Landscape Analysis of Tennessee Pharmacy Benefit Managers

Final Report

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PUBLIC CONSULTING GROUP

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EXECUTIVE SUMMARY

Public Consulting Group (PCG) was contracted by the Tennessee Department of Commerce and Insurance (the Department) to complete a landscape analysis of the State's active Pharmacy Benefit Managers (PBMs). By comparing current Tennessee market trends to national best practices, this analysis aimed to identify whether and to what extent additional legislative or regulatory action in this area may benefit Tennessee consumers and stakeholders.

Our analysis begins with a review of published PBM best practices, including optimal PBM contracting terms and proposed model legislation. We then provide a national review of enacted PBM legislation, identifying the most common issues and trends as well as settled and pending litigation impacting such legislative efforts. As noted throughout the best practices and legislative review in this report, a major focus for health plans and regulators is understanding where health care dollars are spent and what value is gained. The complexity of PBM operations and their various roles as an intermediary has stoked a desire for greater transparency in this area. To help navigate this space and provide a quick reference guide to accompany this report, Appendix A provides a glossary of common terms related to PBM operations.

To understand the relevancy of such policies to the Tennessee market, we completed two additional Tennessee-specific analyses. The first included a comparative analysis of Tennessee and neighboring states, identifying trends in publicly available drug cost data across coverage markets. The second analyzed contracting and operating policies as submitted by PBMs and sponsoring health plans (carriers) active in the Tennessee market. The findings from both analyses form the basis for the recommendations provided in this report.

BEST PRACTICES AND STATE LEGISLATIVE ACTIONS

From existing legislation, associated litigation, and published best practices described in this report, we note the following key takeaways:

- Transparency, accountability, and consumer cost containment are the most common goals of both enacted and model legislation in this area.
- Tennessee has already implemented several of the best practices observed in other states regarding PBM operations.
- Legislation that has commonly triggered legal challenges include specific PBM pricing controls and changes that may impact Employee Retirement Income Security Act (ERISA) plan administration, which is governed by federal law.
    - The December 10, 2020 US Supreme Court decision may limit the success of future cases challenging State law based on ERISA preemption.
    - Maine has avoided ERISA preemption challenges to date by regulating the carriers that contract with PBMs rather than regulating the PBMs directly.
- Anti-claw back legislation has gained traction across the country, prohibiting PBMs from charging a copayment that exceeds the submitted pharmacy charges for a given drug.
    - Tennessee's recently passed anti-gag clause legislation may provide valuable data to inform the impact of anti-claw back legislation should the State choose to pursue such a path in the future.
- Clarifying and regulating the use of Maximum Allowable Cost (MAC) lists in PBM operations continues to gain traction nationally even as legal challenges to some models persist.

- As part of broader legislation addressing prescription drug costs and PBM practices, Maine established an independent Drug Affordability Review Board to provide recommendations on additional policy actions and purchasing options.

TENNESSEE MARKET SCAN

The market scan and PBM and carrier responses analyzed under this scope produced the following key findings:

- Prescription drug costs in Tennessee are markedly higher than both the national average and comparable peer states. This difference in price is only partially explained by broader economic differences among peer states.
- Rebates, the most cited source of both spread revenue and national debate on PBM transparency, do not pose a significant risk in the Tennessee fully insured market. Carrier responses indicated either 100 percent pass through of rebate revenue or dollar value guarantees of such revenue from their PBM vendors, both policies aligning with industry best practices.
- MAC list policies provided through carrier and PBM responses leave open the possibility for spread revenue capture by PBMs on generic drugs.
- Audit rights provided under PBM contracts are largely robust and flexible in their application.
- Performance guarantees vary greatly, most often included only on specific client request. This trend tends to disadvantage smaller clients, who may not be aware of – or have the negotiating power to stipulate – such guarantees.
- Contract language provided by most responding PBMs did not include mechanisms to protect clients against drug manufacturer price inflation.

DISCUSSION AND RECOMMENDATIONS

State governments across the country are working to find the right balance of regulatory oversight to ensure that PBMs are operating transparently and responsibly. The regulations that have been most successful in meeting this goal while avoiding legal challenges include anti-gag clause, PBM registration, and oversight and audit laws that avoid pricing stipulations. In the future, however, we expect states to continue to seek more proactive ways of regulating PBMs that help contain costs and ensure financial transparency.

