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June 14, 2017

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

A.2317-A (Peoples-Stokes)
S.5022-A (Serino)

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 oppose enactment of this bill, which would limit a health insurer's ability to change its prescription drug formulary to reflect changes in the marketplace and clinical guidelines.

Specifically, by precluding a health plan from removing a prescription drug from its formulary or revising the clinical criteria for the use of such drugs (except under limited circumstances), this bill would inhibit a health plans ability to ensure that our members 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. Instead of allowing for the introduction of new more effective and less costly drugs or for the refinement of medical criteria for the appropriate use of certain drugs, this legislation 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.

The limitations imposed are highlighted by recent amendments to the bill, which were added to 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 legislation 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.

Flexibility in a dynamic prescription marketplace is essential as drug manufacturers change retail drug costs multiple times in a single year. Drug formulary changes are often precipitated by a sudden increase in the retail cost set by the manufacturer or competing drug manufacturers entering the marketplace. A recent example of this occurred when Merck introduced Zepatier, a Hepatitis C treatment, to compete with the exorbitantly priced Gilead product, Harvoni. The price of Zepatier was set to nearly half that of a Harvoni treatment. 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. Under this legislation, such a cost saving action would be impossible until the annual enrollment process. Drug manufacturers would be empowered to raise retail costs with impunity, since New York health plans would be barred from exercising their only recourse in the face of a price hike, altering the drug formulary. These unchecked prescription drug price increases would inevitably lead to increased health care premiums for all New Yorkers.

Growth in spending on prescription drugs in 2015, while slightly lower than prior years, continued at the highest levels since 2001. Specifically, consistent with all other independent analysis, a recent independent study by the IMS Institute for Healthcare Informatics (April 2016), found that **spending on prescription drugs increased by double digits in 2015 and reached $425 billion based on invoice prices. Even after adjusting for estimated rebates and price concessions by manufacturers, net spending was $310 billion, up 8.5% over 2014 levels. Specialty drug spending alone reached $121 billion on a net price basis, up more than 15% from 2014**.

This legislation, 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 chain – health insurance – without addressing cost divers will have deleterious

[1] 45 C.F.R. § 156.122(a)(3).

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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