andrew J.) (MD 6972) – Interim Consent Agreement for Practice Restriction – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective March 12, 2012.

Zerrudo, Chito D. (MD 28313) – Non-Disciplinary – Interim Consent Agreement for Practice Limitation – Physician’s practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective March 26, 2012.

**Arizona Board of Osteopathic Examiners (DOs)**

Sansom, Donald (DO 2995) – Interim Consent Agreement for Practice Restriction – Respondent is restricted from practicing medicine until the investigation in Case No. DO-12-0065A is completed and he appears before the Board of Osteopathic Examiners for resolution. Effective May 17, 2012.

**Arizona Board of Dental Examiners (DDSs, DMDs)**

Cook, Kelly J. (DDS 04037) – Case No. 270064 – Officially adjudicated; Monitored Aftercare Treatment Program (MATP) completed. Effective April 16, 2012.

Dodd, Michael W. (DDS 05063) – Case No. 280303 – Amended Stipulation Agreement – Dr Dodd’s prescribing privileges are no longer restricted and he is eligible to apply for a license through the Drug Enforcement Administration. Effective June 4, 2012.


**Arizona State Board of Nursing (NPs)**

Newmoon, Elaine Marie (RN 064934; AP 1516) – Decree of censure against respondent’s registered nurse license RN064934 and advanced practice certificate AP1516 and acceptance of voluntary surrender of respondent’s advanced practice certificate AP1516. Effective March 27, 2012.