

Jim Doyle
Governor

Celia M. Jackson
Secretary

**WISCONSIN DEPARTMENT OF
REGULATION & LICENSING**



1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@drl.state.wi.us
Voice: 608-266-2112
FAX: 608-267-0644
TTY: 608-267-2416

Joint Public Hearing
Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief, and Revenue
And
Assembly Committee on Public Health
Senator Jon Erpenbach and Representative Chuck Benedict, Chairs

Statement of Greg Weber, M.S., R.Ph., Wisconsin Pharmacy Examining Board
SB 354 and AB 506: Substitutions by Pharmacists Dispensing Epilepsy Drugs

Room 412 East, State Capitol, Thursday, October 22, 2009, 1 P.M.

Senator Erpenbach, Representative Benedict, and Committee members, my name is Greg Weber. I serve as chair of the Wisconsin Pharmacy Examining Board. Thank you for the opportunity to provide this statement on behalf of the Board. The Board is opposed to SB 354 and AB 506. As noted by the Legislative Reference Bureau, under current Wisconsin law a pharmacist may not substitute a drug product equivalent if a prescription indicates that no such substitution may be made (by the prescribing practitioner).

In a January 11, 2008 letter to the Iowa Pharmacy Association, Gary Buehler, R.Ph., Director of the Food and Drug Administration's Office of Generic Drugs made the following statements:

"FDA is aware that certain individuals and groups have expressed particular concern about the switching of anti-epileptic drug products. To date, we have no scientific evidence that demonstrates a particular problem with this group of products. Further, there are frequently circumstances other than the switch that may cause untoward responses. We continue to follow-up such reports and interact with those concerned."

"If FDA has determined a generic to be therapeutically equivalent to the innovator product, FDA continues to believe that it is not necessary for the healthcare provider to approach any one therapeutic class of drug products differently from any other class when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration."

In summary, the Wisconsin Pharmacy Examining Board opposes SB 354 and AB 506 for the following reasons:

1. Current Wisconsin law requires pharmacists to dispense a therapeutically equivalent generic prescription drug if it is lower in cost (Wis. Stats. 450.13 (1)).
2. Current Wisconsin law allows prescribing practitioners to prohibit pharmacists from substituting drug product equivalents (generics) (Wis. Stats. 450.13 (2)).
3. As of January 2008, the FDA has no scientific evidence that there are problems with anti-epileptic drug products and their therapeutic equivalents.
4. If enacted, this legislation will result in higher health care costs for patients, employers, insurers, state and federal government.

Thank you for the opportunity to submit this statement of opposition.



State of Wisconsin
Department of Health Services

Jim Doyle, Governor
Karen E. Timberlake, Secretary

Joint Hearing of the Senate Committee on Health, Health Insurance, Privacy, Property Tax Relief and Revenue and the Assembly Committee on Public Health

Thursday, October 22, 2009
AB 506 and SB 354

Wisconsin Department of Health Services
Rachel Currans-Sheehan, Legislative Liaison
Lynn Radmer, Pharmacist, Division of Health Care Access and Accountability

Chairman Erpenbach, Chairman Benedict, thank you for the opportunity to provide written informational testimony on SB 354 and AB 506.

As the state health agency, we agree with the authors that persons should have access to necessary medications to best manage their care. If there is a medical need for a specific drug to manage epilepsy, then it is important for that person to have access to that medication. Thus said, we do believe that current mechanisms are in place that allows this to occur.

For example, current dispensing regulations allow for a physician to prescribe a brand name medication when a generic equivalent is available by writing "Brand Medically Necessary" on the prescription. The physician is best positioned to work with individuals who may be extremely sensitive to medication changes. Therefore, the physician who is ordering labs and monitoring the patient is best positioned to assess whether a substitution is risky.

If the patient is on BadgerCare Plus or SeniorCare, and the physician determines that due to the seizures or other medical complications the patient's care would be best managed by brand name prescriptions, then they can receive a Prior Authorization to approve use of the brand-name medication by demonstrating the medical necessity of a brand drug.

The medications in question can be used for many other diseases beyond epilepsy. Since the physician does not indicate the disease on the prescription, there is no way for the pharmacy to know which drugs they can substitute and which ones they cannot. Therefore, the default would be that the pharmacist would need to consult with physician and patient or patient's agent before substituting generic equivalents regardless of the disease they are treating.

The bill prohibits substitution of a drug equivalent product *unless the pharmacist obtains consent of the prescribing practitioner and the patient or patient's agent*. We realize that the notification of a physician, patient or patient's agent does not mean that in all cases pharmacists will fill brand-name only medication. However, we do believe that there would be *less generic substitution* with this bill which would result in a fiscal impact on the Medicaid program.

DHS has not completed a fiscal estimate for this bill. Estimates from LFB from the 2008 session indicate there is potential for increased Medicaid and SeniorCare costs. These costs represent cost-savings Medicaid would no longer realize through the use of generic drugs once the brand-name drugs go "off-patent" in the future.