



September 1, 2020

Commissioner Andrew Stolfi and Acting Administrator TK Keen

Chairs, Pharmacy Benefit Manager Regulatory Issues (B) Subgroup  
National Association of Insurance Commissioners  
444 North Capitol Street NW, Suite 700  
Washington, D.C. 20001-1512

Forwarded via email: Jolie H. Matthews

**RE: AHIP Comments on PBM Model Draft v7.6.2020**

Dear Chairmen Stolfi and Keen:

America's Health Insurance Plans (AHIP)<sup>i</sup> appreciates the opportunity to provide comments on the Pharmacy Benefit Manager Licensure and Regulation Model Act Draft dated July 6, 2020 as released by the NAIC's Pharmacy Benefit Manager Regulatory Issues (B) Subgroup.

Everyone should be able to get the medications they need at a price they can afford. AHIP and our members share this commitment with you. Pharmacy benefit managers (PBMs) play an important role in negotiating lower costs for hardworking Americans, and the savings achieved are passed on through lower premiums and lower out of pocket costs that health insurance providers offer to members.

We support an NAIC PBM Licensure Model that encourages uniformity among states on licensure requirements and gag clause prohibitions and we are encouraged by many elements of the first draft. We are providing technical recommendations on the licensure and gag clause portions of the model to align the draft with federal policy that was recently enacted and supported by a broad range of stakeholders. We are, however, extremely concerned with Section 8 (Regulations) of the model, which could effectively eliminate the few remaining tools health plans have to fight against out-of-control high-priced drugs. We believe this approach is wrong. Not only will it fail to solve the problem of ever-increasing drug prices, it will make it worse. Americans should not have to choose between paying their bills and accessing life-saving medicines, and AHIP is committed to working with NAIC to improving affordability through constructive policies that recognize drug pricing is a complex problem that cannot be solved without addressing the entire supply chain.

***High drug prices have created an affordability crisis for Americans.***

Ever-increasing list prices for prescription drugs means they now represent the largest segment of health care spending, accounting for more than 23% of commercial premiums<sup>ii</sup> and 19% of all Medicare costs.<sup>iii</sup> From 2020 to 2027, the Centers for Medicare & Medicaid Services (CMS) projects prescription drug spending will grow by 6.1% per year on average.<sup>iv</sup> To combat rising costs, health insurance providers have implemented consumer-driven and data-supported innovative pharmacy programs, such as medication utilization management programs and competitive formulary placement to ensure people have access to medically necessary care while lowering their out of pocket costs. These programs benefit the health care system overall by driving out waste while improving quality.

There are many links in the U.S. drug supply chain – drug manufacturers, PBMs, health insurance providers, pharmacies/pharmacists, pharmacy services administrative organizations (PSAOs), drug wholesalers, and providers – and all are involved in the process of prescribing and supplying prescription

drugs to Americans. When looking at how a drug's price impacts the final link in the supply chain – the patient – it is important to look at the entire chain, both individually and how they relate to one another. For example, PSAOs—which are typically owned and operated by drug wholesalers—provide negotiating power for independent pharmacies not only on drug supply purchasing, but also for contracting with PBMs, while their parent wholesalers supply all types of pharmacies (large chain, mail order, and specialty) with the drugs that will be dispensed to patients. In fact, the three largest PSAOs (each owned by drug wholesalers) provide services for almost 80% of independent and small chain pharmacies.<sup>v</sup> To fully understand independent pharmacy reimbursements, policymakers must consider the practices, activities, and relationships between all parts within the drug supply chain.

Even with all those entities in the supply chain, it's critically important to remember the process begins with, and is therefore driven by, the list price – which is set only by the drug manufacturer. This draft model's focus on just one facet of the drug supply chain is misplaced and will not substantively address the problem of list prices, to the detriment of patients. **We continue to urge the NAIC and policymakers across the country to review all aspects of the drug supply chain to ensure policy actions improve, rather than impair, access to affordable prescription drugs.**

### *PBMs ensure affordable and accessible medications for patients.*

In response to out-of-control drug prices, employers, health insurance providers, and government programs have turned to PBMs as an efficient and effective way to administer prescription drug benefits. PBMs' expertise and ability to negotiate directly with drug manufacturers leads to lower prices for health plans, employers, and taxpayers, ultimately resulting in lower out-of-pocket drug costs for patients. An overwhelming body of independent research shows that, thanks to their ability to negotiate, PBMs are part of the solution to lower health care costs. For example, the average price PBMs obtained from retail pharmacies for 14 brand name drugs was about 18% below the average price paid by customers without third-party coverage.<sup>vi</sup>

