MEMORANDUM

TO: Assembly Health and Senior Services Committee

FROM: April Alexander, Assistant Vice President, PCMA

DATE: March 18, 2019

RE: A. 3176—Prior Authorization

PCMA submits this memo to express concern regarding A. 3176, relating to prior authorization. The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans with health coverage through large and small employers, health insurers, labor unions, Medicare, Medicaid, and other programs.

Prior authorization is a requirement that a health plan pre-approves a prescription drug before a pharmacy can dispense it to an enrollee as a covered benefit. The major goals of prior authorization are to ensure appropriateness and suitability of the prescribed medication for the specific patient, as well as to control costs. Health plans and PBMs rely on independent Pharmacy & Therapeutics Committees, comprised of experts that include physicians, pharmacists, and other medical professionals to develop evidence-based guidelines used in drug management programs—including prior authorization—and to ensure that these management controls do not impair the quality of clinical care.

It is important to remember that under NJ law,[1] all prescription benefit plans must cover all drugs. Thus, prior authorization is the only tool that health plans in New Jersey have to ensure that drugs are used for the appropriate patients, helping prevent abuse, misuse, and diversion.

A.3176 would eliminate the ability of health plans and PBMs to effectively monitor patient safety, prevent fraud, waste, and abuse, and keep costs low for consumers—essentially creating a "rubber stamp" for drug approval as opposed to allowing a meaningful review of medical necessity that protects both the patient and the plan sponsor. In addition to controlling costs, prior authorization is used to manage the utilization of drugs that may pose a safety risk, have a high potential for off-label or experimental use, are very high in cost, are prescribed at dosages exceeding the highest FDA approved dose, etc. Prior authorization is widely used in commercial insurance, as well as in Medicare, Medicaid, the Children's Health Insurance Program, and the Federal Employees Health Benefits Program.

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[1] N.J.A.C. 11:22-5.9.

Today, prior authorization is used by 92% of employer plan sponsors to improve clinical safety and decrease inappropriate utilization and waste.[2] A range of studies demonstrate that prior authorization substantially reduces expenditures in targeted drug categories. For example, one study found that prior authorization for a high-cost antibiotic resulted in 37% lower pharmacy costs and 38% lower total cost of care for patients prescribed the antibiotic.[3] One specialty pharmacy program that used prior authorization to identify inappropriate utilization across six drug categories based on nationally recognized clinical guidelines achieved a 24% cost reduction in targeted categories.[4] A study of 22 state Medicaid programs found that prior authorization lowered total drug expenditures by 0.6% based on its use in just one drug category alone.[5] Other studies have demonstrated that prior authorization for specialty drugs can generate savings of up to 50% for targeted drugs or categories.[6,7] A recent study by research firm Visante found that if New Jersey institutes prohibitions on prior authorization and step therapy, projected drug costs for fully insured employers and commercial health plans would increase by $1.8 billion in the state over the next ten years.[8] Finally, according to a study conducted by the Federal Trade Commission (FTC), upon a plan sponsor's request, "[l]arge PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance." The FTC also determined that "[p]rior authorization often involves a clinical justification for the use of drugs that are prone to misuse or are especially costly."[9]

A.3176 would prohibit the use of prior authorization to prevent dangerous off-label use and to ensure that prescriber guidelines have been followed. "Off-label" use is the use of a drug to treat a condition for which the drug has not been shown to be effective, and it not only drives up health care costs, it doesn't result in better patient outcomes. Some examples where health plans may require prior authorization for drug products in an effort to ensure appropriate use include:

- Growth Hormone: prevents use for bodybuilding, anti-aging, and athletic performance.
- Testosterone: prevents use for bodybuilding, anti-aging, and athletic performance.
- Opioids: ensures opioids are prescribed according to guidelines, at the lowest dose possible for the shortest time possible, which helps prevent drug diversion and overuse.
- Diabetes Drugs: prevents inappropriate use for weight loss.
- Dementia Drugs: prevents inappropriate use for autism.
- Anti-psychotic Drugs: prevents inappropriate use for insomnia.

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[2] Pharmacy Benefit Management Institute.
[3] Starner, et al., "A linezolid prior authorization program: clinical and economic outcomes," *Am J Pharm Benefits*. 2014;6(2):81-88.
[4] "Specialty Pharmacy: Historical Evolution and Current Market Needs," presented at PCMA Specialty Pharmacy Symposium, May 5, 2008.
[5] Fischer, et al., "Medicaid prior-authorization programs and the use of cyclooxygenase-2 inhibitors," *N Engl J Med.* 2004;351:2187-2194.
[6] "Specialty utilization management proves effective: ampyra prior authorization improves safety and saves money," Prime Therapeutics, 2011.
[7] "Specialty prior authorizations reduce costs and enhance medication safety," Walgreens Specialty Pharmacy, 2009.
[8] "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools," Visante, February 2018, available at https://www.pcmanet.org/wp-content/uploads/2019/01/Visante-Study-on-the-Increased-Costs-Associated-With-State-Legislation-Impacting-PBM-Tools-Jan-2019-FINAL.pdf.
[9] Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005. Available at http://ftc.gov/reports/index.htm#2005. [Emphasis added].

- Hepatitis C Products: ensures drugs are used for the correct stage of liver disease and for the shortest amount of time required to treat the condition.
- Oncology Drugs: ensures the correct genetic testing is done prior to treatment and ensures the most current treatment guidelines are followed.

Preventing off-label use is both a safety and cost issue, because these drugs can be thousands of dollars a month and come with significant side effects. Inappropriate use can be dangerous for patients and result in unnecessary health care expenditures. It is for these reasons that PCMA must respectfully oppose this bill. Please contact me at 202-756-5743 if you have any questions.