The recently decided PCMA v Rutledge US Supreme Court case regarding ERISA preemption helps clarify the history of conflicting findings from lower court appeals and – given the 8-0 decision – appears to open the door for broader State regulation of PBM operations. Whether PCMA can successfully pivot strategies to block future legislation remains to be seen. In the near term, Maine's most recent approach, which focuses on regulating insurance carrier contracts rather than PBM actions, continues to offer a path forward for states intending to increase regulation and oversight of pharmacy management. This pathway offers two additional advantages. Strategically, by focusing on the fully insured market, the State may directly communicate with and monitor the outcomes for the carriers being impacted as their plans fall under State regulatory purview. Operationally, this approach directly leverages several existing processes guiding State insurance regulation, augmenting current workstreams rather than creating anew.

The table below summarizes the key policy considerations, resource requirements, and limitations of each recommendation described in this report. Given the overlapping expertise required to implement and effectively monitor Recommendations #2-4, we have collapsed the resource estimates to identify total additional State hours. Hiring a dedicated resource within the Insurance Division of the Department of Commerce and Insurance would provide the level of consistent support and internal expertise required to successfully implement such measures across all applicable markets.

Summary of Policy Recommendations

Recommendation	Justification and Policy Goal	Policy Considerations	Resources[1]	Limitations

#1 Establish an independent review board to examine drug affordability issues statewide and propose recommendations for future consideration.	Despite rebate pass-through and guarantee provisions, significant audit protocols, and relatively streamlined benchmarking, per capita drug spend and average drug price indicate higher costs than the national average as well as states with similar prevalence of chronic conditions.
	
	Goal: Mitigate factors external to PBM operations that may contribute to high drug prices in Tennessee.
		• Board Membership representing cross-section of clinical and health economic expertise
		• Charge:
		  ○ Establish parameters to define affordability.
		  ○ Review drug pricing for key cost drivers.
		  ○ Report findings and recommendations.
		• Activities may be funded by grants or State allocation and operated in accordance with § 9-1-118 as applicable
		• Term may be limited to five years
		• Requirements for open meetings and record disclosure define in accordance with TN Code 10-7-503.
			Expense allocation for Board members: Est. $18,176 annually.
			
			With optional FTE for project management: Est. $122,462 annually.
				Board authority limited to providing recommendations. Implementation of such recommendations may require additional operational, or in some instances, legislative actions.

#2 Require carriers contracting with PBMs to stipulate the use of a single MAC list, which dictates both PBM reimbursement from the carrier and pharmacy reimbursement from the PBM.	MAC list standards varied for each PBM and from client to client. Some PBMs maintain multiple lists across clients and within client contracts, leaving open the possibility for spread revenue capture. **Goal**: Minimize opportunities for spread revenue across pricing schedules and create more transparent funds flow across entities.	• Carriers must require their contracted PBM to employ the same MAC list for all contracted pharmacies and the plan sponsor. • Annual oversight and monitoring processes, as well as additional plan guidance and communication, to be provided through the Department of Commerce and Insurance.	Estimated FTE requirement specific to form filing and market conduct activities: 0.4 – 0.7 FTE. New requirements in this area will likely require additional communications and technical support for carriers and impacted PBMs beyond the time needed to complete specific oversight activities. Fully loaded FTE: Est. $110,417[2]	• ERISA limits applicability to the fully insured market. • Pass-through requirement may trigger renegotiation of administrative fees charged by the PBM. ○ How MAC list revenues and administrative fees balance out will in part determine the overall cost impact of this requirement.
#3 Require carriers contracting with PBMs to include performance guarantees in such contracts, with consistent checks and repercussions	Performance guarantees in PBM contracts vary greatly depending on the client. Most are only included if specifically requested by the client. **Goal**: Expand applicability of performance guarantees, ensuring that plan sponsors of all sizes and levels of	• Require carriers to include measurable and auditable guarantees that may be monitored at least annually by the plan sponsor. • Require reasonable repercussions for PBMs failing to meet contractual guarantees. • Carriers may be required to provide evidence of the PBM performance against guarantees.		• ERISA limits applicability to the fully insured market. • Impact depends on the robustness of contract terms.

