



June 1, 2023

The Honorable TK Keen, Chair
Pharmacy Benefit Manager Regulatory Issues (B) Subgroup
National Association of Insurance Commissioners
444 North Capitol Street NW, Suite 700
Washington, DC 20001-1512

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

Submitted via email to Jolie Matthews: JMatthews@naic.org

RE: BCBSA Comments on NAIC's Draft PBM White Paper, *Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation*

Dear Chairman Keen and members of the Subgroup:

The Blue Cross Blue Shield Association (BCBSA) appreciates the opportunity to provide comments on NAIC's draft PBM white paper, "Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation." BCBSA values the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup's (Subgroup) development of a white paper to analyze the role of Pharmacy Benefit Managers (PBMs) and the associated regulatory landscape. To meet the expansive charge of analyzing and assessing the role of all supply chain entities in the provision of prescriptions drug benefits and examining regulatory approaches to PBM practices, we have included comments and recommendations to this white paper.

BCBSA is a national federation of 34 independent, community-based and locally operated Blue Cross and Blue Shield (BCBS) companies (Plans) that collectively provide health care coverage for one in three Americans. For more than 90 years, Blue Cross and Blue Shield companies have offered quality health care 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.

Given the unsustainable increases in prescription drug prices over the years, BCBS Plans contract with PBMs to drive value for our members. One way this is accomplished is by PBMs leveraging their volume of covered lives to negotiate with manufacturers and others in the drug supply chain to secure the lowest net prices. Savings secured by PBMs through rebates and other negotiations are passed along to their health plan and employer clients, who use those savings to decrease premiums and/or reduce out-of-pocket costs for prescription drugs for all members.

BCBSA and BCBS Plans are committed to lowering drug costs and increasing access and have taken active steps in recent years to address the ongoing challenges of prescription drug affordability. In 2020, BCBSA announced a partnership with Civica Rx to create a new, non-profit subsidiary – CivicaScript – dedicated to lowering the cost of select, outpatient generic drugs. The \$65 million investment by BCBSA and 19 independent BCBS companies will help ensure Americans can access/get the generic prescription drugs they need at a price they can afford. For example, in 2022, CivicaScript launched the generic drug, abiraterone 250mg, used in combination to treat prostate cancer. The average cost of a month's supply of abiraterone 250mg to Medicare Part D in 2021 was over \$3000. However, CivicaScript's selling price is \$160.

Last year, Civica Rx expanded its work, partnering with BCBSA and 12 Plans, to increase access to affordable insulin. Civica's insulin initiative has brought together partners from across the industry,

representing nearly every corner of the diabetes ecosystem. Through this insulin initiative, Civica will manufacture and distribute three analog insulins – that will cost consumers no more than \$30 per vial or \$55 for a box of five pens – starting in 2024.

As outlined above, BCBSA and BCBS companies are committed to improving the affordability of prescription drugs and enhancing the public’s understanding of the prescription drug supply chain. Our priority recommendations for consideration in the White Paper are as follows:

1. *Insurers contract with PBMs to provide their members with more affordable health insurance by leveraging larger discounts for prescription drugs than an insurer could negotiate on its own. **Therefore, we recommend incorporating details on the relationship between insurers and PBMs.***
2. *Employers play a decisive role in the drug pricing ecosystem, for example, employers looking to finance coverage of prescription drug benefits have the option to finance via a spread pricing mechanism rather than an administrative fee to the PBM, freeing up resources for other business priorities. **Therefore, we recommend highlighting employers in the “Key Players” section of the paper.***
3. *Provide additional discussion of PBM 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.*** In addition, we suggest describing key federal statutes such as the Robinson Patman Act and a series of pivotal class action lawsuits in the 1990s that shaped the current rebate system.
4. *Copay coupons can increase utilization of expensive drugs when more affordable options are available. Copay coupons are prohibited in government programs. Copay accumulator programs are a vital tool to keep health insurance affordable. **Therefore, we recommend incorporating additional details on the role of manufacturer copay coupons and copay accumulator programs.***
5. *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 a new model would likely be low. **We believe it would not be prudent for the NAIC to pursue the development of a new or updated model at this time.***

In what follows, we expand on our key recommendations and include redlined suggestions in the white paper for the Subgroup’s consideration. We appreciate your consideration of our comments and look forward to continuing to work with NAIC as it works to finalize the white paper. If you have any questions or want additional information, please contact Randi Chapman, Managing Director, State Affairs at Randi.Chapman@bcbsa.com or Paul Eiting, Managing Director, Legislative and Regulatory Policy at Paul.Eiting@bcbsa.com.

