HINMAN STRAUB PC
ATTORNEYS AT LAW

121 State Street
Albany, New York 12207-1693
Tel: 518-436-0751
Fax: 518-436-4751

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RE: AN ACT to amend the public health law, in relation to prohibiting the preferred drug program from restricting or imposing delays in the distribution of antiretroviral prescription drugs to certain persons; to amend the social services law, in relation to prohibiting managed care programs from restricting or imposing delays in the distribution of antiretroviral prescription drugs to certain persons; and to amend the insurance law, in relation to prohibiting insurers from restricting or imposing delays in the distribution of antiretroviral prescription for certain persons

A.1619 (Rosenthal L)
S.1001 (Hoylman-Sigal)

MEMORANDUM IN OPPOSITION

Submitted on behalf of the Blue Cross and Blue Shield Plans

The Blue Cross and Blue Shield Plans of New York oppose enactment of this bill, as it would prohibit commercial health plans and Medicaid Managed Care plans from applying prior authorization requirements, step therapy requirements, or any other protocol that could restrict or delay the dispensing of a prescription drug to treat or prevent HIV or AIDS. This prohibition would apply to pre-exposure prophylaxis ("PrEP") and post-exposure prophylaxis for HIV, along with drugs to treat HIV and AIDS. Prior authorization ensures that a drug is clinically appropriate for a patient before they start taking it. However, this bill ignores this critical function of prior authorization, and will ultimately contribute to the rising health insurance premiums for individuals and New York businesses.

Notably, pursuant to the Affordable Care Act ("ACA"), health plans must provide coverage of preventative services for which the U.S. Preventive Services Task Force ("USPSTF") has issued an "A" or "B" recommendation – including PrEP – without cost-sharing (i.e., copayments,

deductibles or coinsurance.)[1] Pursuant to the USPSTF's recommendation, issuers must provide coverage of PrEP for the prevention of HIV infection to persons at high risk of HIV acquisition; and the Department of Financial Services ("DFS") noted in Circular Letter No. 21, Supplement No. 2 (2020) that such coverage shall include any tests and services "recommended by the USPSTF to be undertaken prior to prescribing PrEP and for ongoing follow-up and monitoring."[2] Additionally, the Insurance Law was recently amended to require large group comprehensive health insurance to provide coverage for PrEP and post-exposure prophylaxis.[3]

Notably, the USPSTF's recommendation statement recommends specific medical testing before prescribing PrEP. "Before prescribing PrEP, clinicians should exclude persons with acute or chronic HIV through taking a medical history and HIV testing."[4] The recommendation statement further explains that PrEP, when used alone, is not effective treatment for HIV, and use in persons with HIV can lead to the emergence of, or selection for, drug-resistant HIV.[5] Further, the statement recommends that testing for other sexually transmitted diseases, pregnancy (where appropriate), and for certain drugs, testing kidney function, Hepatitis B, and a lipid profile.[6] The prior authorization process allows plans to ensure these critical health and safety criteria are met before the drug is used.

Unfortunately, this bill takes the position that the existing protections are insufficient and disregards the important role that prior authorization serves in the administration of health insurance coverage. Medical necessity review is a vital component of the prior authorization process by applying evidence-based treatment criteria developed and used by nationally renowned provider organizations and insurers to support better patient outcomes and ensure health care decisions are consistent and clinically appropriate. These guidelines reduce over and underutilization and facilitate appropriate care by applying evidence-based decision-making standards. These criteria, like USPSTF recommendation, are also consistently reviewed and updated by clinicians and health care experts.

This bill presumes that prior authorization and step therapy act as excessive delays to receiving care. In fact, health plans must respond to requests for prior authorization within the earlier of three (3) business days of receipt of the necessary information from the health care provider or 15 days of receipt of the request.[7] For step therapy protocol override determinations, the timeframe

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[1] U.S. Preventive Services Task Force, Final Recommendation Statement - Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis, *available at* https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

[2] N.Y. Department of Financial Services, Supplement No. 2 to Insurance Circular Letter No. 21 (2017), *available at* https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_s02_cl2017_21.

[3] N.Y. Insurance Law §§ 3221(l)(21) and 4303(tt).

[4] U.S. Preventive Services Task Force, Final Recommendation Statement - Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis, *available at* https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

[5] *Id*.

[6] *Id*.

[7] N.Y. Insurance Law § 4903(b)(1), N.Y. Public Health Law § 4903(2)(a), and 29 CFR 2560.503-1(f)(2)(iii)(A).

under New York law for a health plan to make a decision could be even shorter, at 72 hours of receipt of the information.[8]

Further, while this bill is well-intentioned, it creates a scenario under which health plans are prohibited from conducting a medical necessity review before the drugs are dispensed, but would allow a plan to deny a claim for these drugs as not medically necessary after the patient has already received and used the medication. As a result, it would potentially expose patients to liability for costs associated with these drugs that are not medically necessary – or, worse yet, clinically detrimental. This undesirable outcome is unnecessary and entirely avoidable under existing protections.

Further, step therapy is an important tool used by health plans to combat the rising costs of prescription drugs. Managing prescription drug costs benefits all enrollees as it these costs are paid by enrollees through health insurance premiums.

In sum, this bill would provide an extremely limited benefit by removing the ability of health plans to use prior authorization and step therapy, and would increase the costs borne by health insurers, unions, employers, and state and local governments – which would ultimately by borne by all New Yorkers in the forms of higher premiums and increased taxes. It will also expose individuals to higher out-of-pocket costs by prohibiting plans from using prior authorization and step therapy to prevent the imposition of costs related to unnecessary, and potentially harmful, treatments.

For the foregoing reasons, the Blue Cross and Blue Shield Plans opposes this bill and urges that it not be enacted.

Respectfully submitted,

HINMAN STRAUB ADVISORS, LLC
Legislative Counsel for the Blue Cross and Blue Shield Plans

4864-2844-5855, v. 1

[8] N.Y. Insurance Law § 4903(c-2), and N.Y. Public Health Law § 4903(3-a).