[1] Annual cost is based on current dollars, not adjusted for inflation in future years.
[2] Based on current salary levels for Manager/Associate Director positions within the Department of Commerce and Insurance https://salary.app.tn.gov/public/searchsalary, and a 30% benefit load.

for not meeting those guarantees.	purchasing power may access the same guarantees.	• Annual oversight and monitoring processes, as well as additional plan guidance and communication, to be provided through the Department of Commerce and Insurance.		• Carriers may benefit from communication of sample protections and/or dissemination of guides for developing such protections.

#4 Require carriers contracting with PBMs to stipulate PBM programs that mitigate the financial risk of mid-year drug manufacturer price inflation as well as the introduction of high-priced new market entrants.	Specific terms providing plan sponsor protections against drug manufacturer price inflation were not identified in contract language provided by respondents.
	
	Goal: Leverage PBM position to protect against drug manufacturer price inflation.
		• Require carriers to include in PBM contracts mechanisms by which PBMs protect against manufacturer price inflation, which may include:
		  ○ Establishing a rigorous cost effectiveness evaluation process for all new drugs to market before they may be added to formulary
		  ○ Requiring the contracted PBM to establish and demonstrate the existence of price inflation caps with drug manufacturers.
		  ○ Establishing mid-year procedures for utilization management review
		• Require savings resulting from price inflation protections to be passed through to the plan sponsor.
		• Annual oversight and monitoring processes, as well as additional plan guidance and communication, to be provided through the Department of Commerce and Insurance.		

PURPOSE AND CONTEXT

Public Consulting Group (PCG) was contracted by the Tennessee Department of Commerce and Insurance (the Department) to complete a landscape analysis of the State's active Pharmacy Benefit Managers (PBMs). By comparing current Tennessee market trends to national best practices, this analysis aimed to identify whether and to what extent additional legislative or regulatory action in this area may benefit Tennessee consumers and stakeholders.

PBMs have been operating in the United States since the 1960s when insurance companies first began covering prescription drugs as a health benefit. Their main function is to administer the drug benefit – processing pharmacy claims, managing utilization and pharmacy networks, and often negotiating directly with drug manufacturers on pricing and various discounts. As PBMs have become more sophisticated in their use of data and leveraging their pharmacists' clinical expertise, some have expanded the scope of services they may offer to include various forms case management, specialty drug counseling, consumer hotlines, mail order pharmacy dispensing, etc. Some PBMs have also divested and streamlined certain functions, opting to subcontract with separate entities to, for example, design and manage client formularies or complete medical necessity determinations.

Driven largely by increasing drug costs, health plans and regulators alike have paid increasing attention to the specifics of PBM contracts and operating models. The details of PBM payment models are as diverse as their operations. Broadly, however, the two most basic pricing models are:

1. **Spread Pricing (Traditional)**: The PBM charges their health plan client or plan sponsor a negotiated price on a per-drug basis. They also negotiate reimbursement prices on a per-drug basis with each pharmacy in their network. The difference between these two prices, or spread, is retained by the PBM and covers their costs of adjudicating claims and other administrative activities. The PBM also negotiates rebates and other discounts directly with drug manufacturers. Until recently, the details of those negotiations were largely absent from PBM contracts.

2. **Pass-Through Pricing**: The PBM charges their health plan client the same price on a per-drug basis as they reimburse to the dispensing pharmacy. The PBM's operating expenses are covered under a separate administrative fee that may be charged on a per-drug or per-member basis. Under a pure pass-through model, revenue from any and all rebates or other discounts negotiated by the PBM are also passed through to their health plan clients or plan sponsors.

Each model has its advantages. Spread pricing places both the risk and reward on the PBM, incentivizing administrative efficiency and deeper rebate discounts. Pass-through pricing prioritizes transparency and fair pricing, valuing the dispensing pharmacy's role and specifically accounting for each dollar in the value chain. Most contracts today are designed with a combination of both elements. For example, a PBM may pass through 100 percent of all rebates to their plan sponsor but still retain the difference between reimbursement from the plan sponsor and claims paid to pharmacies. They may also retain this drug pricing spread to cover basic operating costs while charging separate administrative fees for add-on services, such as consumer education or case management.

As noted throughout the best practices and legislative review in this report, a major focus for health plans and regulators is understanding where health care dollars are spent and what value is gained. The complexity of PBM operations and their various roles as an intermediary has stoked a desire for greater transparency in this area. To help navigate this space and provide a quick reference guide to accompany the remainder of this report, Appendix A provides a glossary of common terms related to PBM operations.

