



Missouri Board of Pharmacy

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New Medication Therapy Services Rules

In 2007, the Missouri legislature amended [§338.010](#) of the Revised Statutes of Missouri to grant Missouri pharmacists authority to perform “medication therapy services” after obtaining a **certificate of medication therapeutic plan authority** issued by the Missouri Board of Pharmacy. The Board’s rules implementing the new provisions will become effective on August 31, 2012. A [Q&A](#) has been posted on the Board’s Web site with detailed information on the new **certificate of medication therapeutic plan authority**. The following excerpts from the [Q&A](#) are provided for informational purposes:

1. What are “medication therapy services” (MTS)?

Pending rule [20 CSR 2220-6.060\(1\)\(F\)](#) defines “medication therapy services” as “the designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has **authority to initiate or implement a modification of the patient’s medication therapy or device usage pursuant to a medication therapy protocol.**”

2. Is MTS the same as Medication Therapy Management (MTM)?

No. As commonly defined, MTM includes a group of pharmacist provided services designed to optimize patient therapeutic outcomes. “Medication therapy services” as used in [§338.010](#), RSMo, refers to those medication therapy management services performed by pharmacists who have authority to initiate or modify a patient’s drug/device therapy.

4. What do I need in order to perform medication therapy services?

Pharmacists must hold a certificate of medication therapeutic authority (MT certificate) issued by the Board. [The MTS certificate application fee is \$50.]

5. What are the requirements for a MTS certificate?

Pharmacists must have a current and active Missouri pharmacist license and must hold, or have completed, **one of the following:**

A PharmD degree from an ACPE [Accreditation Council for Pharmacy Education] accredited school; OR

A post-graduate medication therapy certificate course or program accredited or granted by the ACPE, American Society of Health-System Pharmacists [ASHP], American Society of Consultant Pharmacists [ASCP], or the American Pharmacists Association [APhA]; OR

A current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; OR

A qualifying post-graduate medication therapy certificate course.

8. Do I need a certificate to counsel patients or for Medicare Part D MTM services?

No. Under [§338.010](#), these activities are within the scope of the practice of pharmacy and can be performed by any Missouri licensed pharmacist. A MTS certificate is only required if a pharmacist is engaged in or has authority to initiate or modify drug/device therapy through a protocol with a physician.

14. Will I need to take additional courses/training if I have a bachelors degree in pharmacy?

Possibly. To qualify for a MT certificate, [§338.010.7](#) requires additional post-graduate training after a bachelors degree in pharmacy. Additional training may not be needed if you’ve already completed a certificate course/training program designated in [20 CSR 2220-6.070](#) or if you hold any of the certifications identified in the pending rule.

16. Why is the Board treating pharmacists with a bachelors degree differently?

The 2007 legislation specifically included language that requires post-graduate training beyond a bachelors degree to qualify for a MT certificate. The language was not proposed by the Board and can only be changed through the legislative process. The Board is in the process of reviewing legislative options and will notify licensees of any changes.

17. Can I use a medication therapy course that I’ve already taken?

Yes, previously taken courses that comply with the rule may be used.

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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 sent 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 pre-

scriptions. 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-



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sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at www.safemedicines.org/resources-for-healthcare-professionals.html. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

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 AWARE_xE[®] 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 AWARE_xE Web site at www.awarerx.org/OTCMedUse.php. The AWARE_xE 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.

20. Are there any courses available now?

Information regarding ACPE, ASHP, ASCP, or APhA courses/programs can be found via an online search. Additionally, several Missouri organizations have expressed an interest in developing alternative certificate courses/programs. The Board may post additional information on available courses on its website in the future.

21. When will the Board start issuing MTS certificates?

The Board will begin issuing certificates on August 30th. Applications are available online now at <http://pr.mo.gov/pharmacists-forms.asp>.

