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February 3, 2023

RE: AN ACT to amend the insurance law and the public health law, in relation to requiring a utilization review agent to follow certain rules when establishing a step therapy protocol

A.901 (McDonald)
S.1267 (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 opposes enactment of this bill, which would severely diminish a health insurer's ability to use step therapy policies to ensure patients are taking appropriate medications, manage prescription drug costs, and provide affordable coverage to members. By significantly limiting the requirements utilization review ("UR") agents may apply in implementing step therapy protocols, this bill would undercut these critical functions while – given the fulsome range of options for clinically appropriate overrides available under existing law – providing patients with little added benefit.

Generally, "step therapy" describes the process by which an insurer or pharmacy benefit manager ("PBM") encourages the use of a lower cost, yet equally effective, drug therapies before covering more expensive equivalents. Such required 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 insurer will cover the more expensive option – regardless of the cost. These policies have been implemented by Medicare, Medicaid, and the vast majority of commercial health insurance plans across the country; and are designed by physicians and pharmacology experts who regularly review the most current peer-reviewed medical literature. Typically, they are 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 alone in one year.¹

By prohibiting insurers from utilizing step therapy protocols when an insured was previously approved for coverage by a plan for a specific medical condition, and such medication was since removed from a plan's formulary, **this bill would statutorily prohibit insurers from ensuring that New Yorkers are afforded the most cost effective and highest quality drugs available.** This flexibility is critical as prescription drug treatment protocols are constantly evolving, and pharmaceutical expenses 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 per course of treatment. Within a few years, Merck obtained FDA approval of an equally effective drug with an approximate cost of \$30,000; and health plans were then able to either negotiate more favorable rebates for the existing medications, or simply replace Harvoni and Savoldi with Merck's Zepatier on their drug formularies. In either case, the immediate impact was a reduction in health care costs borne by consumers. However, instead of encouraging enrollees to first try a new drug that would save hundreds of thousands of dollars in premiums and out of pocket costs, this bill would require insurers to continue covering more expensive versions for individuals who have used them previously – even if the older pharmaceuticals proved to be less effective than newer medications. Further, it is important to note that, for patients who are “stable on a prescription drug or drugs selected by their health care professional for the medical condition under consideration,” a step therapy override is available under current law, “provided that [] a utilization review agent [may require] an insured to try an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug or drugs.”²

Similarly, provisions prohibiting UR agents from requiring that an insured try more than one medication before receiving coverage for a prescribed medication are particularly problematic given that many patients – particularly those seeking relief from psychiatric conditions – often try multiple medications prior to finding a drug that best fits their needs. While one in five adults now take at least one psychotropic medication, nearly four out of five prescriptions for such drugs are written by physicians who aren't psychiatrists.³ By precluding step therapy protocols that require patients to try several pharmaceutical options based on recognized, evidence-based, and peer-reviewed clinical criteria, this bill would negate measures that serve to protect patients from inappropriate prescribing.

Troublingly, this bill would further undermine the ability of insurers to use step therapy protocols to ensure that patients receive clinically appropriate care by prohibiting UR agents from requiring that an individual try a step therapy-required drug for longer than 30 days. As noted by the National Alliance on Mental Illness (“NAMI”), “[a]ntidepressant and antipsychotic medications may take 6 weeks or more to fully work.”⁴ By limiting trial periods under step therapy protocols to 30 days,

¹ 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.

² N.Y. Insurance Law §4903 and N.Y. Public Health Law §4903.

³ Brendan L. Smith, American Psychology Association, “Inappropriate prescribing,” June 2012, *available at* <https://www.apa.org/monitor/2012/06/prescribing>.

⁴ NAMI, “What to Expect From Your Medications,” *available at* <https://www.nami.org/About-Mental-Illness/Treatment/Mental-Health-Medications/What-to-Expect-From-Your->

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