METHODOLOGY

Our analysis begins with a review of published PBM best practices, including optimal PBM contracting terms and proposed model legislation. We then completed a national review of enacted PBM legislation, identifying the most common issues and trends as well as settled and pending litigation impacting such legislative efforts.

To understand the relevancy of such policies to the Tennessee market, we completed two additional Tennessee-specific analyses. The first included a comparative analysis of Tennessee and neighboring states, identifying trends in publicly available drug cost data across coverage markets. The second analyzed contracting and operating policies as submitted by PBMs and sponsoring health plans (carriers) active in the Tennessee market. The findings from both analyses form the basis for the recommendations provided in this report.

MARKET SCAN: DRUG COSTS ACROSS STATES

To better understand relative drug costs in Tennessee, publicly available data was collected from:

- Kaiser Family Foundation (KFF),
- Medical Expenditure Panel Survey (MEPS),
- Centers for Disease Control and Prevention (CDC), and
- American Community Survey (ACS).

Per capita drug costs and prescribing levels in Tennessee were then compared to neighboring states as well as states with a similar prevalence of common chronic conditions. Data was normalized using both per capita sales and sales as percent of gross domestic product (GDP) to account for economic differences among comparison states.

PLAN AND PBM POLICY REVIEW

Based on best practices research and market trends, we developed and reviewed with the Department the data requests provided in Appendix B. The requests intended to capture contract language and operating policies that may impact coverage quality, oversight, and consumer cost. The Department issued the requests to each applicable health plan carrier and PBM in the Tennessee market. We then created a checklist identifying best practices in PBM contracting. The checklist template is provided in Appendix C.

The 29 PBMs with active contracts in the Tennessee market provided full or partial responses to the initial data request. Following receipt of initial responses, the team populated the checklist with applicable language from each response. We then prepared follow up questions for 28 of the 29 PBMs to capture additional detail that had not been identified in the initial response. Once follow up information was processed, we identified key trends as described herein.

Comparing both the market scan and data request responses, we then developed a set of recommendations for policy impact analysis.

POLICY IMPACT ANALYSIS

For each recommendation, we defined key policy stipulations and resource requirements as well as an initial set of milestones to guide implementation. Policy and resource requirements are based on a combination of existing State legislation, comparative State practices, and our professional experience conducting State form filing reviews and market conduct examinations.

LIMITATIONS

The resource requirements and expected impacts described herein are informed by the practical experience of other states and industry research. The analysis does not include an actuarial analysis of any potential premium or drug price impacts specific to the Tennessee market. Additionally, information provided by PBMs and carriers during the course of this analysis reflects the products and policies implemented in the fully insured market. ERISA related policies and contract language were omitted, noting the limitations of State oversight in this area.

PBM CONTRACTING BEST PRACTICES

The following section identifies best practices across PBM vendor contracting and regulatory levers. Best practices included here have been published by a variety of sources and stakeholders impacted by PBM operations. The section concludes with a review of model legislation elements proposed by national organizations.

INDUSTRY DISSEMINATED PRACTICES

The Pharmaceutical Care Management Association released a list of best practices, detailed below.[3] Originating from an industry source, these practices are useful in describing the value proposition of the PBM model but largely fall short of providing specific terms to guide performance and contract management and/or compliance practices.

- Deliver the lowest net cost of drugs for clients and improve patient health outcomes
- Offer clients programs that facilitate timely patient appeals to help ensure appropriate medication use
- Provide clients with contractual audit rights
- Perform drug utilization reviews to help reduce drug-drug interactions, increase patient safety, and improve appropriate use
- Negotiate all client contractual terms, including rebate arrangements ranging from 100% pass-through to shared savings
- Offer network options that include high quality, credentialed pharmacies
- Provide clients with programs to protect against drug manufacturer price inflation
- Provide patients 24-7 access to pharmacists or other clinicians
- Use independent clinical experts and specialists to develop formularies and clinical programs to help ensure patients have access to clinically appropriate treatments
- Guarantee financial terms and service levels to maximize overall contract value

CONTRACTING TERMS

A white paper published in February 2020 by Milliman identifies nine contracting provisions and strategies to create and manage PBM contracts:[4]

