

by Tom Engels, PSW Vice President of Public Affairs

At the request of our readers, JPSW will periodically publish answers to questions that have been submitted to the Pharmacy Examining Board. We acknowledge the assistance of Attorney William Black, legal counsel to the PEB. Please submit any questions or suggestions regarding this feature directly to the Pharmacy Examining Board at the Wisconsin Department of Regulation and Licensing, 1400 E. Washington Avenue, PO Box 8935, Madison, WI 53708; dorl@mail.state.wi.us.

H NCPDP makes the statement: "Throughout the health care industry electronic prescribing (e-Prescribing) is defined in numerous ways. Some consider e-prescribing to be the use of a PDA or computer to produce a printable prescription that is then given to the patient. Others think of it as the two-way communication of new prescriptions and renewal requests between the prescriber and the pharmacy. Still others define e-Prescribing as being the provision of formulary information, drug reference information and patient medication history in an electronic format during the prescribing process."

If a clinic or medical facility uses Tablet computers to supply physicians with drug reference information, common doses and frequencies associated with the medication, and patient medication history during the prescribing process, can they also use those Tablet computers to produce a printable prescription that can be given to a patient?

Please review Wis. Admin. Code § Phar 7.08(1). The transmission must arrive at the pharmacy electronically to be an electronic transmission.

If the practitioner prints it and hands it to the patient, it is a written order, and must be manually signed to be valid.

I have a licensed pharmacy in a nursing home. Our patients often get eye drops from outside ophthalmologists when having procedures done. I know that we are required to have medications labeled on the units. We in the

pharmacy cannot label the eye drops as if they are coming from our pharmacy. My question is would it be acceptable for the pharmacy to print a label and remove or cut off all of the information that identifies our pharmacy, leaving only the name of the patient, name of the patient's physician, name of the medication and directions for administration? The pharmacy name, RX number and pharmacist initials are removed.

If the medication was previously dispensed by the physician, which it appears to be, the physician should have labeled it. The physician must comply with MED 17, otherwise it makes the pharmacist's job tougher.

Assuming it isn't labeled, yes the pharmacist could have a collaborative agreement to label on behalf of the physician, but note, the pharmacist takes on risk to insure it is labeled correctly. The pharmacist would absolutely need sufficient information from the physician to comply with labeling requirements of MED 17.

If this information can't be obtained, depending on the drug at issue, I would be reticent to advise that the pharmacist merely label as a consumer service. It is not pharmacy dispensing, it is incomplete physician dispensing and the pharmacist is being asked to meet patient need by supplying information that should have been provided by the physician but wasn't.

The PEB has addressed this issue to some degree in the instance of repackaging to meet patient need. The pharmacist takes on risk by creating an "informational" label, without the information needed to make it correctly labeled.

So the collaborative agreement and protocol is the wiser course in this scenario. ●

New OTC Labeling Requirements

The Food and Drug Administration has issued new labeling requirements for OTC products containing calcium, magnesium, potassium. The following summary of these new requirements was published in the Federal Register on March 24.

The Food and Drug Administration (FDA) is amending the general labeling provisions for over-the-counter (OTC) drug products to require that the labeling of all OTC drug products intended for oral ingestion include: The calcium content per dosage unit when the product contains 20 milligrams (mg) or more per single dose; a warning statement that persons with kidney stones and persons on a calcium-restricted diet should ask a doctor before using when the product contains more than 3.2 grams (g) of calcium in the labeled maximum daily dose; the magnesium content per dosage unit when the product contains 8 mg or more per single dose; a warning statement that persons with kidney disease and persons on a magnesium-restricted diet should ask a doctor before using if the product contains more than 600 mg magnesium in the labeled maximum daily dose; the potassium content per dosage unit when the product contains 5 mg or more per single dose; and a warning statement that persons with kidney disease and persons on a potassium restricted diet should ask a doctor before using if the product contains more than 975 mg potassium in the labeled maximum daily dose. FDA is issuing this final rule in order to provide uniform calcium, magnesium, and potassium content and warning labeling for all OTC drug products intended for oral ingestion whether marketed under an OTC drug monograph, the ongoing OTC drug review, a new drug application (NDA) or abbreviated new drug application (ANDA), or no application.

This final rule is effective April 23, 2004.