Sincerely,



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

SECTION B – KEY PLAYERS IN PHARMACEUTICAL DRUG PRICING ECOSYSTEM

- **Additional details on definition of insurer and manufacturer**
 - BCBSA recommends adding to the Key Player-Insurer section that insurers contract with PBMs primarily to leverage steeper discounts than an insurer could negotiate on its own. [Pg. 4]
 - Insurers contract with PBMs to manage the pharmacy benefit portion of their health care benefits provided to their insureds and enrollees. Insurers contract with PBMs because of the increasing complexity of prescription drug benefit management. Insurers leverage a PBM's volume of covered lives (collectively providing coverage for millions of lives across insurers and employers) to secure larger discounts from manufacturers on prescription drugs for their members, than what an insurer could negotiate on its own. In addition, in response to increasing prescription drug costs some insurers contract with PBMs for their services that help reduce drug costs and overall premiums, including utilization management, prescription drug rebates, and negotiation of pharmacy fees and prescription drug reimbursement, and access to pharmacy networks. Ultimately, the scope of the PBM's role in managing this benefit depends on the insurer.
 - BCBSA recommends noting in the Key Player-Manufacturers section when and how often manufacturers set prices. [Pg. 5]
 - Pharmaceutical manufacturers research, develop, produce, market, and sell prescription drugs to treat medical conditions. The development of a new pharmaceutical product involves an investment of resources to create a product ready to be tested during clinical trials, where the safety and clinical efficacy of the drug are evaluated for a specific disease or condition. The U.S. Food and Drug Administration (FDA) reviews all applications for the sale of new drugs from manufacturers following clinical trials and decides whether the drug will be made available on the market to consumers. When a drug is approved, manufacturers then set the list price for medications and may change that price over time. Manufacturers have sole discretion to increase prices, which generally are announced and implemented in January and July (<https://aspe.hhs.gov/sites/default/files/documents/d850985c20de42de984942c2d8e24341/price-tracking-brief.pdf>).
- **Include additional Key Players**
 - BCBSA recommends the addition of two “Key Players” to this section: Employers, who are a primary purchaser of health insurance coverage bear financial responsibility for the cost of prescription drugs; and Providers, who drive utilization of drugs via prescribing patterns, and purchase and administer certain injected and infused medicines. [Pg. 4]
 - **Employers:** Employers are the primary purchasers of health insurance coverage for employees and their families in the commercial market. In the fully-insured market, employers purchase health insurance coverage from a regional, state or national insurance carrier. While not a part of the prescription drug supply channel, employers are cognizant of costs for drugs and other health care items and services as the primary consumer of health insurance coverage.
 - **Providers:** Health care providers are a part of the pharmaceutical drug ecosystem in the role of prescriber and treating clinician. Providers write prescriptions that result, collectively, in driving demand for prescription drugs. Providers support patients in selecting the most effective treatment and support

patient access issues (identifying generics or other low-cost therapies; identifying over-the-counter options; providing manufacturer copay coupons, etc.). Providers also purchase and administer infused or injected medicines.

- **Provide additional background on manufacturer copay coupons and copay accumulators**

- *Copay Coupons:* We recommend explaining more fully the role of manufacturer copay coupons in the pharmaceutical drug ecosystem. Coupons can undermine formularies by increasing utilization of expensive drugs when more affordable options are available. They are also prohibited in federal programs. [Pg. 10]

- *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 help 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)

- *Copay Accumulators:* In the context of copay coupons, we recommend language noting how some states and the federal government allow the use of copay accumulators to keep health insurance affordable and encourage use of the lowest cost, most effective drugs. [Pg. 10]

- *Manufacturer and consumer*

...

If the coupon constitutes a third-party paying the consumer's cost share, some state laws require insurers to count this payment towards the consumer's deductible and pharmacy benefit maximum out of pocket amount. Other states allow an insurer to calculate true out-of-pocket spending without counting drug manufacturer coupons toward a member's deductible or out-of-pocket maximum (i.e., copay accumulator programs). The Centers for Medicare & Medicaid Services' (CMS) policy explicitly allows copay accumulator programs.