Without PBMs, acting alone, carriers, businesses, states, and individuals would be unable to achieve the same level of discounts or efficiencies. This is primarily due to the PBMs' ability to leverage the covered lives of *all* their plan sponsor and health insurance provider clients. Individual plan sponsors acting alone, can only leverage their own membership. By combining the covered lives of multiple types of payors, PBMs are a critically important lever, enabling patients to obtain the medications they need at the lowest possible cost.

PBMs also bring efficiencies to providing critical services to effectively manage increasingly complex drug benefits, including:

- Negotiating with drug manufacturers on price, with the goal of achieving the lowest price for individuals;
- Processing drug claims;
- Operating mail-order pharmacy programs;
- Providing drug formulary management, which may include pharmacy and therapeutics committees;
- Establishing and managing pharmacy networks to meet health plans' network adequacy requirements;
- Performing drug utilization review; and
- Managing disease management and drug adherence programs.

Health plans use PBMs to perform these services because they have the expertise and technology solutions to administer these functions in a cost-effective and efficient manner.

Health insurance providers are patients' bargaining power and use PBMs to strengthen that bargaining power against drug manufactures that dictate the price patients must pay for pharmacy care. By combining our bargaining power, PBMs will:

- save plan sponsors and consumers more than \$1 trillion this decade;
- help prevent 1 billion medication errors over the next decade; and
- reduce costs by \$10 for every \$1 spent on their services.<sup>vii</sup>

With this background on the critical functions that PBMs play to address the high price of drugs, the following are AHIP's recommendations on changes to the draft PBM Model.

### **AHIP Comments on NAIC draft PBM Model**

AHIP supports the adoption of a PBM model to establish state oversight through licensure and registration and codifies the federal gag clause law. We believe a measured approach to ensure uniformity and appropriate oversight of PBMs is sound policy that will meet the objectives of a model act. However, without the changes noted below, this model will have a severely detrimental impact on the ability of health insurance providers to lower the cost of pharmacy care for the hundreds of millions of Americans they serve every day.

#### ***Section 1: Short Tile***

AHIP has no suggested changes to this section.

#### ***Section 2: Purpose***

AHIP has no suggested changes to this section.

#### ***Section 3: Definitions***

In Section 3(C)(1)(c), we request "are employed" to be deleted as PBMs are not able to determine where a covered person is employed.

- (1) "Covered entity" means:
  - (c) An employer, a labor union or other group of persons organized in the state that provides health coverage to covered individuals who ~~are employed or~~ reside in the state

In Section 3(J), AHIP requests "covered entities" be excluded from the definition of "pharmacy benefit manager" to ensure health insurance providers, state programs, and employers do not have to register as such. Having covered entities who perform their own prescription drug services register and be licensed as PBMs is counter to the subcommittee's intent to regulate PBMs that are not currently licensed or registered with the department. To achieve this, we suggest the following change to Section 3(J)(2).

- (2) "Pharmacy benefit manager" does not include:
  - (a) A health care facility licensed in this state;
  - (b) A health care professional licensed in this state; ~~or~~
  - (c) A consultant who only provides advice as to the selection or performance of a pharmacy benefit manager; ~~or~~
  - (d) A covered entity that performs any claims processing or other prescription drug or device services for its enrollees.

#### Section 4: Applicability

Health insurance providers and PBMs should be given at least one full plan year after enactment to comply with licensure requirements. This will allow insurance departments to develop the appropriate process for licensure and for health insurance providers and PBMs to work through any variations in final legislation adopted by each state. We suggest adding this provision to Section 4, so the legislation can become effective in normal course to allow insurance departments to begin their implementation processes, while not applying to carriers for a full year after such date. “In this state” was added to clarify applicability.

##### Section 4. Applicability

- A. This Act shall apply to a contract or health benefit plan issued, renewed, recertified, amended or extended in this state, twelve months ~~or~~ after the effective date of this Act, including any covered entity that offers pharmacy benefits through a third party.

