



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

September 15, 2023

Commissioner Sharon Clark, Chair  
Regulatory Framework (B) Task Force  
National Association of Insurance Commissioners  
444 North Capitol Street NW, Suite 700  
Washington, DC 20001-1512

Submitted electronically to Jolie H. Matthews (JMatthews@naic.org)

**Re: BCBSA Comments on NAIC PBM White Paper Draft**

Dear Commissioner Clark:

The Blue Cross Blue Shield Association (BCBSA) would like to thank NAIC for the consideration and incorporation of several of our recommendations in the PBM white paper, "A Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation."

We appreciate the opportunity to resubmit our previous recommendations that were not incorporated into the latest version of the white paper. As the Taskforce reviews the white paper, we encourage you to employ more neutral language in reference to the entities highlighted in the paper, make additional changes that will adhere to the Subgroup's white paper charge, and carefully consider whether the "Recommendations" warrant inclusion in an educational resource. Below, we highlight three priority recommendations from our June 1 comment letter, that address critical aspects BCBSA believes could further enhance the white paper:

1. **Incorporate additional details on the role of manufacturer copay coupons.** Specifically, inclusion of language noting: (1) copay coupons can increase utilization of expensive drugs when more affordable options are available and (2) copay coupons are prohibited in government programs.
2. **Provide additional discussion of rebates.** We recommend including additional examples and context for when rebates are and are not available to provide a more comprehensive description of the issue.

3. **Include details on patent thickets.** BCBSA recommends including details, under the section covering manufacturer licensing, on how patent thickets delay competition. This occurs when pharmaceutical manufacturers obtain multiple patents that cover one drug or minor variations of the drug.

In our June 1 letter, we suggested the following edits to address these three recommendations:

1. **Incorporate additional details on the role of manufacturer copay coupons** [Pg. 11]

- *Pharmaceutical manufacturer and consumer*

Pharmaceutical manufacturers can offer coupons or occasionally free samples of medications to consumers. The coupons can reduce a consumer's cost sharing below that which they would have paid had they used their pharmacy benefit plan. While coupons lower costs for some patients at the pharmacy counter, they mask the true costs, promote the use of high-cost drugs and increase sales for branded drug companies by over 60%, even when lower cost generics may be available.

(<https://www.aeaweb.org/articles?id=10.1257/pol.20150588>) Coupons are prohibited for use by beneficiaries enrolled in Medicare, Medicaid and other government programs because they "induce the purchase of Federal health care program items or services" – that is, the drug manufacturer offering the coupon is directly benefitting from its use.

([https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB\\_Copayment\\_Coupons.pdf](https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf))

2. **Provide additional discussion of rebates**

- The white paper discusses the role of rebates in the pharmaceutical drug ecosystem, and we recommend additional examples and context for when rebates are and are not available. [Pg. 17]
  - Rebates are mostly used on brand-name and specialty drugs where similar competing drugs from other manufacturers exist. Manufacturers commonly do not offer rebates on brand drugs and biologics when competition from other drugs does not exist; and, 64% of Medicare Part D brand drugs analyzed did not have rebates.  
(<https://www.ahip.org/resources/prescription-drug-rebates-and-part-d-drug-costs-analysis>)
- In describing the proportional rebate pass-through model, we note the PBM keeps a percentage of the rebate as *the fee for administering the pharmacy benefit* and passes the remainder back to the plan sponsor. This clarifies the rebate retention acts as the service fee to the PBM [Pg. 17].
  - Proportional pass-through – The PBM keeps a percentage of the rebate as the fee for administering the pharmacy benefit and passes the remainder back to the plan sponsor.
- The paper also discusses providing rebates at the point-of-sale and cites that some insurers have indicated it would result in no additional premium cost [pg.

18]. We recommend citing studies on the impact of rebates at point-of-sale on premiums.

- Rebates at point-of-sale (POS): ... Additionally, members with low or no prescription drug usage might experience a disproportional impact as they would be paying higher premiums and would not have a financial benefit from the POS rebates. In a 2017 proposed rule regarding Medicare Part D plans, CMS requested feedback on a proposal to pass on rebates to beneficiaries at the point-of-sale. According to CMS, this proposal would raise premiums by up to \$28 billion and taxpayer costs by up to \$82 billion over the following decade. (Centers for Medicare & Medicaid Services. Proposed Rule. "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.") Some insurers have indicated...

### 3. Include details on patent thickets [Pg. 24]

- [Start new paragraph] Pharmaceutical manufacturers commonly seek to extend their patent protection period by providing a new formulation of a drug or changing the route of administration for a drug. This can result in a situation where multiple patents, often overlapping or with complex dependencies, create a dense and complex web of patents hindering competition and innovation. Also referred to as, patent thickets, this practice inhibits or delays generic drugs or biosimilars from entering the market. The Initiative for Medicines, Access, and Knowledge (I-MAK), an organization advocating for affordable access to medicines, released a report on the top ten selling drugs in the United States revealed that, 66% of patent applications were filed after the FDA approved the drug to be on the market (<https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf>). Additionally, lower-cost generic and biosimilar versions of three top selling drugs - Humira, Eliquis, and Enbrel - launched in Europe an average of 7.7 years earlier than their expected U.S. entry. During this time, Americans will spend an estimated \$167 billion on branded versions of just these three drugs (Ibid.).

We believe that these recommendations can contribute to the comprehensiveness of the white paper, aligning it more closely with the PBM Subgroup's related charge and the evolving landscape of the Rx drug supply chain and regulations of entities in it.

BCBSA remains concerned with NAIC pursuing any new model guidelines (recommendation #1 in the white paper) or updated model legislation (recommendation #3 in the white paper). The uncertainty of ERISA and Medicare Part D legal issues and the current low uptake of Model 22 across states, creates a policy landscape in which adoption of new model guidelines would likely be low.

We appreciate NAIC's commitment to an inclusive and iterative approach to refining this white paper. If you require any additional information or clarification, please do not hesitate to contact [Randi Chapman](#), managing director, state affairs. Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink that reads "Clay S. McClure". The signature is written in a cursive, flowing style.

Clay S. McClure  
Executive Director, State Affairs  
Blue Cross Blue Shield Association