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RE: AN ACT to amend the insurance law, in relation to prohibiting the application of fail-first or step therapy protocols to coverage for the diagnosis and treatment of serious mental health conditions

S.4867 (Fahy)

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 opposes enactment of this bill, which would severely diminish a health plan's ability to ensure patients are taking appropriate medications, manage prescription drug costs, and provide affordable coverage to members. Specifically, this bill would prevent plans from implementing step therapy protocols, and from applying preauthorization requirements, to drugs prescribed for the treatment of serious mental health conditions – despite the fulsome range of options for clinically appropriate overrides available under existing law.

"Step therapy" describes the process by which a health plan or pharmacy benefit manager ("PBM") encourages the use of lower cost, yet equally effective, drug therapies before covering more expensive equivalents. In fact, such drugs are often generic versions of brand-name drugs that cost significantly less than their novel counterparts. Under all step therapy policies, if the covered drug is tried and does not work for the patient, the health plan will cover the more expensive option – regardless of the price.

Existing law already allows a prescriber to obtain a step therapy override when the required drugs: (1) are contraindicated or will likely cause an adverse reaction; (2) are expected to be ineffective based on the known clinical history and conditions of the insured; (3) were unsuccessfully tried by the insured, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or (4) are not in the best interest of the insured because they will likely cause a significant barrier to the insured's adherence to their plan of care, will likely worsen a comorbid condition, or will likely decrease an individual's

ability to achieve or maintain reasonable functional ability in performing daily activities.[1] Additionally, individuals who are stable on medications selected by a healthcare provider may receive an override – although plans can require such insureds to try an AB-rated generic equivalent.[2] This statute provides the proper balance between allowing a health plan to appropriately manage care, and providing flexibility and deference to providers under certain circumstances.

Additionally, New York recently enacted additional requirements that will apply to step therapy effective for policies that are issued or renewed on or after January 1, 2026.[3] These additional consumer protections would prohibit health plans from: requiring the insured to try more than two drugs to treat the same medical condition or disease; requiring the insured to try a drug longer than 30 days or the duration of treatment supported by evidence based guidelines; be imposed if the insured has been on the requested drug in the past year; requiring a newly enrolled insured from repeating step therapy; or imposing a new step therapy requirement before the prior the prior step therapy override expires. The law also requires health plans to honor step therapy override determinations for the lesser of the treatment duration based on current evidence-based guidelines or 12 months. This new law, in combination with the prior requirements regarding step therapy, ensures that insureds are able to get the care that they need while ensuring that drugs are prescribed in accordance with evidence-based practices.

Step therapy policies have been implemented by Medicare, Medicaid, and the vast majority of commercial health insurance plans across the country. They are designed by physicians and pharmacological experts who regularly review and implement the most current peer-reviewed medical literature. Such policies are typically applied to limited drug classes, where difference in cost between equally effective alternatives can be hundreds of dollars *per day*, *per member.* In fact, an independent study of health maintenance organizations ("HMOs") found that generic antidepressant dispensing rates increased by 20 points (32.5 percent to 52.5 percent) once step therapy was implemented – resulting in $1,880,560 in savings for that class in one year.[4] Furthermore, step therapy drugs have lower copays than expensive brand-name drugs, which decreases the likelihood that a patient will discontinue treatment due to financial constraints. Precluding "step therapy" would have a significant impact on individuals' health insurance premiums as it has been estimated that, in the absence of common care management practices, premiums for plans would be 5 to 10 percent higher than they presently are.[5]

In addition to cost savings, step therapy also plays an important role in consumer safety. The prescription drug market is constantly inundated with the next blockbuster brand-name offering, for which there is significantly less information relating to safety and efficacy. As drug manufacturers continue to aggressively promote their offerings in order to recoup investments in research and development – and bolster profits – step therapy protocols play a critical watchdog

[1] N.Y. Ins. Law § 4903 (McKinney).
[2] *Id.*
[3] Chapter 20 of the Laws of 2025 and Chapter 641 of the Laws of 2024.
[4] Dunn JD, Cannon E, Mitchell MP, Curtiss FR. *Utilization and drug cost outcomes of a step-therapy edit for generic antidepressants in an HMO in an integrated health system*, J MANAG CARE PHARM. 2006;12(4): 294-302.
[5] Congress of the United States Congressional Budget Office, "Key Issues in Analyzing Major Health Insurance Proposals," 2008. Available online at http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/99xx/doc9924/12-18-keyissues.pdf

function by ensuring that only clinically appropriate regimens are covered. Importantly, while step therapy protocols provide plans, and therefore consumers, with significant savings – estimated to be as high as $10 million annually for one commercial insurer in New York alone – they generally comport with prescribers' recommendations. In fact, an assessment of prescriptions for behavioral health medications in Connecticut found that, of nearly 15 thousand such initial prescriptions in 2021, only 56 claims required a step therapy edit.

Similarly, preauthorization is designed to ensure patients receive the appropriate medical care, as determined by current evidence-based guidelines. This process can help protect patients from unnecessary costs when equally effective and more affordable medications are available. In fact, it is estimated that 21 percent of medical care provided in the United States is not supported by available medical literature, and results in over $210 billion of excess spending annually across all specialties.

This bill presumes that preauthorization and step therapy act as excessive delays to receive 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.[6] Step therapy protocol override determinations must be made within 72 hours from receipt of necessary information for standard requests and 24 hours from receipt of information for urgent requests.[7] An insured may also request an internal and external appeal to dispute a health plan's determination that a service is not medically necessary. Under current law, expedited appeals must be completed within 72 hours of the request.[8] These short timeframes ensure that consumers can quickly appeal any denials of care.

This bill also fails to take into consideration that step therapy and preauthorization requirements that are applied to serious mental health conditions are already subject to review under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA").[9] Under MHPAEA, health plans must perform a comparative analysis of non-quantitative treatment limitations ("NQTLs") to determine whether they are permitted.[10] This additional protection applicable to mental health treatment ensures that any requirements applied to mental health treatment are comparable to those applied to medical or surgical conditions.

Thus, with the cost of healthcare and prescription drugs rising, preauthorization and step therapy strikes the balance needed to control health insurance premiums and cost sharing for insureds, while facilitating access to more expensive alternatives when clinically appropriate. By attempting to allow providers, who are frequently incentivized by pharmaceutical manufacturers, to have sole discretion over the exact drug prescribed, this bill would upset a critical equilibrium.

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[6] N.Y. Insurance Law § 4903(b)(1), N.Y. Public Health Law § 4903(2)(a), and 29 C.F.R. § 2560.503-1(f)(2)(iii)(A).
[7] N.Y. Insurance Law § 4903(c-1) and (c-2), N.Y. Public Health Law § 4903(3-a) and (3-b).
[8] N.Y. Insurance Law § 4904(b) and N.Y. Public Health Law § 4904(2).
[9] Pub. L. No. 110-315.
[10] Under 29 C.F.R. § 2590.712-1, NQTLs may not imposed on mental health or substance use disorder ("MH/SUD") benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification.

Notably, as the new law adding additional step therapy requirements will go into effect in 2026, that law should be permitted to go into effect before any additional changes are made, as that law should address many of the concerns this bill is also attempting to address.

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

Respectfully submitted,

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