HINMAN STRAUB PC
ATTORNEYS AT LAW

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

January 7, 2024

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-

this bill would result in the most vulnerable individuals changing medications before the true effects of a required drug can be realized. The resultant risks to patient health would be compounded by provisions in this bill that prohibit plans from requiring that prescription drugs authorized are FDA-approved for the medical condition being treated. Notably, while physicians may prescribe drugs for off-label uses, due to concerns that physicians were responding to false and misleading promotional claims, pharmaceutical companies are prohibited from marketing drugs for non-FDA-approved conditions – and have paid billions of dollars in settlements for off-label marketing of their drugs, including antidepressants and antipsychotics.[5] This bill would hinder insurer's abilities to counter such claims regarding experimental uses of a drug with clinically sound, peer-reviewed, and evidence-based standards.

Finally, in addition to precluding the use of critical cost-control and quality-of-care measures, this bill would effectuate "patient protections" that are unnecessary in light of current law.. Existing safeguards **allow a prescriber to obtain an override when: (1) the required drugs are "contraindicated or will likely cause an adverse reaction"; (2) the required drugs are "expected to be ineffective based on the known clinical history and conditions of the insured"; or (3) "the insured has tried the required prescription drug or drugs while under their current or a previous health insurance or health benefit plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action and such prescription drug or drugs was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event."[6]** Determinations regarding step therapy protocol overrides must be made within 72 hours of a plan receiving supporting documentation – and within 24 hours for "an insured with a medical condition that places the health of the insured in serious jeopardy without the prescription drug or drugs."[7] These safeguards strike the proper balance between allowing the plan to properly manage the care while allowing for a process whereby a provider can override a step therapy protocol. Indeed, to date, few, if any complaints have been registered with the Department of Financial Services relating to this law and process.

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

For all the foregoing reasons, we strongly oppose the passage of this bill.

Respectfully submitted,

Medications#:~:text=Antidepressant%20and%20antipsychotic%20medications%20may,or%20more%20to%20fully%20work.

[5] Kate Greenwood, Am. J. Law Med., "The ban on "off-label" pharmaceutical promotion: constitutionally permissible prophylaxis against false or misleading commercial speech?," 2011, *available at* https://pubmed.ncbi.nlm.nih.gov/21847882/; *and* Brendan L. Smith, American Psychology Association, "Inappropriate prescribing," June 2012, *available at* https://www.apa.org/monitor/2012/06/prescribing.

[6] N.Y. Insurance Law §4903 and N.Y. Public Health Law §4903.

[7] *Id.*

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