STATE OF MAINE
DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION
BUREAU OF INSURANCE

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Senator Donna Bailey, Senate Chair
Representative Anne Perry, House Chair
Joint Standing Committee on Health Coverage, Insurance and Financial Services
100 State House Station
Augusta, ME 04333-0100

Re: L.D. 2114, "An Act to Improve Patient Access to and Savings from Generic Drugs and Biosimilars", 131st Second Regular Session

Dear Senator Bailey, Representative Perry, and Members of the Committee:

The Bureau takes no position on L.D. 2114; however, we do have some concerns as explained below. This bill amends the Health Plan Improvement Act in five ways for a carrier providing prescription drug coverage.

Under this bill, carriers must:

- include on their formulary any FDA-approved generic drug or biosimilar that has a lower wholesale acquisition cost than the equivalent brand drug.
- post formulary changes due to adding such generic drugs or biosimilars on its publicly accessible website.
- cover the generic drug or biosimilar at a lower out-of-pocket cost to the insured than the brand drug.

In addition, carriers may not impose:

- prior authorization, step therapy, or other requirements making it more difficult for an insured to obtain the generic drug or biosimilar than the brand drug, or
- any restriction on a pharmacy making it more difficult for an insured to obtain the equivalent generic drug or biosimilar than the brand name drug.

The bill allows – but does not require – routine technical rulemaking for implementation.

As drafted the bill raises a number of concerns for the Bureau. First, the bill's requirements and prohibitions are on the carrier alone. It is unclear whether this would apply to pharmacy benefit managers acting on behalf of the carrier.

Second, it requires carriers to include the generic drug or biosimilar on the formulary "with a lower out-of-pocket cost to the insured," but does not specify the amount of savings required. This could, theoretically, result in a situation where carriers place the generic drug or biosimilar on their formulary at a price just below that of the brand drug, in effect raising the existing price of a generic drug or biosimilar.

Third, part of paragraph 6 is not necessary, and part raises an issue. The paragraph states that the carrier's Pharmacy and Therapeutics (P&T) committees can remove a drug or biosimilar – whether brand or generic – from the formulary if it is "no longer medically appropriate or cost-effective." Carriers' P&T committees can already remove from the formulary drugs which are no longer medically appropriate; new statutory language is not required. Since the prior section allows carriers to drop coverage for a brand drug after an equivalent generic drug or biosimilar is approved by the FDA, it is unclear what the additional cost-effectiveness language in this section references.

Lastly, paragraph 8 needs a quick word fix: since this bill is within Title 24-A, the "department" should be changed to the "superintendent of insurance."

I hope this information is useful to the Committee. Please let me know if I can provide any further assistance.

Sincerely,

Timothy N. Schott
Acting Superintendent