OPLA Bill Analysis
Joint Standing Committee on Health Coverage, Insurance and Financial Services
Legislative Analyst: Colleen McCarthy Reid, Esq.
March 7, 2022

LD 1636, An Act To Reduce Prescription Drug Costs by Using International Pricing

SUMMARY: This bill requires the Superintendent of Insurance to create a list of 250 referenced drugs that are subject to a referenced rate. The referenced rate must be calculated as the lowest cost from official publications of certain Canadian provincial government agencies and the wholesale acquisition cost. Any savings generated as a result must be used to reduce costs to consumers.

The bill would make it unlawful for health insurance carriers to pay more than the referenced rate for a referenced drug, subject to a fine of $1,000 per transaction. The same prohibition and penalty would apply to any state agency (other than Maine Care), to any self-insured ERISA plan that chooses to participate in the reference pricing program, and to any licensed retail pharmacy that buys drugs for sale or distribution to anyone covered by a health plan or program subject to reference pricing.

The bill would also prohibit manufacturers and distributors of a referenced drugs from withdrawing them from sale or distribution in Maine to avoid the effect of reference pricing, or from withdrawing them for any reason without giving 180 days' advance notice, subject to a $500,000 fine for any violation.

TESTIMONY: Written testimony can be found at this link

LD 1636, An Act To Reduce Prescription Drug Costs by Using International Pricing

CURRENT LAW:

Title 5, chapter 168 established the Wholesale Prescription Drug Importation Program to provide for the wholesale importation of prescription drugs from Canada by or on behalf of the State. The program may not be implemented unless the State obtains approval and certification, pursuant to section 2046, subsection 3, from the United States Department of Health and Human Services. Although the State submitted an application in accordance with rules adopted by Maine DHHS and approved by the Legislature, no action has been taken by the United States Department of Health and Human Services.

ISSUES FOR CONSIDERATION:

1. Consider effect of language in bill prohibiting a health insurance carrier, other payer or pharmacy from purchasing a drug at a price exceeding the referenced rate? Concerns raised in testimony about whether the bill might disrupt access to certain medications if a pharmacy cannot obtain drug needed by a consumer at the permitted price and whether coverage for the drug could be required by state and federal law so that a carrier may be forced to violate the bill's requirements and pay more than permitted.

2. Concerns raised in testimony from Healthcare Distribution Alliance about impact of prohibition on withdrawal of drugs for sale in section 8 of proposed Section 2688 on wholesale distributors. If committee moves forward, suggested in testimony that references to "distributors" be removed and language added to ensure that distributors are not penalized for decisions made by manufacturers.

LD 1636, An Act To Reduce Prescription Drug Costs by Using International Pricing

ISSUES FOR CONSIDERATION (cont'd):

3. Concerns raised in testimony about use of Quality Adjusted Life Years (QALYs) in determining prescription drug pricing in Canada as the use of QALYs in determining a formulary may have a discriminatory impact against people with disabilities. If committee moves forward, suggested in testimony submitted by Alan Cobo-Lewis that the bill be amended to add this language related to the determination of savings for referenced drugs: *In making this determination, the Superintendent of Insurance, in consultation with the Maine Prescription Drug Affordability Board, must also ensure that the determination does not discriminate against persons with disabilities.*

4. If the committee moves forward, consider the following technical and drafting issues

- As drafted, the language is allocated to Title 22 yet the responsibility for identifying the 250 prescription drugs subject to a reference rate is assigned to the Superintendent of Insurance. Should allocation of language be moved to Title 24-A? Or another entity assigned responsibility for identifying drugs subject to reference rate?
- The bill authorizes the Superintendent of Insurance to adopt rules and designates those rules as routine technical. Consider whether to require the adoption of rules and whether to make the rules major substantive and subject to legislative approval before final adoption?

LD 1636, An Act To Reduce Prescription Drug Costs by Using International Pricing

ISSUES FOR CONSIDERATION (cont'd):

5. Concerns were raised in testimony related to legal issues associated with the proposal:

- Is this unlawful regulation of interstate commerce?
- Does it violate liberty and property interests of drug manufacturers and other entities?
- Is the bill preempted by federal patent law?
- Does it implicate federal antitrust laws?

Written testimony received related to the constitutionality of the bill in support of proposal from Peter Brann on behalf of NASHP (and supplemental memo following hearing) and in opposition to proposal from Nolan Reichl on behalf of PhRMA.

6. As drafted, the bill is based on a model law developed by the National Academy of State Health Policy. The model was developed in a manner to help safeguard against legal challenges in response to a policy brief commissioned by NASHP. According to NASHP's legislative tracker, 6 state legislatures (including Maine) are considering or have considered similar legislation. Representatives of NASHP are also available to answer questions.

7. Recent report submitted by the Prescription Drug Affordability Board, established in Title 5, section 2041, included a recommendation that the Legislature consider instituting international reference-basing pricing.

LD 1636, An Act To Reduce Prescription Drug Costs by Using International Pricing

ISSUES FOR CONSIDERATION (cont'd) :

8. As you recall, the HCIFS Committee considered 2 bills addressing the costs of prescription drugs in the First Regular Session: LD 675, An Act To Protect Maine Consumers from Unsupported Price Increases on Prescription Medicines, and LD 1117, An Act To Prevent Excessive Prices for Prescription Drugs. Similar legal concerns were raised about these 2 bills. LD 675 and LD 1117 were reported out of committee with divided reports (4-4-3 votes); enacted by the Legislature and then vetoed by the Governor.

FISCAL INFORMATION:

Not yet determined; testimony submitted by the Bureau of Insurance states the bill would have a significant fiscal impact on the Bureau of Insurance because the bureau does not currently have the expertise or staff to conduct the required studies and compile the annual listing of referenced rates.