- Include aggressive guaranteed discounts and dispensing fee provisions
- Adopt limited retail and specialty pharmacy networks to improve discount rates
- Include clear and auditable exclusionary language in minimum pricing and rebate guarantees
- Create clear definitions and key terms to eliminate confusion and frustration
- Include performance guarantees that are measurable and auditable to allow the client to track, measure, and clearly explain the guarantees to all stakeholders
- Include a termination clause that gives the plan sponsor the right to cancel without penalty
- Include auditing provisions that allow the health plan the right to choose and hire an independent auditor to intermittently confirm the PBM's contractual performance
- Define rebate terms clearly
- Conduct annual market checks to ensure competitive PBM terms over the contract life

[3] Pharmaceutical Care Management Association, infographic. https://www.pcmanet.org/wp-content/uploads/2017/04/PBM-Best-Practices_infographic_FINAL.pdf
[4] Anderson, B. and Callahan G. PBM Best Practices Series: Effective Contracting. Milliman White Paper. Published February 2020. https://milliman-cdn.azureedge.net/-/media/milliman/pdfs/articles/best-practices-effective-pbm-contracting.ashx

AUDIT RIGHTS

In December 2019, the Burchfield Group published *Best Practices for Including Audit Terms in Your PBM Contract*. The article intends to help "health plans gain a better understanding of the importance of paying close attention to audit terms specified during the PBM contracting process, best practices for maximizing audit rights, and common pitfalls to avoid."[5] The article highlights three important areas for audit: rebates, claims, and compliance for health plans.[6]

Rebates

- Ensure that PBMs do not have specific limits or requirements for the rebate audit
- Confirm that audits can be done every year and are not limited to a calendar year but any one-year period
- Ensure that the rebate audit will examine 50 percent or more of rebate dollars spent
- Specify that the look back period for the audit can be for one to two years
- Confirm that health plan can audit both PBM rebates and the actual rebate invoicing and collections by rebate aggregators
- Stipulate the right to audit rebates even after contract termination
- Ensure that the health plan has access to the detailed data files that substantiate the rebate and administrative fee amounts submitted to CMS annually for direct and indirect remuneration (DIR) reporting
- Consider separate audit rights for any downstream clients (employer groups, ASO clients, etc.)

Claims

- Review offset language in the contract related to discounts and pricing fees
- Identify corrective action timelines for performance guarantees
- Conduct a claims audit review annually and include a lookback period of one to two years
- Ensure audit terms specify review of 200 or more discrepancies per line of business
- Note the timeline for audits – they may require 180 days or longer
- Ensure that audits performed by downstream clients of the health plan do not prohibit the health plan from completing their own claims audits
- Identify when a PBM can charge "data access fees" or "audit support fees" and what those fees will be

Compliance

- Design audit terms so the health plan will have time to review the PBM's work before submitting to the requesting agency
- Ensure that audit rights are in line with regulatory protocols used by CMS
- Create a look back period of at least one year with more time given to high compliance risk sections
- Create performance guarantees in the audit terms, requiring the PBM to disclose any pending disputes immediately

PBM MODEL LEGISLATION

In addition to the contracting and operating best practices above, pharmacy advocacy groups and policy consortiums have published model legislation to identify those practices that they believe should be

[5] Baumgardner, S. and Frye, D. Best Practices for Including Audit Terms in Your PBM Contracts. The Burchfield Group. https://www.burchfieldgroup.com/health-plan-insurer-blog/best-practices-for-including-audit-terms-in-your-pbm-contract
[6] Ibid.

universally applied and regulated. These template bills seek to regulate PBMs by focusing on the most common challenges experienced by plan sponsors and consumers alike.

The summary below addresses common themes among four organizations' model legislation: The National Community Pharmacists Association[7], the National Academy for State Health Policy[8], the National Council of Insurance Legislators[9], and the National Association of Insurance Commissioners[10].

Clear and Specific Definitions: As with any legislation, including comprehensive definitions of all terms is critical to successful implementation. For PBMs, specificity with respect to the many roles a PBM may play is especially important. For example, a PBM may be both a drug benefit manager and a pharmacy, as well as providing "other prescription drug or devices services" such as rebate negotiation, rebate distribution and pharmacy incentive program management. Other terms specifically defined in model bills include spread pricing, rebates, and other pricing related conditions.

