March 14, 2024

Hon. Herb Conaway
Chairman
Assembly Health Committee
Delran Professional Center
8008 Rt. 130 North, Bldg. C, Suite 450
Delran, NJ 08075

RE: OPPOSE - A. 1825 – Step Therapy

Dear Mr. Chairman:

Thank you for the opportunity to submit written testimony on A. 1825 on behalf of the Pharmaceutical Care Management Association ("PCMA"). PCMA believes some of the definitions and language in this well intended legislation may be overly broad, which will lead to an increase in health care costs. Additionally, recently passed legislation regarding pharmacy benefit managers and prior authorization already addresses several provisions of A. 1825, and will become effective soon. Moreover, the current step therapy exemption and appeals processes can best address the concerns raised by this bill, which is why we are respectfully opposing this legislation at this time.

PCMA is the national association for America's pharmaceutical benefit managers, or PBMs. PCMA New Jersey members include CVS Health, Cigna, OptumRx, and Prime Therapeutics. PBMs help to reduce prescription drug costs and increase quality standards for large and small employers, health insurers, labor unions, Medicare, Medicaid, and other programs. Nationally, PBMs helped patients and payers save $941 per enrollee per year in prescription drug costs, which is projected to be $654 billion over the next 10 years.

PCMA agrees with the preamble of A. 1825, which states that "step therapy protocols, if based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs." Simply put, step therapy is a proven tool to lower costs. Both prior authorization and step therapy are widely used by PBM clients to help ensure appropriate and cost-effective use of high-cost and/or high-risk drugs.

Without the tools of prior authorization and step therapy, projected drug costs for fully insured employers and commercial health plans are estimated to increase by $1.7 billion in New Jersey over the next ten years.[1] Step therapy demonstrates savings of more than 10% in targeted categories.[2] Additionally, the Federal Trade Commission stated that "large PBMs and small or insurer-owned PBMs have used step-therapy … programs to lower prescription drug costs and increase formulary compliance."[3]

As you may know, PBMs utilize Pharmacy & Therapeutics Committees ("P&T Committees"), which are comprised of experts that include physicians, pharmacists, and other medical professionals. These

[1] "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools," Visante, January 2019.
[2] Yokoyama, et al., "Effects of a step therapy program for angiotensin receptor blockers on antihypertensive medication utilization patterns and cost of drug therapy," J. Manag. Care Pharm. 2007; 13(3):235-244.
[3] "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," Federal Trade Commission (FTC), Aug. 2005

committees are responsible for utilizing evidence-based medicine guidelines in making recommendations that are used in pharmacy benefit management programs based upon well-developed scientific standards. Under C.17B:27F3.3 of P.L. 2023, c. 107, P&T Committees exclude individuals with conflicts of interest, and must meet the "requirements for conflict of interest as set by the Centers for Medicare and Medicaid Services or meets the accreditation standards of the National Committee for Quality Assurance or another independent accrediting organization." Accordingly, we recommend the deletion of A. 1825, Section 3(a)(2)(a), which would add unnecessary requirements to the conflict-of-interest provisions of existing statute.

Moreover, A. 4815 references the work of these P&T Committees in 1(f) when it describes that step therapy protocols should be required to be based upon "appropriate clinical practice guidelines, or published peer-reviewed data developed by independent experts with knowledge of the condition or conditions under consideration." While this portion of the bill accurately depicts the high clinical standards used by P&T Committees, Section 3 of the bill however mandates an establishment of specific clinical review criteria and review process for step therapy in a one-size-fits-all manner that is outside the existing P&T Committee, including an opportunity for public review.

Accordingly, we recommend the following changes to the definitions section of this legislation. This includes deleting existing defintions of: "Clinical practice guidelines," "Clinical review criteria," and "Medically necessary", which are too inflexible. These definitions may inhibit appropriate care, which would be contrary to the purpose of this legislation. Worse, they may counterintuitively create additional barriers that could cause patient conditions to deteriorate through lack adherence to prescribed medication. Furthermore, we recommend amending the definitions of "Step therapy exception" and "Step therapy protocol". We recommend changing the former to become more of a reasonable process that may result in coverage of a health care provider's selected prescription drug, as opposed to "immediate coverage." In terms of the latter, we recommend that the definition become more expansive by adhering to the standard of care and by reflecting the reasonable process towards making a decision, as opposed to inflexibly being "required to be administered."

Additionally, we recommend deleting the last sentence of 4(a), which pertains to the disclosure of all rules and criteria related to step therapy protocol. Such disclosure, while well intended, could allow a prescriber to subvert the utilization review protocols which serve an important standard for allowing appropriate, and affordable care. A better approach is to require that the rules and criteria meet the standard of care, and that an explanation of the process is available upon request.

Clients of PBMs decide if and how such programs like step therapy will be applied to their health benefit plan. Additionally, every plan already possesses both exemptions from the step therapy protocols, and an appeals process, which are both contemplated by Section 4 of this bill. According to the National Academies of Sciences, Engineering, and Medicine, "Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a physician provides information about side effects the patient has experience from a lower-tiered drug or offers another medical reason for switching."[4] To strengthen Section 4(b) for patients, providers and payers, we respectfully suggest the following additions:

[4] "Making Medicines Affordable: A National Imperative," National Academies of Sciences, Engineering, and Medicine (NASEM), Nov. 2017.

b. A step therapy exception shall be granted if **the prescribing practitioner's submitted justification and supporting clinical documentation, if needed, is determined to support the prescribing practitioner's statement that**:

(1) the required prescription drug is contraindicated **with currently prescribed drugs**~~, or is likely to cause an adverse reaction or physical or mental harm to the patient~~;

(2) the required prescription drug is ~~expected to be~~ ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

(3) the patient has tried the required prescription drug ~~or another prescription drug in the same pharmacologic class or with the same mechanism of action~~ and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

~~(4) the required prescription drug is not in the best interest of the patient, based on **[**medical necessity**]** **the standard of care**; or~~

~~(5) the patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.~~

Also, in terms of the definitions used in A. 1825, we recommend the following changes to "health benefits" plan:

"Health benefits plan" means a benefits plan which pays or provides hospital and medical expense benefits for covered services, and is delivered or issued for delivery in this State by or through a carrier. Health benefits plan includes, but is not limited to, Medicare supplement coverage and risk contracts to the extent not otherwise prohibited by federal law. For the purposes of this act, health benefits plan shall not include the following plans, policies, or contracts: accident only, credit, disability, long-term care, CHAMPUS supplement coverage, **or a self-insured health benefits plan governed by the provisions of the federal "Employee Retirement Income Security Act of 1974," 29 U.S.C. s.1001 et seq.**, coverage arising out of a workers' compensation or similar law, automobile medical payment insurance, personal injury protection insurance issued pursuant to P.L.1972, c.70 (C.39:6A-1 et seq.), or hospital confinement indemnity coverage.

Lastly, we recommend that the term "utilization review agent" mean: **"an individual serving, in good standing, on a utilization review organization**."

Thank you for the opportunity to provide written testimony regarding A. 1825. I am happy to provide any further information, or answer any questions, as this legislation is considered further.

Sincerely,

Heather R. Cascone

Heather Cascone
Senior Director, State Affairs
202-744-8416 / hcascone@pcmanet.org