The League of Life and Health Insurers of Maryland

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The Honorable Pam Beidle
Chair, Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

Senate Bill 393 - Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars

Dear Chair Beidle,

The League of Life and Health Insurers of Maryland, Inc. respectfully opposes ***Senate Bill 393 - Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars*** and urges the committee to give the bill an unfavorable report.

Senate Bill 393 proposes instant market access for FDA approved generics and biosimilars that would create confusion for consumers, provide unfair trade advantages for qualifying pharmaceutical manufactures, and diminish the role medical professionals have in designing formularies.

The FDA approval process does not compare drugs under review for efficacy, medical outcomes, or cost effectiveness against other available products or therapies. Health plans use medical evidence and the expertise of physicians, pharmacists and other medical professionals to make these determinations when establishing their formularies.

Formularies are updated frequently, with Maryland law already requiring that the formulary be posted, such that prospective members and enrollees can search and compare formularies. State law also requires that enrollees be provided with notice of an adverse change to a formulary unless there is a safety concern. This is a workable framework that provides certainty to patients, providers, health plans, and purchasers of health insurance.

The FDA Orange Book is a 2,000-page guide of approved drug products with therapeutic equivalence evaluations. The agency provides daily Electronic Orange Book product information for new generic

drug approvals. If Senate Bill 393 becomes law with its "shall immediately" provision, health plans could be required to instantly add all 32,000 FDA-approved generic drugs to their formularies and update formularies daily without determining if a product is even available to Maryland consumers. As you might imagine, automatically adding 32,000 drugs to a formulary, many of which will add no medical benefit, will also have tremendous cost implications.

The bill also restricts practices carriers use to manage utilization. It also provides manufacturers of FDA approved generics or biosimilars with unfair trade advantages with its limitations on prior authorization, step therapy requirements, and coverage limitations. It also would require plans to make generic or biosimilars available to consumers at a lower out-of-pocket cost to an insured than a brand drug based on a comparison of wholesale acquisition costs. Because net costs negotiated between a plan and manufacturer may be lower than the WAC, this requirement could create an unfair market advantage for a higher cost product.

For these reasons, the League urges the committee to give Senate Bill 393 an unfavorable report.

Very truly yours,

Matthew Celentano
Executive Director

cc: Members, Senate Finance Committee