MAINE ASSOCIATION
OF
HEALTH PLANS

Testimony of Dan Demeritt
Joint Standing Committee on Health Coverage, Insurance, and Financial Services

In Opposition to 2114

An Act to Improve Patient Access to and Savings from Generic Drugs and Biosimilars

Senator Bailey, Representative Perry, and Members of the Joint Standing Committee on Health Coverage, Insurance, and Financial Services:

My name is Dan Demeritt, I am the Executive Director of the Maine Association of Health Plans (MeAHP). Our member plans provide or administer health insurance for 600,000 Mainers. We work as an association to improve the health of Maine people by promoting affordable, safe, and coordinated healthcare.

LD 2114 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 mechanics of the proposal are like giving every Maine teen with a driver's permit a license on their 16th birthday that will be revoked somewhere down an unsafe road if they eventually fail a driver's test.

Prioritize Efficacy, Safety and Affordability

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.

Health insurance carriers are required by Maine law to use Pharmacy and Therapeutics Committees, including physicians and pharmacists, to develop and manage their drug formularies. Maine Law requires P&T Committee members be free of conflicts of interest associated with the pharmaceutical supply chain.[1]

LD 2114 creates an end-around of these protections in Maine Law by requiring carriers to immediately include FDA approved generics and biosimilars on their formularies. The FDA has approved more than 32,000 generic drugs that health plans would immediately have to add to their formularies.

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[1] Title 24-A §4347 and §4350-B

Daily Consumer Confusion

Formularies are updated annually, with Maine law 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 at least 60 days' written notice of an adverse change to a formulary unless there is a safety concern.[2]

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.[3]

If LD 2114 becomes law with its "shall immediately" provision, health plans could be required to instantly add all 32,000 FDA-approved generic drugs[4] to their formularies and update formularies daily without determining if a product is even available to Maine consumers.

Unfair Trade Advantages

The bill 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.

Section 6: Reversal

Like issuing a driver's license and then revoking it after a teen fails their driver's test, LD 2114 first requires coverage and then allows for reversal of the inclusion of the generic or biosimilar in a formulary if a P&T Committee later determines is not medically appropriate or cost-effective.

We are not going to allow teens to be licensed to drive without passing a driver's test. Using the same logic, we should not force health plans to add drugs to their formularies without allowing unbiased experts to conduct a comparative review for medical and cost effectiveness.

We urge the Committee to vote ought not to pass.

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[2] Title 24-A, §4303-20, Information about Prescription Drugs & §4311 (C) Access to Prescription Drugs
[3] https://www.fda.gov/drugs/drug-approvals-and-databases/frequently-asked-questions-orange-book#
[4] https://www.fda.gov/drugs/generic-drugs/office-generic-drugs-2022-annual-report