- **Provide employer perspective on spread pricing optionality**

- BCBSA recommends including details under the description of spread pricing to describe the role of large and small employers. 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. [Pg. 10]

- Spread pricing – The payor, which may include employers, will either not pay or pay a reduced administration fee and the PBM will retain certain risk related to the difference between the price paid by the customer and the price paid to the pharmacy (whether the spread is profitable will vary from drug to drug). This provides set price assurance to the payor. Spread pricing provides a financing

mechanism for employers, in particular mid-sized employers, with limited liquid capital to apply toward employee benefit plans. Such employers have the option to finance pharmacy benefits via a spread pricing mechanism rather than an administrative fee to the PBM, freeing up resources for other business priorities.

SECTION D – FUNCTIONAL ISSUES

- **Provide fuller discussion on formulary design (1. Formulary Design)**
 - BCBSA recommends including additional details on payor formulary design to explain how formularies are developed using external clinical experts, the factors used to evaluate drugs for inclusion on formularies and tiers and the standards in place to ensure patient access to safe and effective treatments for diseases and conditions. [Pg. 15]
 - PBMs implement formularies or lists of covered drugs. The primary purpose of the formulary is to encourage the use of safe, effective, and affordable medications based on the latest scientific evidence. PBMs' customers – payors, such as insurers or self-funded employer plans, may request open formularies, develop their own formularies, or purchase formularies from PBMs. Even closed formularies typically require coverage for at least one drug per therapeutic class.

For PBM developed formularies, PBMs and insurers use panels of multidisciplinary experts who form called Pharmacy and Therapeutics (P&T) Committees. These committees, made up of independent physicians, pharmacists, and other health care providers, evaluate clinical and medical literature to select the most appropriate medications for individual disease states and conditions. The federal Affordable Care Act (ACA) introduced federal regulations on P&T Committees serving qualified health plans (QHPs).

P&T Committees typically review drugs for safety and efficacy to identify those that are required (preferred), unacceptable and acceptable based on medical standards. The category of those that are determined acceptable is where there is leeway on the PBM's part to determine formulary inclusion. Other factors that may influence placement of a drug on the formulary or a particular tier include the presence of alternative therapies in the same class, the drug's relative toxicity compared to similar treatments, the price of the drug in comparison to other drugs used for the same type of treatment, and whether there is an over-the-counter alternative. While the cost-effectiveness of a drug is a factor, it is by no means the only factor.

The PBM will look at acceptable drugs that have been determined "clinically equivalent" and negotiate for the highest rebate and include these drugs in the formulary. PBMs negotiate drug costs with pharmaceutical manufacturers across the board for all customers using their volume of scale and then work with individual customers to create formularies.

Formularies provide lists of pharmaceutical drugs covered by payors and can be differentiated between preferred or discouraged products by dividing into three to five "tiers," each with a separate level of cost sharing. By placing a drug in a preferred tier, PBMs can drive volume to that drug's manufacturer. This is an

effective way for PBMs to generate rebates for either multi-source brands or competing brands in a therapeutic class. The PBM then ~~keeps the rebates or~~ [this language is redundant] shares all or a percentage of the rebate with the plan sponsor or patient, depending on the PBMs contract with the plan sponsor.

Since formularies are essentially coverage decisions, a PBM's step-therapy protocol may be viewed as part of its formulary. Step-therapy requires a patient to try a particular drug before another drug is covered. PBMs may shift drugs between tiers or add or remove them from the formulary entirely during a plan year, a practice which is known as substitution. ~~"non-medical switching."~~ If a drug is excluded from a formulary, plans will cover at least one alternative treatment that is both as effective and safe in treating a disease or condition.

- **Provide additional background on drug manufacturer rebates (2. Rebates)**

- The primary form of drug discounts by PBMs has evolved into manufacturer rebates on some brand and specialty drug products. 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. 15]
 - Rebates are mostly used on branded and specialty drugs where there exist similar competing drugs from other manufacturers. 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>) From a manufacturer's perspective, the rebate is a tool to incentivize PBMs to place the manufacturer's drugs on formularies within preferred tiers. PBMs negotiate based on their volume of scale to obtain highest rebate for selected drugs. From the PBM's perspective, a large rebate results in a smaller amount spent by their customers and more income for the PBM from proportional pass-through contracts.
- 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.
 - 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. We recommend citing studies on the impact of rebates at point-of-sale on premiums.
 - Rebates at point-of-sale (POS): Some believe that rebates should be provided directly to consumers at POS to reduce deductibles or co-insurance amounts owed when the drug is purchased. As a result, these funds would no longer be used to offset the plan sponsor costs and could result in higher premiums for all members. 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 that passing the rebates to the consumer at POS would have a dramatic enough effect on drug adherence that it would cover the potential benefit of using the rebates against premiums and result in no additional premium cost.

