MEMORANDUM

DATE: April 29, 2019

TO: Ms. Leslie Ledogar, Regulatory Specialist
Department of Insurance

FROM: J. Todd Webb – Chairperson
State Council for Persons with Disabilities

RE: 22 DE Reg. 834 [DOI Proposed Regulation Regarding Registration of Pharmacy Benefit Managers (April 1, 2020)]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Insurance’s (DOIs) proposal to implement the registration requirements provided in HB 194 with HA 1. All Pharmacy Benefit Managers (PBMs) are required to register with the Insurance Commissioner before providing pharmacy benefits management services in Delaware to an insurance company, health service corporation, health maintenance organization, managed care organization, and any other entity that: (1) provides prescription drug coverage or benefits in Delaware, and (2) enters into agreement with a pharmacy benefits manager for the provision of pharmacy benefits management services. The regulation provides broad grounds for the Insurance Commissioner to deny, suspend, or revoke an application or registration certificate and includes a record keeping provision to give the Commissioner access to a PBMs practices. The proposed regulation was published as 23 DE Reg. 834 in the April 1, 2020 issue of the Register of Regulations. SCPD has the following observations.

PBM contracts typically cover administration of the retail prescription drug benefit. These private entities process claims to help create the plans’ drug benefits and negotiate with drug companies to obtain discounts, rebates, or other price concessions. Although the primary
function of a PBM initially was to create networks and process pharmaceutical claims, they have been criticized for exploiting a lack of regulation and transparency. In addition, they have been accused by consumer groups of creating conflicts of interest which have significantly distorted competition, reduced choices for consumers and ultimately increased the cost of drugs. States have historically had little defined oversight authority over PBM operations, leaving pharmacies, patients, and plan sponsors with little to no recourse against PBM abuses. To combat the lack of transparency, states are beginning to require that PBMs become licensed or registered with the state department of insurance or board of pharmacy to provide the state with more oversight authority over PBMs.

House Bill 194 as amended by House Amendment 1 added a new Subchapter V to Chapter 33A of the Insurance Code. See 82 Del. Laws, c. 115 (2019) entitled “Registration of Pharmacy Benefits Managers.” The legislation: (1) Requires PBMs to register with the Insurance Commissioner; (2) Permits the Insurance Commissioner to issue cease and desist orders to PBMs who commit fraudulent acts or violations of Title 18, Chapter 33A; (3) Requires PBMs to maintain certain records; (4) Permits the Insurance Commissioner to examine the affairs of PBMs; (5) Grants the Insurance Commissioner the authority to enforce Chapter 33A of Title 18 by imposing fines, requiring PBMs to take affirmative actions, and suspending, denying, or revoking a PBM’s registration; and (6) Updates existing law regarding maximum allowable cost lists and establishes a more transparent appeals process on which a pharmacy may rely if a PBM does not reimburse the pharmacy the amount owed under their contract or pursuant to the maximum allowable cost list.

SCPD endorses legislative and regulatory efforts to promote transparency in drug pricing and in the drug distribution system. However, increased transparency and registration requirements may not be not enough. As an example of an even more aggressive effort to control PBMs, Nevada passed legislation specifying that a PBM has a fiduciary duty to a third party with which it has entered into a contract to manage that party’s pharmacy benefits plan. This means that the PBM must act in the best interest of the pharmacies or consumers it serves. While the proposed regulation includes strict licensing requirements and provides important oversight of PBMs that will help provide insight and information on how PBMs conduct business, SCPD believes even stronger legislation may be warranted to keep PBMs accountable and actually promote savings as was originally intended.

Thank you for your consideration and please contact SCPD if you have any questions regarding our position or observations on the proposed regulation.

cc: The Honorable Trinidad Navarro  
Ms. Laura Waterland, Esq.  
Governor’s Advisory Council for Exceptional Citizens  
Developmental Disabilities Council

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