New York
HPA
Health Plan Association
41 State Street • Suite 900
Albany, NY 12207-1717
518.462.2293
Fax: 518.462.2150
www.nyhpa.org

MEMORANDUM IN

FOR IMMEDIATE RELEASE: APRIL 23, 2021

Re: S.4532 (Brouk) / A.4667 (Sayegh) - AN ACT to amend the public health law and the insurance law, in relation to the use of abuse-deterrent technology for opioids as a mechanism for reducing abuse and diversion of opioid drugs

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The New York Health Plan Association (HPA) has serious concerns that S.4532/A.4667 will undermine plan efforts to manage the pharmacy benefit and will increase pharmacy costs for New Yorkers. Abuse-deterrent opioid analgesics are not intended for all individuals who require an opioid; they should only be used in a clinically appropriate manner. HPA is opposed to this legislation as it would mandate coverage for any and all such drug products without balancing patient need and the significantly higher cost of these drugs.

The Governor vetoed nearly identical legislation in 2015 and in 2016. In Veto Message Number 283 of 2016, the Governor stated: "First, there is still no consensus on the efficacy of utilizing abuse-deterrent drugs. Much greater study is warranted to ensure such drugs would achieve their intended effect and not cause greater harm. Second, it is undisputed that the cost of abuse-deterrent opioid drugs remains significantly higher than opioid drugs that lack abuse-deterrent properties. This would necessarily result in substantially higher, and unplanned, costs to the State and consumers. Third, this bill still does not include an exception for pharmacies which directly administer medications in hospitals. Hospital costs would increase because the facility would have to dispense abuse-deterrent drugs if prescribed even though there is minimal opportunity for abuse. Finally, the bill contains numerous technical flaws that could not be addressed given the time constraints under which this bill was delivered. The Governor directed the Department of Health (DOH) and the Department of Financial Services (DFS) to study the costs associated with prescribing abuse-deterrent drugs and whether the benefits of such drugs necessitate a change to the drug formulary. At this time, neither DOH nor DFS has released any findings as to whether abuse-deterrent drugs as mandated by this legislation are appropriate.

Unlike previous iterations of the bill, S.4532/A.4667 also prohibits the use of prior authorization for opioid analgesic drug products. Prior authorization is an important tool to protect patients from unnecessary and potentially harmful care. For example, it is utilized to help ensure that medications are safe, effective, and provide value for specific populations or subpopulations who may be affected differently by a medication, and to make sure that a medication is not co-prescribed with another medication that could have dangerous interactions. Additionally, it ensures that the clinician providing the care has the appropriate training to deliver the care being requested. Further, prior authorization enables health plans to improve care coordination by making sure care management supports are in place as members navigate the system and help with follow-up care and other services that help the member succeed in recovery. Prohibiting the use of prior authorization would remove critical protections for patients and undercut efforts to ensure that the care they receive is safe, affordable and effective.

When developing prior authorization policies, health plans review information on the use of inappropriate treatments, practice variation for specific services, the extent to which providers deliver care consistent with evidence, safety concerns, and other relevant factors to determine what services or drugs should be subject to prior authorization. Health plans regularly review the medical services and prescription drugs that are subject to prior authorization and make changes based on new evidence, adherence to recognized standards of care, or, in the case of new and emerging therapies, limited available evidence or safety concerns. These reviews are conducted by Pharmacy and Therapeutics committees with relevant clinical expertise.

HPA is concerned that eliminating prior authorization for these drugs will inhibits plans' ability to coordinate care and treatment plans for members. Treatment for substance use disorder (SUD) goes far beyond just taking medication, and prior authorization is one of the tools plans use to help streamline and manage patient care.

The bill sponsors believe analgesic opioid drug products will be an important tool in New York's efforts to address prescription drug abuse—along with the growing problem of heroin addiction that is in large measure caused by prescription opioids. However, we should not look to address prescription drug abuse with other prescription drugs that have the potential to be abused as well.

Abuse-deterrent formulations are designed to make it more difficult for abusers to crush, chew, snort or inject prescription opioids. However, the abuse-deterrent drugs themselves can be abused—the federal Food and Drug Administration requires they carry a "black box" warning— and, therefore, are not the cure-all advertised by manufacturers and embraced by law enforcement. The legislation does not address the need to educate prescribers and patients on issues surrounding opioid abuse.

Cost and efficacy must also be considered. A drug formulary is a continually updated list of prescription medications that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. They have existed for decades and are commonly used by hospitals, health plans, pharmacy benefit managers, self-insured employers and union welfare funds, and government programs to provide affordable access to proven medications to ensure high quality care. The true value of a formulary is maximized when it is part of an integrated patient care process that encourages physicians, pharmacists and other caregivers to work together to ensure positive and cost-effective results.

This legislation would require that health plan formularies provide coverage "for at least one abuse-deterrent opioid analgesic drug product per opioid analgesic active ingredient." This phrase is overly broad, vague, confusing, and intended to require health plans to cover any and all abuse-deterrent opioid drugs on their formularies. Mandating coverage of multiple abuse-deterrent drugs on drug formularies will deter the appropriate use of these drugs to the detriment of patients. Drug manufacturers have an incentive to raise not lower cost if government mandates each health plan to offer their drugs.

Post-marketing studies for abuse-deterrent opioid drugs have not yet determined whether these drugs, which are often priced up to ten times the cost of various generic opioids, effectively curb misuse or abuse of opioids. Mandating formularies to cover all versions of abuse-deterrent opioid drugs solely because an existing formulary contains an "opioid active ingredient" will result in businesses and consumers paying more for drugs and may not result in lowering the incidence of opioid misuse or abuse. This legislation will result in higher medication costs for public and private payers with no

increased benefit for at-risk patients. It is important to note that any increased costs associated with this legislation will also have a direct impact on the Medicaid global cap.

This bill is overbroad and will result in a dramatic increase in pharmacy costs for both the state Medicaid program, State Employer, and commercial insurance. For these reasons, HPA opposes S.4532/A.4667.