Contracting: Regulating contracting between PBMs and plan sponsors has proven particularly effective in enforcing best practices while avoiding legal challenges. One common component among model legislation mandates that carriers assume responsibility for monitoring all activities carried out by, or on behalf, of the health carrier and ensuring that all requirements of the legislation are met.

Fiduciary Duty: As noted in our review of existing legislation, model legislation also commonly mandates that a PBM has a fiduciary duty to their health carrier client and must act with "care, skill, prudence, diligence, and professionalism."

Network Adequacy: Model legislation often requires PBMs to secure the participation of a sufficient number of retail pharmacies to ensure access to their members, which may include:

- Requiring a PBM to contract with any willing pharmacy
- Prohibiting the requirement that a patient receive prescription drugs from a mail-order pharmacy
- Ensuring patients may access specialty medications at the pharmacy of their choice
- Prohibiting accreditation standards as a condition of network participation

While access may improve medication adherence and thus lower total cost of care, network design is an established lever to control costs and more closely manage drug expenditures. Any network adequacy provisions, therefore, should seek to balance and optimize these outcomes.

PBM Transparency: To increase oversight and information available to regulators, many bills include some form of reporting requirement. One model bill requires the PBM to submit a "transparency report" to the State. The report covers all aspects of rebates and is eventually published on the State's website. In compliance with confidentiality regulations and to maintain proprietary information, the reports are published with any information that would violate a State's trade secret regulations redacted.

Price Setting: PBMs have traditionally operated with significant freedom in determining both the cost of the drugs they supply and the methods they use to determine prices. To curtail price increases and improve transparency, model bills set strict requirements on the amount a PBM may charge per prescription and how much the PBM may retain. Many bills mandate that PBMs may not retain any

[7] NCPA, Key Provision: Comprehensive State PBM Regulation http://www.ncpa.co/pdf/model-pbm-regulation-outline-0819.pdf
[8] NASHP, PBM Model A: A Model At Relating to Pharmacy Benefit Managers https://nashp.org/wp-content/uploads/2019/02/Updated-MODEL-A-PBM-legislation-1_31_2019.pdf
[9] NCOIL, Pharmacy Benefits Manager Licensure and Regulation Model Act, http://ncoil.org/wp-content/uploads/2018/12/PBM-Model-FINAL.pdf
[10] NAIC, Health Carrier Prescription Drug Benefit Management Model Act, https://www.naic.org/store/free/MDL-022.pdf

portion of spread pricing. Other standard language mandates that a PBM may only require a covered person to pay the lowest of the following pricing categories:

- The applicable copayment for the prescription medication,
- The allowable claim amount for the prescription medication,
- The amount a covered person would pay for the prescription medication if the covered person purchased the prescription medication without using a health benefit plan or any other source of prescription medication benefit or discount, or
- The amount the pharmacy will be reimbursed for the drug from the Pharmacy Benefit Manager or health carrier.

Severability: To protect against litigation from industry representatives, model legislation also often includes severability clauses as protection against preemption. The clauses state that if any provision of the act is held invalid, all other provisions remain valid and enforceable.

CASE LAW AND LEGISLATION REVIEW

Several of the policies described in model legislation and best practices have been included in State legislation across the country. In this section, we describe specific State efforts to regulate PBM operational practices as well as the court cases challenging such efforts.

SUMMARY

Nationally, recent legislative efforts include a range of PBM contracting and reimbursement topics, many of which are currently represented in Tennessee code as illustrated in Table 1 below.

Table 1. National PBM Legislative Trends

Legislative Category	Description of PBM Practices Impacted by Legislation	# of States[11]	Enacted in TN?
Gag Clause	Gag clauses prohibit pharmacies contracted with PBMs from informing their consumers that the drug they are purchasing has different cost options available.	33 and federal law	Yes
Funds Flow	Claw backs occur when a consumer's copayment exceeds the total cost of the drug to their insurer or pharmacy benefit manager. The PBM retains the difference in payment. Spread pricing occurs when a PBM charges an insurance plan more for a drug than the amount they pay to the dispensing pharmacy, retaining the difference.	20*	No
Maximum Allowable Cost (MAC)	A Maximum Allowable Cost, or "MAC," list refers to a payer or PBM-generated list of products and the maximum amount that a plan will pay for generic drugs and brand name drugs that have generic versions available. Some legislation allows pharmacies to appeal a PBM's MAC lists and receive retroactive reimbursement for any pricing difference.	20	Yes (Appeals)
Fiduciary Duty	Third-party fiduciary duty measures require PBMs to act in the best interest of the pharmacies or consumers they serve rather than the health plans.	5	No
Pharmacy Audits	Pharmacy audit legislation outlines procedural requirements and limitations for pharmacy audits, as well as registration requirements for PBMs	38	Yes

*Most state action in this area focuses on claw back restrictions.

