



**BlueCross BlueShield
Association**

An Association of Independent
Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4800
www.BCBS.com

September 1, 2020

Commissioner Andrew R. Stolfi, Chair
Acting Administrator T.K. Keen, Chair
Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street, N.W., Suite 700
Washington, D.C. 20001-1512

Submitted via email to Jolie Matthews (JMatthews@naic.org)

**RE: BCBSA Comments on Draft [STATE] Pharmacy Benefit Manager (PBM) Licensure
and Regulation Model Act**

Dear Commissioner Stolfi and Mr. Keen:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on the draft Pharmacy Benefit Manager Licensure and Regulation Model Act (Model Act) dated July 6, 2020.

BCBSA is a national federation of 36 independent, community-based and locally operated Blue Cross and Blue Shield companies (Plans) that collectively provide healthcare coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality healthcare coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare and Medicaid.

General Comments

Health plans are committed to ensuring consumers have access to affordable prescription drugs. Health plans and their pharmacy benefit manager (PBM) partners utilize key tools that encourage patients and their physicians to select the safest and most effective drugs at the lowest possible price. For example, PBMs negotiate with manufacturers to lower the cost of drugs; establish reimbursement lists to incentivize pharmacies to purchase generic drugs at the lowest price; manage pharmacy networks to drive competition on service, price, convenience and quality; and enact safety protocols to reduce negative drug interactions, increase safety and ensure appropriate use.

Today, prescription drugs are the fastest growing part of the healthcare system with 21 cents of every healthcare dollar spent on prescription drugs – about the same percentage spent on physician and clinical services.¹ Drug manufacturers frequently point the finger at others in the

¹ BCBSA, "Why does healthcare cost so much?" 2018.

supply chain – including PBMs – for high list prices of medications and escalating drug costs, even though manufacturers alone set those prices. However, there is overwhelming evidence that PBMs help lower drug costs.

BCBSA agrees with the subgroup on the need for reasonable PBM regulations. PBMs provide critical services on behalf of health plans, employers and states (in the form of state employee plans and Medicaid) that ultimately affect consumers' pocketbooks. For that reason, neither PBMs nor any other entity in the drug supply chain – including manufacturers and pharmacy service administrative organizations (PSAOs) – should function without oversight by state regulators. Importantly, any model law should be focused on designing a comprehensive framework for regulation, not leaving some drug supply chain entities free from state oversight.

For example, PSAOs serve an important function in the drug supply chain by representing approximately 80 percent of independent pharmacies in contract negotiations with health plans and PBMs,² but they function with little to no state oversight. A Government Accountability Office (GAO) report from 2013 provides the limited publicly available information on these organizations. According to the report, 22 PSAOs represent 20,000 to 28,000 pharmacies, with most PSAOs each contracting with 500 to 5,000 pharmacies in 2011 or 2012. By aggregating the purchasing power of pharmacies, PSAOs gain substantial leverage in negotiations with health plans and PBMs. PSAOs are mainly owned by drug wholesalers and independent pharmacy cooperatives, and their business practices warrant state regulators' oversight.

Equally important, this model law should be designed in a manner that aligns rules across health insurance markets. As such, any rules and regulations on PBM business practices in the commercial insurance market also should be applied to state health programs and government-sponsored employee health plans. It is with these core regulatory principles in mind that we would support the following provisions:

- Requiring PBMs to be licensed with the state Department of Insurance (DOI)
- Housing PBM oversight within state Insurance Departments, not within provider-specific state boards of licensure
- Disclosing the list by health insurers and the kinds of health plans (e.g., health maintenance organization (HMO), preferred provider organization (PPO)) administered by PBMs within the state
- Prohibiting gag clauses in state law consistent with federal law to protect consumers and enable regulators to exercise traditional state insurance roles in oversight and enforcement

In light of BCBSA's support for reasonable regulation and oversight of PBMs, BCBSA recommends modifications to the Definitions, Licensing Requirement, Gag Clauses Prohibited, Enforcement, and Regulations sections, as described below:

Section 3 – Definitions

BCBSA recommends adding health plans to the list of entities that "are not a PBM" in Section 3(J)(2) because they are already licensed by the state and, therefore, should not face an additional licensure requirement. Under the draft Model Act language in Section 3, a health

² GAO Report. ["The Number, Role, and Ownership of Pharmacy Services Administrative Organizations."](#) January 2013.

insurer who provides “other prescription drug or device services” as defined in Section 3(F) may qualify as a PBM. This inclusion is counter to the National Association of Insurance Commissioners (NAIC) subgroup’s objective to draft a Model Act to license and to regulate PBMs. To ensure appropriate application of the Model Act to entities that administer the pharmacy benefit (i.e., PBMs), BCBSA recommends adding: “A nonprofit hospital or medical service corporation, health insurer, health benefit plan or health maintenance organization who does not administer and/or contracts with another entity to administer the pharmacy benefit” to Section 3(J)(2). Health plans remain in the model under the definition of “covered entity.”

