



January 4, 2018

Senator Paul A. Sarlo
Chairman

Senator Brian P. Stack
Vice Chairman
Senate Budget and Appropriations Committee
125 West State Street
Room 4, 1st Floor
Trenton, NJ 08625

RE: S. 3185 – Prescription Drug Patient Protection Act (Oppose)

Dear Chairman Sarlo, Vice Chairman Stack, and Members of the Committee:

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans and operate mail-order and specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and other programs.

Organized Delivery System

S. 3185 would require PBMs to register with the New Jersey Department of Banking and Insurance (DOBI) as an organized delivery system (ODS), as defined in N.J.S.17:48H-1 *et seq.* We believe that this is the wrong regulatory scheme for PBMs, which do not neatly fit into the construction of the ODS statute or regulations. PBMs are currently regulated by departments of insurance in many states—including New Jersey—and PCMA and its member companies have been constructive partners with legislators and regulators to develop appropriate oversight structures.

The Department of Banking and Insurance (DOBI) already has direct regulatory authority over PBMs operating within the State.¹ DOBI has oversight authority in the areas of maximum allowable cost (MAC) pricing terms between PBM and contracted pharmacies, and DOBI also regulates PBMs through the regulation of insurance carriers that contract with PBMs to provide pharmacy benefits to consumers. The Department of Human Services regulates PBMs operating within the Medicaid program through its oversight over Medicaid managed care organizations (MCOs). Further, the Department of the Treasury regulates PBMs through its State Employee Health Benefits Program and School Employees' Health Benefits Program contracts. In sum, the State already exercises significant oversight of PBMs, both directly and indirectly, through regulations and contract requirements.

We believe that requiring a PBM to register with DOBI as a certified ODS would raise serious operational and legal issues, including the following:

- The current ODS statute at N.J.S.17:48H-1 *et seq.* defines an ODS, in part, as providing or arranging to provide "substantially all or a substantial portion of the comprehensive health

¹ See N.J.S.A. 17B:27F-1 *et seq.*



care services.” PBMs typically contract with plan sponsors to administer the prescription drug portion of the health insurance benefit, but no two PBM contracts are the same, and a PBM may not necessarily even contract to administer the entire prescription drug benefit.

- The statutory definition of an ODS also signals that an ODS may be organized to subcontract to provide or arrange to provide “a separate category of benefits and services apart from...[a] comprehensive benefits plan.” Pharmacy benefits, as administered by PBMs, are usually part of the plan sponsor’s comprehensive package of services, not a limited health care service.
- At N.J.S. 17:48H-4(e), the statute requires an ODS to provide to DOBI a “copy of the standard form of any provider agreement made or to be made between the applicant and any providers relative to the provision of health care services,” however, PBMs do not have standard provider contracts (i.e., contracts with pharmacies, as PBMs do not contract with individual pharmacists). Contracts vary widely, depending on what a PBM’s client desires.
- At N.J.S. 17:48H-4(g)(1), the statute requires an ODS to provide to DOBI “a list of the persons who are to provide the health care services, and the geographical area in which they are located and in which the services are to be performed,” yet it would be operationally infeasible for a PBM to list individual pharmacists at thousands of pharmacies across the State of New Jersey. It may also prove administratively burdensome to even list individual pharmacies for the purposes of this filing requirement, as a PBM may include different pharmacies in its network based on its client.
- At N.J.S. 17:48H-4(g)(5), the statute requires an ODS to provide to DOBI with a “description of the means by which the organized delivery system shall be compensated for each contract entered into with a carrier,” however this raises significant anticompetitive issues, targeting a key way that PBMs compete for business within the State.

Limitations on Prior Authorization

As currently drafted, S. 3185 limits PBMs’ ability to require prior authorization of certain prescription drugs, raising serious patient safety and cost concerns for both public and private programs in New Jersey.

S. 3185 would gut 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. **The State of New Jersey requires MCOs to use prior authorization for both medical services and prescription drugs,² and prior authorization is also used in the State**

² New Jersey FamilyCare contract, July 2017. Available at: <http://www.state.nj.us/humanservices/dmahs/info/resources/care/hmo-contract.pdf>.



Health Benefits Program and the School Employees' Health Benefits Program,³ demonstrating that the State recognizes the importance of this prescription drug benefit management tool.

Health plans and PBMs use various tools, such as prior authorization, to keep health care costs low for consumers and employers. These tools are also the first line of defense in combatting fraud, waste, and abuse. Formulary management is an integrated patient care process enabling physicians, pharmacists, and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes. Effective use of drug management tools and plan formularies can minimize overall medical costs, improve patient access to more affordable care, and provide patients with an improved quality of life.

Research shows that management tools, such as prior authorization, are proven to bring down health care spending and slowing down growth in prescription drug spending. Removing this tool will raise costs on employers and consumers. 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."⁴

As drafted, PCMA opposes S. 3185 and urges the Committee to reject the bill. PCMA and its member companies are ready to work with the bill sponsors in both the Senate and the Assembly, Members of the Committee, and DOBI to develop PBM registration or alternative oversight language. If PCMA can answer any questions or be of further assistance, please contact me at 202-756-5736 or swoods@pcmanet.org.

Sincerely,

A handwritten signature in blue ink that reads "R. Scott Woods".

R. Scott Woods
Senior Director, State Affairs
Pharmaceutical Care Management Association

cc: Members of the Senate Budget and Appropriations Committee

³ New Jersey State Health Benefits Program and School Employees' Health Benefits Program Prescription Drug Plans Member Handbook, Plan Year 2017. Available at: <http://www.state.nj.us/treasury/pensions/pdf/handbook/hp0506.pdf>.

⁴ Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005. Available at <http://ftc.gov/reports/index.htm#2005>. [Emphasis added].