To understand the relative success of such legislative efforts, PCG reviewed current and past court cases challenging PBM legislation. Results of this review are summarized in Table 2.[12] To date, the Pharmaceutical Care Management Association (PCMA) has brought all major legal challenges against these regulations. While PCMA cites several different precedents to challenge these laws, they have been most successful with claims based specifically on the Employee Retirement Income Security Act (ERISA) preemption clause. ERISA preempts "any and all States' laws insofar as they may now or hereafter *relate to* any [ERISA governed] employee benefit plan" (29 U.S.S ss 1144(a)).

A state law "relates to" ERISA's coverage when the law has an impermissible *explicit reference* to ERISA and/or when it has an *impermissible connection* with ERISA. An "explicit reference" means a law "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to

[11] National Council of State Legislatures https://www.ncsl.org/research/health/pbm-state-legislation.aspx This count is based on information available at the writing this report. Some states may have more than one applicable law in a single category but for the purposes of this chart are counted as one.
[12] Ibid.

the law's operation[.]" An "impermissible connection" to ERISA means a law that "governs . . . a central matter of plan administration" or "interferes with nationally uniform plan administration." In cases citing ERISA preemption, PCMA most commonly alleges that certain laws regulating PBMs are preempted by ERISA because implementing the law would interfere uniform plan administration.

Table 2: PBM Case Law Summary

State	PBM Law	PCMA Challenge	Final Decision	Main Legal Challenge
Maine	2003 – Unfair Prescription Drug Practices Act (Maine Rev. Stats., Title 22 § 2699)	PCMA v. Rowe	Not preempted 1st Circuit, SCOTUS Review Denied (2006)	Fiduciary Duty
District of Columbia	2004 – Title II of Access Rx Act (D.C. Code § 48-832.01 et seq.)	PCMA v. DC	Partially preempted, D.C. Circuit (2010)	Fiduciary Duty
Iowa	2014 – Act Relating to the Regulation of Pharmacy Benefits Managers (Iowa Code § 510B.8)	PCMA v. Gerhart	Preempted, 8th Circuit (2017)	MAC
Arkansas	2015 – Act 900 (Arkansas Code § 17-92-507)	PCMA. v. Rutledge	Preempted 8th Circuit (2018) SCOTUS granted review October 6, 2020 and held 8-0 not preempted.	MAC
North Dakota	2017 – SB 2258 and SB 2301	PCMA. v. Tufte	Not preempted, Pending 8th Circuit	Funding Flow Spread Pricing
Oklahoma	2019 – Patient's Right to Pharmacy Choice Act	PCMA. v. Mulready	Pending, Western District of Oklahoma	MAC

Following six separate lawsuits with varying results, the US Supreme Court (SCOTUS) agreed to hear PCMA. v. Rutledge, originating in Arkansas. Oral arguments were originally scheduled for April 27th, 2020 but were postponed to October 6, 2020 due to COVID safety measures. During the finalization of this report on December 10, 2020, SCOTUS held 8-0 that the Arkansas statute is not preempted by federal law. The decision described PCMA's contention that the Arkansas law had an impermissible connection with ERISA as "unconvincing," adding that operational efficiencies caused by compliance requirements under State law were insufficient to trigger ERISA preemption for interfering with uniform national plan administration.

The remainder of this section provides additional detail on legislative trends, their connections to case law, and ways states have avoided potential ERISA preemption to date.

