



American Pharmaceutical Services

An Omnicare Company
9210 Cameron Road Suite 800
Austin, TX 78754
512-928-8282

January 29, 2013

Gay Dodson, Executive Director
Texas State Board of Pharmacy
333 Guadalupe, Ste 3-600
Austin, TX 78701

RE: Substitution of Drug Product Dosage Forms – Proposal

Dear Ms. Dodson,

Omnicare proposes the Texas State Board of Pharmacy clarify, interpret, or (if necessary) support amending Texas Statute or Texas Administrative Code. Specifically, we propose that pharmacies and pharmacists be exempt from patient consent and prescriber notification when changing a medication dosage form to another dosage form that contains the identical amount of active ingredients as the dosage prescribed for the patient.

Although contrary to current law, a licensed pharmacist could safely exercise professional judgment to change medication dosage form with the same active chemical ingredients and strength as the prescribed medication (e.g. a change from Amoxicillin capsule to Amoxicillin suspension) without patient consent or prescriber notification. This proposed practice would streamline care, limit unnecessary provider communication, and enhance patient compliance by using more appropriate medication delivery methods.

At present, pharmacists routinely request and notify prescribers before changing oral solid dosages to liquid solutions for nursing home residents who cannot swallow capsules or tablets. Compounding this issue, nursing home patients may not be able to provide consent due to cognitive impairment. In extreme circumstances, obtaining consent is virtually impossible if a patient is legally incapacitated. Residents placed on feeding tubes require a “top-down” change in medication delivery methods, which necessitates consent and notification resulting in unnecessary medication delay. These are a just a few scenarios where a proposed change in the practice would result in streamlined care and reduced delay and administrative burden on pharmacists, prescribers, and patients without altering the desired clinical outcome.

Omnicare still suggests prohibiting changes in dosage form when the physician states orally, electronically, or in his/her own handwriting “Do not substitute.” Also, it is our intention that this proposal would not apply to substitution of enteric-coated or time release products.

Thank you for your consideration regarding this matter. If requested, Omnicare can provide more information or insight into these concerns. Please contact me at the above number if you have any questions.

Respectfully,

Roberta Halverson, RPh, CGP
Omnicare Texas State Board of Pharmacy Liaison