HCR 198 of the 2008 Legislature requested the Board to convene its Regulation Revision Committee to consider changes to the rules and regulations of the Board to expressly prohibit a pharmacist from interchanging an antiepileptic drug or a formulation of an antiepileptic drug for the treatment of epilepsy without the prior notification of both the prescribing physician and the patient. The resolution further directed the Board to specifically solicit the advice, input, and recommendations of several organizations: Board of Medical Examiners, Xavier College of Pharmacy, University of Louisiana at Monroe (ULM) College of Pharmacy, and the Epilepsy Foundation of Louisiana. The resolution also directed the Board to include interested pharmacists, interested physicians, interested neurologists, as well as other interested consumers.

The Board's Regulation Revision Committee met on January 8, 2009. Invitations were extended to the following organizations: Board of Medical Examiners, Xavier College of Pharmacy, ULM College of Pharmacy, Epilepsy Foundation of Louisiana, Louisiana Pharmacists Association, Louisiana State Medical Society, and the Louisiana Neurological Society. In addition, the Board circulated invitations and notices to all consumers and other parties enrolled in the Board's List of Interested Parties. Of the invited organizations, only the Epilepsy Foundation of Louisiana sent a representative to the meeting. There were several consumers in attendance.

The committee chair opened the meeting by acknowledging receipt of several written communications from other interested parties, including the Orleans Parish Medical Society, American Academy of Neurology, and the National Epilepsy Foundation. All of the written communications, as well as the comments offered during the meeting, encouraged the Board to require prior notification of both the prescriber and the patient prior to permitting a pharmacist to substitute an antiepileptic drug.

The committee then reviewed its current law and rule relative to the dispensing procedures for generic substitution. The committee noted the law and rule are applicable to all prescriptions, regardless of the medication ordered. When a prescriber orders a medication, part of the prescription includes the instruction to the pharmacist as to whether or not substitution is permitted. When the prescriber instructs the pharmacist to "Dispense as Written" (or "DAW"), then the pharmacist shall dispense what is written and nothing else. Even if the patient were to request a generic substitute, the pharmacist may not grant that request, unless the patient contacts the prescriber and obtains another order that permits generic substitution. When the prescriber does not restrict the pharmacist to "Dispense as Written" (or "DAW"), then the pharmacist may select a generic substitute, but only if the patient is aware of – and consents to – the proposed cost-saving substitution. Thus, the current law and rule for generic substitution require not only notification – but approval – of both the prescriber and the patient. The committee noted the current law and rule are more stringent than the requirements suggested by the legislative resolution, not just for antiepileptic drugs but for all drugs dispensed on prescriptions.

During the committee meeting, one participant suggested that some prescribers may not be aware of the DAW instruction to pharmacists. Several participants suggested that some pharmacists may not be aware of the proper dispensing procedures relative to generic substitution. The committee agreed that education and enforcement of the current law and rule relative to generic substitution were the most appropriate remedies.

The committee reported on its deliberations to the full Board during its February 11, 2009 meeting. Following substantial discussion, the Board made the following ***findings***:

1. The current language of the pharmacy law and rules exceed the requirements requested by the legislative resolution.
2. Stakeholder input has identified educational opportunities to ensure prescribers are familiar with proper prescribing procedures.

3. Stakeholder input has identified educational opportunities to sure pharmacists are familiar with proper dispensing procedures.
4. The number of complaints received by the Board does not appear to correlate with the number of anecdotal reports offered at the committee hearing.
5. Stakeholder input has identified educational opportunities to ensure consumers are aware of how to file complaints against pharmacies and pharmacists.

By consensus, the Board then made the following ***recommendations***:

1. Engage in collaborative efforts with prescribers to ensure their understanding of proper prescribing procedures.
2. Engage in additional educational efforts with pharmacists to ensure their understanding of proper generic substitution procedures.
3. Engage in collaborative efforts with the Epilepsy Foundation of Louisiana and other consumers to ensure their understanding of the requirements for generic substitution and how to file complaints against pharmacies and pharmacists for alleged violation of those requirements.
4. To make no changes in the requirements for generic substitution at this time.

Respectfully submitted,
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