BCBSA encourages the subgroup to examine the model definitions to ensure a level playing field for health plans managing the pharmacy benefit in-house and health plans contracting with a PBM. For example, Section 6 – Gag Clause Prohibited and Section 7 – Enforcement should apply in both arrangements.

Section 5 – Licensing Requirement

BCBSA recommends requiring PBMs to notify regulators of any changes to their application within 90 days of the change and disclosing the list by health insurers and the kinds of health plans (e.g., health maintenance organization (HMO), preferred provider organization (PPO)) administered by PBMs within the state as suggested in Section 8(B)(10).

We also recommend removing “financial and reporting” from Section 5(B) as this section is intended to focus on licensing requirements, not financials or reporting stipulations. Additionally, we recommend inclusion of an appeals process to Section 5(E) available to PBM license applicants or a cross reference to a general section in the insurance code setting forth the right to appeal.

Section 6 – Gag Clauses Prohibited

We support the inclusion of prohibiting pharmacy gag clauses, but recommend modifying this section to align with federal law per the Patient Right to Know Drug Prices Act and the Know the Lowest Price Act, which eliminated pharmacy gag clauses in commercial and Medicare markets, respectively. The term “gag clause” is commonly referred to as a contractual provision that restricts a pharmacy’s ability to provide an enrollee with drug pricing information based on whether it is purchased using insurance or without. The language in the draft Model Act extends beyond this common definition. Alignment with federal statute will provide clarity to stakeholders and prevent unnecessary confusion.

Furthermore, the draft Model Act provisions in Section 6(A)4-5 allow pharmacists to disclose information to which a pharmacist would not have access and could lead to consumer confusion. For example, a pharmacist would not know the “process that is used to authorize or deny healthcare services or benefits,” and providing incorrect information may deter patients from obtaining needed medications. Second, a pharmacist would not know the “[i]nformation on financial incentives and structures used by the insurer” as this information would not be included in a PBM-pharmacy contract. Therefore, we recommend Section 6(A)4-5 be removed and the entire section align with federal law.

Section 7 – Enforcement

We agree broadly with the enforcing mechanisms in this section and recommend: (1) adding clarification on the parameters of a triggering event for an investigation (e.g., a substantial complaint); and (2) noting that the scope of the investigation be confined to the complaint. Also, we appreciate the protections in this section recognizing that any information or data acquired

during an audit or examination may be highly sensitive, proprietary and/or competitively sensitive.

Section 8 – Regulations

NAIC creates model laws and regulations to “establish standards and best practices, conduct peer review, and coordinate their regulatory oversight.”³ We have concerns that the inclusion of broad topics in Section 8(B) of the Model Act does not align with this NAIC objective and does not further the goal of greater uniformity across the states. Individual states have the discretion to add to, remove from or revise NAIC Model Acts, and the broad language in Section 8(B) is unnecessary and will likely result in significant variability in how states adopt the Model Act.

BCBSA recommends the subgroup direct NAIC to develop a white paper on the topics in Section 8(B) to understand the key considerations related to each before including any portion of the subsection in a model. A white paper would provide more effective guidance to states on these outstanding issues particularly since a majority of states have previously enacted PBM statutes or regulations. BCBSA recommends the subgroup continue its work to define these topics, debate their merits and, where possible, develop consensus to support broad state adoption of the Model Act.

Additionally, state regulations related to the topics in Section 8(B) may have significant impact on PBMs’ and plans’ ability to lower drug costs. Similar to regulators and other state policymakers, BCBSA supports the goal of lowering healthcare costs for patients and, as such, encourages regulators to carefully consider how any changes they are making could disrupt current checks on high-cost prescription drugs. Health plans contract with PBMs to do just that, and many of the topics listed in Section 8(B) relate to tools that health insurers and PBMs use to lower drug costs for high-priced therapies or are unrelated to PBM business activities and should not be included.

In particular, we recommend removing Section 8(B) and provide specific comments on the following subsection topics under Section 8(B):

- **Section 8(B)(1) – Pharmacy Benefit Manager Network Adequacy:** PBMs utilize networks and preferred pharmacies to drive competition on quality, service, convenience and price. According to the Federal Trade Commission’s (FTC) analysis of the Centers for Medicare & Medicaid Services’ (CMS) studies on the Medicare prescription drug program, “research demonstrates that there are savings associated with preferred pharmacies and mail-order pharmacies, and that any willing provider [AWP] regulations tend to increase costs.”⁴ The CMS studies also “found that, on average, branded drugs cost 3.3 percent less at preferred pharmacies and generic drugs, on average, cost 11 percent less at preferred pharmacies” within Medicare Part D.⁵
- **Section 8(B)(4) – Rebates:** Evidence demonstrates that eliminating or significantly restricting rebates will substantially increase premiums and drug costs. Previous federal rule-making, which was not finalized, would have eliminated rebates in Medicare and Medicaid and was estimated to increase premiums 14 to 19 percent and increase federal

³ NAIC. “[FAQ](#).” Accessed on August 12, 2020.

⁴ U.S. Federal Trade Commission. “[Comments on Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs](#).” March 7, 2014.