#### Section 5: Licensing Requirement

AHIP suggests the following change to the proposed licensing standards in Section 5(E). We believe criteria for refusing a license should be *objective* and judgments of competence, trustworthiness, and reputation are *subjective* and would lead to more confusion and variation among states, undermining the intent of setting uniform national standards.

- E. The commissioner may refuse to issue a license if the commissioner determines that the applicant or any individual responsible for the conduct of affairs of the applicant is not ~~competent, trustworthy,~~ financially responsible ~~or of good personal and business reputation,~~ or has had an insurance or other certificate of authority or license denied or revoked for cause by any jurisdiction.

#### Section 6: Gag Clause Prohibition

The term “gag clause” most commonly refers to 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. These gag clauses were banned by Congress (S.2553, Know the Lowest Price Act of 2018 and S.2554, Patient Right to Know Drug Prices Act). The bi-partisan legislation was supported by a broad group of stakeholders and according to the National Conference of State Legislatures, this is the type of gag clause prohibition used by a number of states; 33 state legislatures enacted gag clause prohibitions as of as of May 2019.<sup>viii</sup> AHIP supported the federal ban on gag clauses, and we support states that wish to adopt the federal law into their state insurance codes.

During the subcommittee’s exploratory presentations, a number of presenters spoke about gag clauses, but the data elements included in the NAIC draft model were not discussed in those presentations, nor is this the commonly used definition of “gag clauses.” We have the following concerns with this section as written:

- Pharmacists may not know or have full knowledge of any “financial incentives or structures used by the insurer” or a “process that is used to authorize or deny healthcare services or benefits.” Health insurance providers and PBMs may have proprietary financial arrangements which would not be known to the pharmacist. Allowing pharmacists to provide potentially incomplete and incorrect information is troubling and could cause consumer confusion.
- We are unsure of what the phrase “the covered person’s total cost for pharmacist services for a prescription drug” describes. Varying interpretations may unnecessarily foster confusion for plan enrollees. Using the federal statutory language clarifies what information is covered appropriately.

For consistency and uniformity, we propose the following changes so this section conforms to federal law.

## Section 6. Gag Clauses Prohibited

- A. In any participation contracts between a pharmacy benefit manager and pharmacists or pharmacies ~~providing prescription drug coverage for health benefit plans~~, no pharmacy or pharmacist may be prohibited, restricted or penalized ~~in any way~~ from disclosing to any covered person ~~any healthcare information that the pharmacy or pharmacist deems appropriate regarding:~~ any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health insurance coverage.
- ~~(1) — The nature of treatment, risks or alternative thereto;~~
  - ~~(2) — The availability of alternate therapies, consultations, or tests;~~
  - ~~(3) — The decision of utilization reviewers or similar persons to authorize or deny services;~~
  - ~~(4) — The process that is used to authorize or deny healthcare services or benefits; or~~
  - ~~(5) — Information on financial incentives and structures used by the insurer.~~
- B. ~~A pharmacy or pharmacist may provide to a covered person information regarding the covered person's total cost for pharmacist services for a prescription drug.~~
- C. ~~A pharmacy benefit manager may not prohibit a pharmacy or pharmacist from discussing information regarding the total cost for pharmacist services for a prescription drug or from selling a more affordable alternative to the covered person if a more affordable alternative is available.~~
- D. ~~A pharmacy benefit manager contract with a participating pharmacist or pharmacy may not prohibit, restrict, or limit disclosure of information to the commissioner, law enforcement or state and federal governmental officials investigating or examining a complaint or conducting a review of a pharmacy benefit manager's compliance with the requirements under this Act.~~
- E. A covered entity must ensure that any contracted pharmacy benefit manager does not prohibit, restrict, or penalize a pharmacy that dispenses a prescription drug from informing an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health insurance coverage.

## Section 7: Enforcement

AHIP has no suggested changes to this section.

## Section 8: Regulations

Section 8(A) must be clarified to ensure it provides a clear enabling legislative statute such that the intention of the law is accounted for accurately when promulgating regulations -- promoting clarity for all stakeholders. In addition, the broad and ambiguous delegation of authority does not follow the proper structure of an NAIC model act. We therefore respectfully suggest the following amendments so that this provision aligns with other NAIC Model acts' regulatory authority sections (e.g. Model 74, Model 36, and others).

