

MedChi

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

FROM: Danna L. Kauffman
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J. Steven Wise

DATE: March 9, 2017

RE: **SUPPORT** – Senate Bill 997 – *Pharmacists – Substitution and Dispensing of Biological Products*

The Maryland State Medical Society (MedChi), which represents more than 7,000 Maryland physicians and their patients, **supports** Senate Bill 997.

Senate Bill 997 will authorize a pharmacist to substitute a biological product with an interchangeable biologic product approved by the U.S. Food and 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 biological product” means a biological product that is (1) licensed and determined by the FDA to meet the standards for interchangeability under federal law; or (2) determined to be therapeutically equivalent under FDA’s current list of approved drug products with therapeutic equivalence evaluations (the “Orange Book”).

Senate Bill 997 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 within five business days of the substitution so that the prescriber’s medical record will reflect the interchangeable biologic product dispensed.

Therefore, MedChi believes that Senate Bill 997 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 997.

For more information call:

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