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March 12, 2021

RE: AN ACT to amend the insurance law and public health law, in relation to prescription drug formulary changes during a contract year

A4668 (Peoples-Stokes)
S4111 (Breslin)

MEMORANDUM IN OPPOSITION

Submitted on behalf of the Blue Cross and Blue Shield Plans

The New York State Conference of Blue Cross and Blue Shield Plans strongly oppose enactment of this bill, which would limit the ability of health insurers to manage and deliver a cost-effective prescription drug benefit formulary that reflects changes in the marketplace and clinical guidelines. Rather than allow health insurers to control prescription drug costs, this bill will empower drug manufacturers to increase prescription drug costs, as insurers would be barred from exercising their only recourse in the face of a price hike, altering the drug formulary, leading to increased health care premiums for all New Yorkers.

This bill effectively precludes health insurers from removing a prescription drug from its formulary or revising the clinical criteria for the use of such drugs during a plan year (except under limited circumstances), requiring all changes to a plan's formulary to occur once a year (during the renewal and enrollment period leading up to the start of an employer's or individual's policy year). As a result, insurers will be statutorily prohibited from ensuring that New Yorkers are afforded the most cost effective and highest quality drugs when available, especially as new emerging drugs are introduced. This flexibility is critical as prescription drug treatment protocols are constantly evolving and as prescription drug costs are the fastest growing component of health care costs.

For example, when the Hepatitis C blockbuster drugs Harvoni and Savoldi were introduced, the average price was approximately $130,000 for the drug. Within a few years, Merck obtained FDA approval of an equally effective drug for an approximate cost of $30,000. Health plans were able negotiate changes to their drug formularies to either negotiate more favorable rebates, or simply replace Harvoni with Zepatier on the drug formulary. In either case, the immediate impact was a reduction in health care costs to benefit consumers. Instead of allowing for the substitution mid-year of the drug which would save hundreds of thousands of dollars in premiums and out of pocket costs, this bill would lock the plan is locked in to offering the more expensive drug until the end

of the year, even for members who were not using the drug. Instead of allowing for new more effective and less costly drugs or for the refinement of medical criteria for the appropriate use of certain drugs, this bill places a barrier to such innovation and artificially guarantees manufacturer pricing, akin to price controls, even in the face of market conditions which may drive cost reductions. With prescription drugs accounting for the fastest growing component of the premium dollar, this legislation further exacerbates the problem by eliminating the flexibility to effectively controlling costs without imposing any harm on consumers.

The limitations imposed are highlighted by the exceptions contained in this bill, which clarify that a health plan can remove a prescription drug from their formulary when the FDA removes a prescription drug from the market. This provision should not be necessary for any legislation, as it is clear that a prescription drug that is no longer approved by the FDA for use should not be available on any health insurance formulary in any state or be made available to members. Yet, this provision is required under this proposal as the restrictions it imposes are so onerous that express authorization is required to remove a prescription drug that has been deemed no longer safe and appropriate for any use.

Moreover, this bill is unnecessary as Federal and State law already impose requirements on plan formulary development that ensure appropriate access to drug treatment regimens for all plan members. Health plan drug formularies are developed, reviewed and revised on a regular basis by pharmacy and therapeutics ("P&T") committees, which consist of independent practicing physicians in the community, pharmacists and other health care professionals. The revisions are based on the review of evidence based medical literature, which is either introduced or modified on a regular basis as a result of independent research and ongoing scientific and clinical analysis.

Indeed, the Affordable Care Act ("ACA") requires that health plans adhere to Federal standards[1] for P&T committees. These standards require P&T committees to ensure that drug formularies: 1) cover a broad range of drugs across a wide distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, and do not discourage enrollment by any group of enrollees, and 2) provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time. Specific to formulary changes, health plans are obligated to ensure that no formulary change jeopardizes the health or treatment regimen of any enrollee. Likewise, beginning January 1, 2016 health plans must publish an up to date, accurate, and complete list of all covered drugs on its formulary list, including any tiering structures, and any restrictions on the manner in which a drug can be obtained in a manner that is easily accessible and can be viewed on the plans web site.

It is noteworthy that on the federal level, the Department of Health and Human Services (HHS) considered restricting mid-year formulary changes in 2019, yet ultimately determined that that it would not impose this restriction and study the issue further due to "the complexity of this issue, and the challenges of balancing the interests of consumers with the importance of mitigating the effects of rising prescription drug costs."

This bill, absurdly, locks in, or guarantees drug manufacturer pricing, even as market conditions may lead to reductions. Implementing price controls on the end of the prescription drug financing

[1] 45 C.F.R. § 156.122(a)(3).

chain – health insurance – without addressing cost divers will have deleterious effects. As policy makers struggle with efforts to control runaway drug costs, instead of trying to address the contributing factors to the increase in health care costs, this legislation actually exacerbates the problem.

For the foregoing reasons, the New York State Conference of Blue Cross and Blue Shield Plans urge that this bill not be enacted.

Respectfully submitted,

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