### Section 8. Regulations

- A. The commissioner may after notice and hearing, promulgate reasonable ~~adopt~~ regulations to carry out the provisions of this ~~regulating pharmacy benefit managers that not inconsistent with~~ Act. The regulations shall be subject to review in accordance with [insert statutory citation providing for administrative rulemaking and review of regulations].

Section 8(B) is of most concern to health insurance providers and prevents us from supporting this Model Act as drafted. We strongly recommend its removal. Several of the items included would prohibit the only levers health insurance providers have to combat outrageously high list prices set by drug manufacturers. The regulations that could be adopted according to this section may prohibit or severely limit the use of key tools for health insurance providers to counter pharmaceutical companies' continued practices of manipulating the market to their advantage, and such restrictions would hand them a revenue windfall while harming consumers. We encourage the subgroup to instead focus on the root of the problem: out of control list prices set by the manufacturer.

We are concerned some of the items in Section 8(B) are a health insurance provider's responsibility and are inappropriate to include in a PBM model. These include:

- **Pharmacy network adequacy**, Section 8(B)(1), which is the carrier's responsibility, not the PBM's. The NAIC Health Benefit Plan Network Access and Adequacy Model Act (Model 74), includes pharmacies on the list of providers that a plan needs to have to illustrate an adequate provider network. Though PBMs may establish pharmacy networks for health insurance providers, network adequacy standards are the carrier's duty to meet.
- **Medical loss ratio (MLR)**, in Section 8(B)(8), is also a requirement of health insurance providers, not PBMs. Health plans are already required to include revenue from rebates in their MLR calculations. The 2021 Notice of Benefit and Payment Parameters was just adopted to require more granular rebate data to be reported, whereby issuers will report and deduct from incurred claims, prescription drug rebates and other price concessions when received by the issuer or by a PBM.

Additionally, we note several topics in Section 8(B) were not explored in the subcommittee's work yet are included in the draft model. A search through the subcommittee and stakeholder presentations found that no presenters discussed **data reporting under price-gouging laws** (Section 8(B)(3)), **corporate practice of medicine** (Section 8(B)(5)), or **affiliate information-sharing** (Section 8(B)(9)). A topic that was not raised by any stakeholder or regulator in the exploratory process should not rise to the level of inclusion in an NAIC model without a more detailed examination to understand all aspects of the issue.

AHIP believes the inclusion of **rebates** in Section 8(B)(4) results from misperceptions of what they are, and their role within the admittedly complex drug pricing and reimbursement process. It is important to note the majority of brand-name drugs do not have rebates; only those that have one or more competitors within the drug's class typically do.<sup>ix</sup> Working on behalf of health insurance providers, employers, and state government, PBMs effectively negotiate rebates from drug manufacturers.

- Rebates have consistently been shown to save consumers money. Most recently, the Office of Inspector General (OIG) in the Department of Health and Human Services (HHS) found the federal "Rebate Rule" proposal to eliminate rebates in Medicare and Medicaid would increase premiums by up to 25% and increase drug spending in the Medicare program by \$196 billion.<sup>x</sup>
- Any restrictions on use of manufacturer rebates could significantly impair the ability of health plans and PBMs to develop and implement Value-Based Payment (VBP) designs in the drug benefit space. This is because the primary mechanism for reconciling payment based on past performance for value is a rebate. VBP inherently relies on evaluating a drug's performance and adjusting payment according to whether measures on quality, safety, adherence, etc. have been met. We urge NAIC to carefully consider the significant effects restricting rebates could have on the development of innovative benefit designs that foster value over fee-for-service models.
- Additionally, the Robinson-Patman Act and an ensuing class action lawsuit<sup>xi</sup> limited drug companies' ability to provide direct discounts, so rebates are left as the only lever health insurance providers and PBMs can use to demand lower drug prices.

AHIP is also concerned with the prohibition of **spread pricing** as described in Section 8(B)(14). Spread pricing is one way a health care purchaser can structure a contract and compensation terms with a PBM. Under a spread pricing model, PBMs set a pricing guarantee for their clients to give predictability

regardless of any fluctuations in manufacturers' price or supply. Spread pricing may be used only when both parties agree to it, after weighing its potential effects.