- We recommend this section include information on barriers to the full elimination of rebates, specifically citing the Robinson Patman Act and 1990s chain pharmacy litigation, and the consequences if rebates were eliminated. [Pg. 16]
 - Elimination of rebates: The manufacturer rebate system arose from a series of class action lawsuits in the 1990s when drug manufacturers faced Sherman Act conspiracy claims and Robinson-Patman Act pricing discrimination claims that threatened manufacturers’ ability to provide up-front discounts to purchasers. The result was the rapid conversion of manufacturer up-front discounts to manufacturer back-end rebates.

Some have recently called for the elimination of rebates to provide more price transparency within the system. Given the legal barriers to providing up-front discounts in place of back-end rebates, While the elimination of rebates might serve to achieve this, it could also would cause a major disruption in the drug supply channel and decrease the level of discounts manufacturers offer to payors. In an analysis of a CMS proposal to restrict rebates in Medicare Part D, the CMS’s Office of the Actuary estimated that manufacturers would retain 15 percent of current rebates, meaning manufacturers would offer lower discounts. (<https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationmpact.pdf>) current market conditions. In the short term, eliminating rebates could lead to increasing the cost of drugs to PBMs, plan sponsors and ultimately consumers without corresponding legislation to lower pharmaceutical manufacturer prices. In the longer term, eliminating rebates could lead to increased transparency in price competition between manufacturers of similar drugs as price setting would no longer happen in a private contractual setting with a PBM. In an alternative finding from the FTC, if manufacturers learn the amount of the rebates or discounts offered by competitors, then “tacit collusion among manufacturers is more feasible” and may lead to higher drug prices. (FTC Letter to California Assembly Member Greg Aghazarian. 7 September 2004. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf)

- **Include additional details on “gag clauses” (3. Pricing and Contracting Practices)**
 - BCBSA recommends citing federal legislation enacted in 2018 that prohibited the practice of “gag clauses”. [Pg. 17]

- Gag clauses: The term “gag clause” refers to a stipulation in a pharmacy benefit contract that prohibits a pharmacy or pharmacist from informing consumers of an alternative option when purchasing a drug. For instance, a gag clause may prohibit a pharmacist from telling a consumer about a generic version of a prescription drug or if a prescription drug can be purchased at a lower price out-of-pocket rather than through their insurance plan. In 2018, Congress passed federal legislation prohibiting “gag clauses” for pharmacists and other providers. (<https://www.congress.gov/bill/115th-congress/senate-bill/2553>; <https://www.congress.gov/bill/115th-congress/senate-bill/2554>)
- **Input from third-party accreditation bodies**
 - BCBSA recommends NAIC reach out to the Utilization Review Accreditation Commission (URAC) or other independent accrediting bodies to provide input on the pharmacy network adequacy standards section of the paper. URAC may be able to provide important information on the value of pharmacy accreditation and the importance of third-party accreditation bodies. [Pg. 20]
- **The role of state regulation over pharmaceutical manufacturers**
 - BCBSA does not agree with the conclusion that, “...there is little states can do about some of the life cycle management practices manufacturers engage in to extend the market exclusivity of their drugs.” Instead, we recommend replacing this with a description of the role state legislators and attorney generals can play over pharmaceutical manufacturers. [Pg. 22]
 - While most states require pharmaceutical manufacturers that produce or distribute drugs within their state to be licensed, ~~states exercise little total control over pharmaceutical manufacturers.~~ the FDA is responsible for approving new drugs and allowing for a given drug's patent protection period, which gives manufacturers a period of exclusivity before generics of that drug are allowed to be produced. Because the federal government is responsible for this function, the role of states to regulate the life cycle management practices manufacturers engage in to extend the market exclusivity of their drugs is primarily conducted through state attorney general led investigations or with state legislation. For example, in 2017, California signed into a law a drug transparency bill (SB-17), requiring pharmaceutical manufacturers to notify purchasers of planned cost increases.
- **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. [Pg. 22]
 - [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.).

