



Epilepsy and Seizure Patient Safety Initiative

Requiring both the patient and prescribing physician to approve a substitution by a pharmacist of any epilepsy or seizure drug.

Questions & Answers

Q: Does the bill promotes name brand AEDs over generics?

A: This bill does not promote name brands over generics. It promotes people with epilepsy and seizure disorders getting the same formulation of the medicine that is working for them. If that medication is a name brand, then they will avoid the high cost of therapy failure by paying a little more for medication. If they are doing well on a generic, they should continue to receive the same generic formulation from the same manufacturer that has been controlling their seizures. Before ANY substitution of any kind takes place at the pharmacy, we'd like patients and their prescribing physicians to consent, so those patients can be monitored for adverse incidents.

Q: If the FDA says it's bioequivalent, isn't it bioequivalent?

A: According to the FDA, two formulations of the same drug are considered bioequivalent if the ratio of the average amount of drug absorbed to the rate of absorption is within 80-125% with 90% assurance. Because two formulations of the same medication are bioequivalent does not mean they are therapeutically equivalent. For most conditions, this difference may not be meaningful, but for epilepsy patients small changes in therapeutic equivalence could result in a breakthrough seizure or in toxic side effects.

Drug 1 could be on the low end of the equivalence scale, leading to low medication levels and a breakthrough seizure. Drug 2 might be right in the middle of the scale without any noticeable difference. Drug 3 could be on the high end of the scale and result in unwanted side effects like slurred speech, stumbling gait, or double vision.

Q: Dispense as written (DAW) already takes care of the problem.

A: Dispense as written instructions from your doctor helps prevent brand name to generic substitutions but it doesn't cover generic to generic switches. If doctors are only allowed to use current dispense as written rules, they would have to write more prescriptions for name brands to insure continuous, consistent dispensing of the same formulation. People with epilepsy would be discouraged from taking advantage of cost-saving generics, even though they might tolerate them well.

Q: Will doctors need to put diagnoses on scripts because some AEDs have off-label uses?

A: This would violate patient confidentiality. The pharmacist merely has to say, “if you’re taking this for epilepsy I’ll need to call your doctor.” The patient can volunteer, “That’s not what I take it for.” They don’t have to disclose what they are taking it for if they don’t want to.

If a State allows electronic transmission of dispense as written prescriptions, electronic consent should be allowable. If a State requires hand-written dispense as written orders, then signed consent may also be required.

Q: Will this legislation raise the cost of medicines?

A: This legislation will allow patients with epilepsy to feel safer switching to generic formulations because they know they will have a chance to consult with their physician if their usual generic is no longer available.

Q: Will patients have to wait for their medications while pharmacists make phone calls?

A: Pharmacists already maintain contact with doctors whenever they have questions about prescriptions. Doctors will not mind getting calls if it insures their patients will maintain appropriate blood levels and remain seizure free.

Q: Will other health conditions want the same informed consent?

A: No other therapy failure includes anything as sudden and drastic as a breakthrough seizure. Breakthrough seizures result in unnecessary ambulance rides, emergency room visits, lost wages, and even a compromised ability to stay on the job. People experiencing breakthrough seizures must surrender their driving privilege even if they can prove the seizure was caused by an inadvertent switch in the medication they received.

Q: Does this bill question the professionalism and quality care that pharmacists provide?

A: This bill recognizes that pharmacists play a critical role for the patient with epilepsy. It promotes a pharmacy “best practice” and enlists the pharmacist as an integral partner in therapy maintenance and patient education.