- Drug prices go up year after year, often multiple times per year. Many health plans and employers choose a spread pricing model because it provides financial predictability against fluctuations in drug prices during a plan year and subsequently stabilizes premiums, which benefit the Americans they serve. Unlike health insurance providers, whose premium rates are set for an entire year, drug manufacturers can change the price of a drug whenever and however often they choose during the year. For this reason, pricing arrangements that provide predictability can be highly attractive to plan sponsors, especially smaller plan sponsors who may not have the resources to absorb drug price fluctuations.
- We believe this should remain a contracting option and the NAIC should not be dictating preferences for contract or compensation terms between two private – and knowledgeable – parties.

### **Section 9: Severability**

AHIP has no suggested changes to this section.

### **Section 10: Effective Date**

As we noted above in Section 4, we ask that health plans and PBMs be given at least one full plan year after enactment to comply with licensure requirements. We suggest adding the following provision here and to Section 4, so that the legislation can become effective in normal course to allow insurance agencies to begin their implementation processes, while not applying to health insurance providers for a full year after such date.

#### **Section 10. Effective Date**

This Act shall be effective [insert date]. A person doing business in this state as a pharmacy benefit manager on or before the effective date of this Act shall have [~~twelve~~ ~~six~~ (6)] months following [insert date that the Act is effective] to come into compliance with the requirements of this Act.

AHIP looks forward to working together to identify language that best permits states to license PBMs while allowing these entities to continue their vital role in lowering drug costs on behalf of purchasers of pharmacy care. With the technical corrections incorporated and removal of Section 8(B), we stand ready to work together in advocating for its adoption in states which have not already addressed licensure or registration of PBMs and gag clause protections.

We truly appreciate the Working Group's collaboration with all stakeholders and look forward to answering any questions as they arise during discussions of the first draft. Please reach out to Miranda Motter at [mmotter@ahip.org](mailto:mmotter@ahip.org) / (202) 923-7346 and Kris Hathaway at [khathaway@ahip.org](mailto:khathaway@ahip.org) / (202) 870-4468 with any questions or concerns related to our comments.

Sincerely,



Miranda Motter  
Senior Vice President, State Affairs and Policy  
America's Health Insurance Plans

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- i America's Health Insurance Plans is the national association whose members provide insurance coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access and well-being for consumers
- ii *Where Does Your Premium Dollar Go?* America's Health Insurance Plans. March 2, 2017. Available at <https://ahip.org/health-care-dollar/>.
- iii *Overview: Medicare Drug Spending.* MedPac. June 16, 2016. Available at <http://www.medpac.gov/docs/default-source/fact-sheets/overview-of-medicare-drug-spending.pdf?sfvrsn=0>.
- iv *National Health Expenditure Projections 2018-2027.* Centers for Medicare and Medicaid Services. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf>.
- v *Pharmacy Services Administrative Organization (PSAO) Coalition.* Scott Pace. Presentation to the Wisconsin Governor's Task Force on Reducing Prescription Drug Prices. June 18, 2020. Available at [https://rxdrugtaskforce.wi.gov/Documents/PSAO\\_Coalition.pdf](https://rxdrugtaskforce.wi.gov/Documents/PSAO_Coalition.pdf).
- vi *Federal Employees' Health Benefits – Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies.* US General Accounting Office (GAO). January 2003. Available at <https://www.gao.gov/assets/240/236828.pdf>.
- vii *Pharmacy Benefit Managers: Generating Savings for Plan Sponsors and Consumers.* Visante. February 2020. Available at <https://www.pcmagnet.org/wp-content/uploads/2020/02/Pharmacy-Benefit-Managers-Generating-Savings-for-Plan-Sponsors-and-Consumers-2020-1.pdf>.
- viii *PBM State Legislation: States Regulating Pharmaceutical Benefit Managers.* NCSL. May 16, 2019. Available at <https://www.ncsl.org/research/health/pbm-state-legislation.aspx>.
- ix *Prescription Drug Rebates and Part D Drug Costs.* Milliman. July 16, 2018. Available at <https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf>.
- x *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.* Office of the Inspector General, Department of Health and Human Services. February 6, 2019. Available at <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.
- xi *AHIP Issue Brief: Rebates and Antitrust.* America's Health Insurance Plans. October 2019. Available at <https://ahip365.sharepoint.com/:b:/g/EfosHGMtY4FDh5u1RZOKinoBn8RbXZxSsmx45c28ro0KTA?e=BIFYmR>