- **Include licensure details of PSAOs**

- BCBSA recommends including information on state action to regulate pharmacy services administrative organizations (PSAOs) while highlighting the lack of federal regulation and transparency. [Pg. 23]
 - ¶ [New section] **Pharmacy Services Organizations**
The regulation and licensing of pharmacy services administrative organizations (PSAOs) varies depending on the jurisdiction. PSAOs are not regulated at the federal level but some states have taken action to license and increase transparency of PSAOs. For example, in 2021, Louisiana passed a bill to regulate and license PSAOs (<https://legiscan.com/LA/bill/HB244/2021>). In Maryland, PSAOs must register and disclose specific information to the Maryland Insurance Commissioner. In Washington, PSAOs must report to the Washington Health Care Authority on the pharmacies they negotiate for and their fee structure (<https://casetext.com/statute/code-of-maryland/article-insurance/title-15-health-insurance/subtitle-20-pharmacy-services-administrative-organizations>; <https://www.hca.wa.gov/assets/program/PSAO-data-submission-guide-v3.0.pdf>).

SECTION E – STATE LAWS THAT OPERATE IN THE SUPPLY CHAIN

- **Remove references to legislation that has not been enacted**

- BCBSA recommends maintaining the focus of the white paper on legislation that has been enacted. The impact and implications of legislation that has not been enacted is uncertain and subject to change during the legislative process. [Pg. 23]

- **Include federal preemption issues regarding state drug importation programs**

- BCBSA recommends noting that while states can create wholesale importation programs to purchase lower-cost drugs, it's important to note that these programs require approval from the federal government and must meet specific standards. [Pg. 25]
 - This legislative approach would create a state wholesale importation program to purchase lower-cost drugs from Canada and make them available to state residents through an existing supply chain that includes local pharmacies. States must work closely with the federal government to ensure the program complies with federal rules and regulations, such as those outlined under Section 804 of the Federal Food, Drug, and Cosmetic Act.

- **Include a description of PSAO transparency laws**
 - BCBSA recommends including a brief paragraph under the “Other Relevant State Laws and Proposed Laws” section to include information on state action to regulate PSAOs. [Pg. 25].
 - **¶ [New section] Licensing and Transparency of Pharmacy Services Administrative Organizations**
Some states have proposed or implemented laws regulating pharmacy services administrative organizations (PSAOs). These laws aim to promote transparency and typically require PSAOs to obtain licensure and registration with the State Insurance Commissioner to ensure compliance with specific standards and eligibility criteria. These regulations may also include reporting and auditing requirements to ensure accountability and compliance with regulations. This can involve submitting regular reports, financial disclosures, or undergoing audits of their operations.

SECTION F – FEDERAL INTEREST AND POSSIBLE REGULATIONS

- **Incorporate neutral language**
 - BCBSA recommends replacing the phrase, “prescription drug middleman industry” with the more neutral phrase, “Pharmacy Benefit Manager industry.” We acknowledge that the term used was a direct quote from the FTC but we believe avoiding this term will be important to keep the white paper fair and balanced. [Pg. 27]

SECTION H – RECOMMENDATIONS

- **Concern with new model guidelines and updating Model 22 (Recommendation #1 and #3)**
 - *Model guidelines:* The white paper includes descriptions of the pharmaceutical drug supply chain, legal considerations and examples of state activities regulating supply chain entities. We believe the creation of this white paper will provide states with adequate resources and creating model guidelines would be duplicative.
 - *Updating Model 22:* Given the amount of uncertainty with the ERISA/Part D legal issues referenced in the paper, as well as the current low uptake of Model 22 across states, we do not believe it would be prudent for NAIC to approve an updated model at this time.
- **Avoid recommendations related to the federal 340B Drug Pricing Program (Recommendation #4)**
 - The 340B program touches many supply chain entities and has complex interchanges on transactions between such entities. While there are state proposals to regulate these transactions, BCBSA does not support NAIC developing recommendations given that the 340B program is not discussed in this white paper.
- **Support maintaining a compendium of state laws, regulations and case law (Recommendation #7)**
 - As a complementary state resource to this white paper, BCBSA supports the NAIC Subgroup continuing to maintain a current listing of laws, regulations and case law of PBMs – and other supply chain entities – for reference by other states to avoid duplication of state laws.