

MedChi

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

FROM: Joseph A. Schwartz, III
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J. Steven Wise

DATE: February 27, 2013

RE: **SUPPORT** – Senate Bill 781 – *Pharmacists – Biosimilar Biological Products - Substitutions*

The Maryland State Medical Society (MedChi), which represents over 7,500 Maryland physicians and their patients, supports Senate Bill 781.

Senate Bill 781 will regulate “substitutions” by a pharmacy benefit manager (PBM) or pharmacy of a “biological product” with a “biosimilar product.” A “biological product” is a medicine which is made from living cells to produce proteins that can be used to treat disease. These medicines, referred to as “biologics,” consist of large and highly complex molecules can be thousands of times more physically complex than chemical drugs. Such biologics treat serious medical conditions including cancers, immune system disorders and neurological disease.

“Biosimilars” are “similar” but not identical to biologics. The Federal Food and Drug Administration (FDA) has been given the authority to determine when a “biosimilar” is “interchangeable” with a biologic. It is up to the States to determine the rules pertaining to such substitutions and Senate Bill 781 is a much needed codification of such rules.

Senate Bill 781 has two principal features. First, the patient will be “notified” by the PBM or pharmacy that he or she has received a “biosimilar” (page 5, lines 1-7). Second, and most importantly from MedChi’s point of view, the doctor will be notified of the substitution so that the doctor’s medical record may reflect the exact “biosimilar” which was substituted. In addition, as with normal chemically based medications, a doctor would continue to be allowed to require that the biologic product be dispensed only as directed.

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MedChi believes that Senate Bill 781 is a necessary framework for the coming generation of “biosimilar” medicines made from living cells. The current Maryland pharmacy law needs to be updated before “biosimilars” enter the marketplace in the next few years.

MedChi would urge a favorable report on Senate Bill 781.

For more information call:

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