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RE: AN ACT to amend the social services law and the public health law, in relation to extending the preferred drug program to Medicaid managed care providers and offering the program to other health plans; and to repeal certain provisions of the social services law relating thereto

A2795 (Gottfried)

MEMORANDUM IN OPPOSITION

Submitted on behalf of the Blue Cross and Blue Shield Plans

The Blue Cross and Blue Shield Plans of New York strongly oppose enactment of this Bill, which would essentially carve the Medicaid prescription drug benefit back into the fee-for-service (FFS) through the establishment of statewide formulary while also significantly expanding "prescriber prevails" under managed care beyond the current scope. The Bill will undermine Medicaid Managed Care Plans' ability to protect the health and safety of Medicaid recipients, fight fraud and abuse, and control costs to ensure that taxpayer dollars are managed appropriately.

1. THE BILL HOLDS MANAGED CARE PLANS ACCOUNTABLE FOR THE COSTS OF A MEMBER PRESCRIPTION DRUG BENEFIT, BUT ELIMINATES THE ABILITY OF PLANS TO OVERSEE THE BENEFIT FOR MEMBERS.

As part of Medicaid Redesign efforts, the Medicaid prescription drug benefit was "carved in" to the Medicaid Managed Care ("MMC") benefit package. The logic behind this change was that MMC plans could more effectively manage the benefit in conjunction with the medical benefit, both from a quality and a cost perspective. However, this Bill would establish a statewide formulary and require plans to reimburse the State for the cost of prescription drugs obtained by members, based on the pricing of the statewide formulary. It removes the ability of plans operate a formulary specifically tailored to the needs of their member population and from operating their prior approval process for prescription drugs to be used by members. In essence, this Bill requires managed care plans to pay for State for the prescription drug benefit, but strips the ability of plans to actually oversee the benefit, resulting in an increase in prescriptions that involve inappropriate utilization, fraud, waste, or abuse. While the prescription drug benefit will

still be included in the capitated payment to plans, the costs incurred by plans in administering the benefit will likely exceed the prescription drug portion of the capitated payment.

2. **THE BENEFITS OF STATE-NEGOIATED PRESCRIPTION DRUG PRICES ARE ILLUSORY AND ARE NOT SUPPORTED BY HISTORICAL DATA.**

This legislation relies on the premises that a statewide formulary will result in cost savings to the State and the health care system by giving the State the power to negotiate drug prices for the entire Medicaid population (over six million "covered lives"). However, this argument fails to consider that the prescription drug benefit under the State-negotiated FFS model failed to achieve sufficient cost-savings. The prescription drug benefit was administered by the State under a FFS model with a statewide formulary as recently as 2011. Facing an unprecedented budget crisis, which included the most expensive Medicaid program in the nation per enrollee, the State carved the prescription drug benefit into the Medicaid managed care model. In 2015, the Department reported that "over the course of the last four years, DOH has collected more than $8 billion in pharmacy rebates and saved an additional $400 million from transitioning pharmacy benefits from fee-for-service to managed care." Thus, the Department of Health has concluded that the transition of the prescription drug benefit into managed care has resulted in a net savings when compared to the trajectory of spending on the prescription drug benefit under the previous, State-negotiated FFS model.

This premise also fails to consider that many managed care plans offer additional products both in New York State and in other states. As a result, some managed care plans negotiate prescription drug prices for a significantly larger population than the New York State Medicaid population. As a result, the cost-savings that would result from the State negotiating prescription drug prices and rebates for the Medicaid population will result in lower savings than anticipated.

3. **IMPOSING 'PRESCRIBER PREVAILS' ON ALL DRUG CLASSES UNDER MEDICAID MANAGED CARE UNDERMINES THE ROLE OF 'MANAGED CARE' AND INHIBITS THE ABILITY OF PLANS TO EFFECTIVELY CONTROL PRESCRIPTION DRUG COSTS.**

This Bill would impose sweeping "prescriber prevails" language on all drug classes, undermining plans' ability to ensure quality and control costs through preferred drug lists and clinical edits. Prescriber prevails already exists in the MMC context for a number of drug classes (including atypical anti-psychotics, anti-depressant, antiretroviral, anti-rejection, seizure, epilepsy, endocrine, hematologic and immunologic therapeutic) and, while touted as a patient protection, has proven itself to undermine the goals of the prescription benefit carve-in.