Quick MTS Facts

- ◆ An MTS certificate from the Board is required to initiate, alter, or modify medication therapy.
- ◆ Pharmacists with an MTS certificate can only perform MTS services under a protocol with a Missouri licensed physician.
- ◆ Pharmacists cannot initiate, alter, or modify any controlled substance prescription.
- ◆ Pharmacists **cannot diagnose** or perform any activity that might be deemed the practice of medicine. Only a duly licensed physician may practice medicine as defined by Missouri law.

The information provided herein does not constitute a rule statement of general applicability or binding law. In the event of a conflict or inconsistency, duly promulgated or enacted state or federal law shall control. Licensees should review the full text of the pending rules in their entirety to ensure compliance.

Upcoming Webinars

◆ 2012 Legislative & Regulatory Update

August 23, 2012 – 11 AM to 1 PM (Board approved for 2.0 hours of Missouri pharmacist continuing education (CE) credit). *Space is limited, register on the Board's [Web site](#) now!*

Board Statement on Compounding Hydroxyprogesterone Caproate

On June 15, 2012, Food and Drug Administration (FDA) issued a [statement](#) indicating it will apply its normal enforcement policies for pharmacies compounding hydroxyprogesterone caproate. In line with the FDA's statement, licensees are reminded that 20 CSR 2220-2.200(9) provides:

Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal [Food and] Drug Administration (FDA) approved drug products is **prohibited**. There shall be sufficient documentation within the prescription record of the pharmacy of the **specific medical need** for a particular variation of a commercially available compound.

Accordingly, licensees must have sufficient documentation of a **specific medical need** prior to compounding hydroxyprogesterone caproate in the future.

Continuing Education Reminder

Pharmacist renewals were mailed on August 1, 2012. **Remember:** To renew, pharmacists must have **completed 30 hours of CE between September 1, 2010 and August 31, 2012**. Do not wait, finish your CE now!

Disciplinary Action

Pharmacists

Connie M. Becker, #029549 – Adrian, MO – May 22, 2012. Probation for five (5) years. Alcohol dependent, misappropriated controlled substances from employer. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Steven M. Gullette, #2012011936 – St Louis, MO – April 13, 2012. Pharmacist license issued on probation until November 22, 2014. Previous discipline on intern license due to admitted theft of controlled substances from employer, impaired. Section 338.055.2(1), (2), (8), (15), and (17), RSMo.

Shirley M. Kribbs, #042296 – Clifton Hill, MO – June 2, 2012. Public censure. Administered vaccinations prior to signing a protocol; administration violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

John T. Markovich, #040853 – Slater, MO – June 2, 2012. Public censure. As pharmacist-in-charge, administration of vaccines violations; provided vaccination that was not pursuant to a valid order by a prescriber; and adulteration and misbranding. Section 338.055.2(5), (6), (13), and (15), RSMo.

Anthony Owens, #2000148345 – Joplin, MO – July 10, 2012. Suspension for thirty (30) days followed by probation for five (5) years. Possessed and consumed illegal drugs. Section 338.055.2(1), (5), (13), (15), and (17), RSMo.

Kerri L. Pomaville, #2006035339 – Mesa, AZ – June 2, 2012. Probation for five (5) years. While pharmacist-in-charge, took prescriptions, including controlled substances, from employer without first paying for them and without following proper release procedures. Section 338.055.2(5), (6), and (13), RSMo.

Pharmacies

CVS Pharmacy #5645, #2009008060 – St Joseph, MO – May 22, 2012. Probation for two (2) years. Technician diversion/theft of controlled substances from pharmacy, did not provide adequate security of controlled substances. Section 338.055.2(6) and (15), RSMo.

Sac-Osage Hospital, #004315 – Osceola, MO – May 22, 2012. Public censure. Technician dispensing with no pharmacist on duty. Section 338.055.2(5), (6), (13), and (15), RSMo.

Drug Distributors

Strong Direct, Inc, #2012003608 – St Louis, MO – May 16, 2012. Drug distributor license issued on probation for four (4) years. Operated with an expired license. Section 338.055.2(6), RSMo.