

MedChi

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TO: The Honorable Joan Carter Conway, Chairman
Members, Education, Health and Environmental Affairs Committee

FROM: Danna Kauffman
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DATE: March 5, 2015

RE: **SUPPORT WITH AMENDMENT** – Senate Bill 537 – *Pharmacists - Substitution and Dispensing - Interchangeable Biological Products*

The Maryland State Medical Society (MedChi), which represents over 7,500 Maryland physicians and their patients, supports with amendment Senate Bill 537.

Senate Bill 537 will authorize a pharmacist to substitute a biological product with an interchangeable biologic product approved by the Federal Drug Administration (FDA). A biological product is a drug which is made from living cells to produce proteins that can be used to treat disease. These products consist of large and highly complex molecules and are more physically complex than chemical drugs. Such biologics treat serious medical conditions including cancers, immune system disorders, diabetes and neurological disease.

Interchangeable biologic products are “similar” but not identical to biologics. A biological product may be demonstrated to be interchangeable if data show that, among other things, the product is “highly similar” to an already-approved biological product and meets the FDA’s standards of safety and efficacy. While the FDA has the authority to approve interchangeable biologic products, individual states must determine the rules pertaining to such substitutions, and Senate Bill 537 is a much needed codification of such rules.

Senate Bill 537 has three principal features. First, it applies the same substitution rules to interchangeable products as generics, preserving the authority of a physician to continue to require a pharmacist to dispense “as written,” if necessary. Second, it requires the patient to be “notified” that he or she has received an approved interchangeable biologic product. Third, and most importantly from MedChi’s point of view, the prescriber will be notified of the substitution so that the prescriber’s medical record will reflect the interchangeable biologic product dispensed. However, on

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this provision, the bill states that notification to the prescriber must be done within a reasonable time, not to exceed ten days. MedChi believes that this notification timeframe should be shortened. While MedChi strongly supports the notification when a substitution is made, it questions the need for notification to occur when the pharmacy has dispensed a biologic as prescribed, without substitution. MedChi believes that this provision should be amended to simply allow notification on a substitution.

Therefore, MedChi believes that Senate Bill 537 is a necessary framework to update Maryland's pharmacy law for the coming generation of interchangeable biologic products. MedChi would urge a favorable report on Senate Bill 537, recognizing the need to reduce the notification timeframe to the prescriber.

For more information call:

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