Not only does this legislation expand the classes of drugs subject to 'prescriber prevails' under managed care to the fee-for service approach which applies prescriber prevails to every single drug class, but it completely eliminates any requirement for the prescriber to demonstrate that, in the prescriber's reasonable professional judgment, the drug is medically necessary and warranted for certain classes (i.e. those classes currently subject to prescriber prevails in MMC). By eliminating any prior authorization for this drug classes, this Bill would prohibit any oversight by managed care plans for these classes. This is especially concerning because New York's

Medicaid program is not permitted to reimburse for prescription drugs for uses that are not included in FDA labeling or listed as an acceptable use in certain compendia. Currently, the "prescriber prevails" provision applies upon demonstration by the prescriber, after consulting with the managed care provider, that such drugs, in the prescriber's reasonable professional judgment, are medically necessary and warranted. This consultation permits confirmation that the drug is being prescribed for an accepted use and is therefore reimbursable under Medicaid. This Bill removes any requirement for prescribers to justify the use of a particular non-preferred drug over another preferred product, such as the patient has tried and failed on a preferred product or the patient is already stabilized on the non-preferred product. Under this bill, even if the prescriber does not supply necessary clinical or demographic information to identify an accepted use, the prescriber's determination would be final, forcing the Medicaid program to reimburse for the drug in violation of its State Plan.

4. **LIMITIATIONS ON PRIOR AUTHORIZATION FOR A BROAD RANGE OF DRUG CLASSES WOULD SIGNIFINCANTLY INCREASE COSTS WHILE REDUCING CLINICAL AND SAFETY OVERSIGHT.**

Beyond "prescriber prevails", this legislation would prohibit prior approval for a broad range of drug classes. This prohibition would eliminate important clinical and safety oversight for these drugs. The prior approval process is not a barrier to access and does not create new clinical documentation requirements, but rather ensures that prescription drugs are provided efficiently and consistent with the law. The process prevents unnecessary utilization in order to ensure the continued access to medically necessary items for all individuals covered under a plan. The process uses evidence based compendia to objectively determine whether the prescribed drugs are medically necessary and meet necessary clinical standards.

Prior approval serves as a check point to ensure that important clinical standards are being met for the use of a particular drug. For example, clinical criteria used by the Medicaid FFS program outlines complex clinical requirements for all Hepatitis-C agents, underscoring the importance of a prior approval step to ensure the safety and welfare of patients, not simply as a means of cost control. The treatment regimens for some of the drugs within the therapeutic classes subject to this Bill are complex, requiring multiple products, baseline testing as well as periodic testing of viral counts throughout treatment, and the general oversight and management of a clinician that is well-versed in these treatments. This legislation would permit any prescriber, whether or not well-versed in a particular complex condition/treatment regimen such as serious mental health issues, HIV/AIDS and anti-rejection therapies, to prescribe any drug or combination of drugs for a host of serious and complex diseases without any backstop to ensure such prescribing is appropriate and safe.

The Bill eliminates the ability of managed care plans to utilize reasonable front-end mechanisms to ensure patient safety and the integrity of the Medicaid program. By eliminating the plan's ability to intervene should a prescriber demand access to a particular prescription drug that is clinically inappropriate for a patient, this Bill would require plans to continue to authorize prescriptions even if the prescription endangers the safety of the patient or results in fraud.

This legislation unjustifiably overbroad and will completely undermine MMC plans' ability to properly manage the prescription drug benefit in Medicaid, resulting in potentially dangerous health outcomes, increased fraud and abuse and increased costs in an already strained Medicaid budget. While this process may be preferable for prescribers and brand name drug manufacturers, it prohibits managed care plans from actually 'managing' the care of their members. For the foregoing reasons, the Blue Cross and Blue Shield Plans urge that this bill not be enacted.

Respectfully submitted,

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