⁵ *Ibid*.

spending for Medicare by up to \$196 billion over 10 years.⁶ Previously proposed legislation in Nevada to prohibit rebates in the state employee benefit program unless 100 percent were passed on at the point-of-sale would have led to a reduction of more than \$11 million in negotiated drug discounts. This reduction in discounts would have then been passed on to members in the form of premium increases, passed on to the state budget in the form of subsidy increases, resulted in reduced annual benefits, or some combination of each. Additionally, rebates only apply to a small subset of prescription drugs. Drug manufacturers do not offer rebates for 89 percent of prescriptions – both brand and generic – dispensed under Medicare Part D, and 64 percent of brand drugs studied offered no rebates.⁷ Ultimately, changing the rebate system will not address a systemic problem driving high drug costs, which is brand drug manufacturers' unfettered ability to price their products and raise their list prices with impunity.

- **Section 8(B)(8) – Medical Loss Ratio (MLR) Compliance:** MLR requirements are not applicable to PBMs. Insurers have exclusive responsibility for MLR reporting and adherence to applicable state and federal requirements. As you know, insurers must provide rebates to members if medical costs fall below 80 percent of total revenues for certain product lines. With regard to PBM negotiated rebates with manufacturers, health plans are required to reduce claims by the amount of pharmaceutical rebates they receive in their MLR calculation and reporting and, beginning in 2022, also will be required to reduce claims for pharmaceutical rebates retained by the PBM.
- **Section 8(B)(11) – Reimbursement Lists or Payment Methodology Used by Pharmacy Benefit Managers:** Maximum Allowable Cost (MAC), or reimbursement, lists incentivize pharmacies to purchase generic drugs at the lowest price. They are designed to support the use of affordable generic medications, which account for 89 percent of filled prescriptions and only 27 percent of overall drug expenditures. A report by the HHS Office of Inspector General concluded MAC lists had “significant value” in “containing Medicaid drug costs.”⁸ Any regulations on MAC lists should not allow for disclosure of any proprietary information. By including this requirement, regulators are removing the incentive for pharmacies to keep costs low and increasing consumer costs at the pharmacy counter or in premiums.
- **Section 8(B)(14) – Spread Pricing Prohibited:** Plans and employers are tasked with finding cost-effective mechanisms to finance coverage of prescription drug benefits, and one such financing mechanism is spread pricing. There are several justifications for allowing private parties to include spread pricing provisions in their contracts. The use of spread pricing: (1) allows for consistent patient cost-sharing obligations throughout a benefit year; and (2) provides an attractive financing mechanism for certain employer groups (e.g., smaller-sized employers) with limited liquid capital, freeing up resources for other business priorities. As the subgroup further examines this issue, regulators could review if the current level of transparency for contracting parties is sufficient or if additional transparency may address regulators' concerns while retaining the flexibility for health plans and employers to use spread pricing to pay for pharmacy benefit management services.

⁶ Office of Inspector General (OIG), Department of Health and Human Services (HHS). [“Proposed Rule - Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.”](#) Federal Register. February 2019.

⁷ Milliman. “Prescription Drug Rebates and Part D Drug Costs: Analysis of historical Medicare Part D drug prices and manufacturer rebates.” 16 July 2018.

⁸ Department of Health and Human Services - Office of the Inspector General. [“Medicaid Drug Pricing in State Maximum Allowable Cost Programs.”](#) August 2013.

* * *

The NAIC's focus on rising prescription drug costs offers an opportunity to address a core issue driving the problem: the underlying list price of prescription drugs. Prices continue to rise – four of the nation's top 10 drugs have increased more than 100 percent from 2011 to 2016, and six others increased by more than 50 percent.⁹ Ultimately, the costs borne by every other entity in the supply chain – including consumers – are driven by the underlying list price charged by drug manufacturers. Meanwhile, PBMs and health plans leverage the tools outlined above to combat high list prices and improve patient outcomes. A recent report demonstrated the value of health plans and PBMs, finding that prescription drugs costs for commercially insured patients have fallen from \$10.83 to \$8.90 in the past five years, with the uninsured paying \$50.78 (up from \$36.77) per prescription.¹⁰ We will continue to work towards solutions that improve access to medicines and lower costs for patients, while aiming to reduce the underlying prices set by manufacturers.

We appreciate your consideration of our comments and look forward to working with you further in development of a uniform model. If you have any questions or want additional information, please contact Clay McClure at 202.626.8649 or at Clay.McClure@bcbsa.com.

Sincerely,



Clay S. McClure
Executive Director, State Relations
Office of Policy and Representation

CC:

Ray Farmer, NAIC President
David Altmaier, NAIC President-Elect
Dean Cameron, NAIC Vice President
Chlora Lindley-Myers, NAIC Secretary Treasurer
Michael Consedine, NAIC CEO
Martin Swanson, Subgroup Vice Chair
Laura Arp, Subgroup Vice Chair

⁹ Humer, Caroline. [Makers Took Big Price Increases on Widely Used U.S. drugs](#). Reuters. April 2016.

¹⁰ The IQVIA Institute. ["Medicine Spending and Affordability in the U.S. – Understanding Patients' Costs for Medicines."](#) Aug. 4, 2020.