ANTI-GAG CLAUSE LEGISLATION

Of the recently enacted state PBM legislation, anti-gag clause restrictions are among the most common. Gag clauses prohibit pharmacies contracted with PBMs from informing their consumers that there are more affordable cost options available for the drug they have been prescribed. Common instances of this occurrence include informing a consumer that the drug could be purchased at a lower cost out-of-pocket rather than through their insurance plan, or the drug might be available in a less costly generic form. In October 2018, the bipartisan Patient Right to Know Drug Prices Act and the Know the Lowest Price Act were signed into federal law, preventing gag clauses from being applied to employer-sponsored group plans and individual market plans, as well as Medicare Advantage and Medicare Part D plans. As of May

2019, at least 33 states, including Tennessee, enacted State laws prohibiting "gag clauses" in contracts with PBMs[13].

Unlike many new state legislative actions, PBMs have not contested these regulations directly and it is expected that they will become common practice. We note, however, that informing a consumer that a lower price is available if paid out-of-pocket extends the time period that a consumer may be subject to their prescription drug deductible. The practical effect for some consumers, particularly those with chronic conditions, is that the consumer may end up paying more in total over the course of the plan year should they consistently choose the lower cost out-of-pocket option.

FUNDS FLOW

One of a PBM's key functions is to liaise among drug manufacturers, health plans, and pharmacies. In this role, PBMs have direct access to data used in determining how much health plans and consumers pay for drugs and how much pharmacies are reimbursed for dispensing those drugs. In facilitating funds flow among these entities, PBMs have many opportunities to capture additional revenue. The legislation described herein seeks to regulate this funds flow, requiring a level of transparency that mitigates revenue capture by the PBM.

Anti-CoPayment Claw Back Legislation

Claw backs occur when a consumer's copayment exceeds the total cost of the drug from their insurer or pharmacy benefit manager. When the total cost of the drug is *less than* the patient's copayment, the insurer or PBM may retain the difference. In a study from 2018 reviewing 9.5 million claims, almost one quarter of filled pharmacy prescriptions (23%) included a patient copayment that exceeded the average reimbursement paid by the insurer by more than $2.00. Among these overpaid claims, the average overpayment was $7.69. Overpayments were more likely on claims for generic drugs versus brand-name drugs (28% vs. 6%), but the average size of the overpayment on generic claims was smaller ($7.32 generic vs. $13.46 brand). In the sample of over 1.5 million Californians, the total overpayments amounted to $135 million, or $10.51 per covered life.[14]

There are 20 states that have enacted anti co-pay claw back provisions, which aim to prevent numerical price overcharges to patients buying retail drugs in a pharmacy. Such prohibitions exist in Arizona, Colorado, Connecticut, Florida, Georgia, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Missouri, New York, North Carolina, North Dakota, Ohio (executive action only), South Carolina, Texas, Utah, and Virginia.[15]

Georgia specifically prohibits PBMs from "charging or collecting from an insured a copayment that exceeds the total submitted charges by the network pharmacy for which the pharmacy is paid".[16] Louisiana requires that "an individual shall not be required to make a payment for pharmacists' services in an amount greater than the pharmacist or pharmacy providing the pharmacists' services may retain from all payment sources."[17] Nevada mandates that "If the pharmacy benefit manager manages a pharmacy benefits plan that provides coverage through a network plan, [the pharmacy shall not] charge a copayment or coinsurance for a prescription drug in an amount that is greater than the total amount paid to a pharmacy that is in the network of providers under contract with the third party."[18] While the wording of the legislation varies, the spirit of the law is consistent: PBMs may not use higher copayments to

[13] Ibid.
[14] USC Schaeffer Center, Overpaying For Prescription Drugs: The Copay Clawback Phenomenon https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drugs_White20Paper_v.1-2.pdf
[15] PBM state legislation https://www.ncsl.org/research/health/pbm-state-legislation.aspx
[16] Georgia SB103 http://www.legis.ga.gov/Legislation/20172018/168775.pdf
[17] Louisiana SB131 2016 https://legiscan.com/LA/text/SB131/id/1420030/Louisiana-2016-SB131-Chaptered.pdf
[18] Nevada SB 539 Sec. 20 (d) 2017 https://www.leg.state.nv.us/App/NELIS/REL/79th2017/Bill/5822/Text

increase their revenue. These provisions have not faced legal challenges to date. We note, however, that anti-claw back regulation typically follows successful implementation of anti-gag clause legislation.

Spread Pricing Legislation

Another practice garnering national attention is spread pricing. Spread pricing occurs when health plans contract with PBMs, and PBMs keep a portion of the amount paid to them by the health plans for prescription drugs instead of passing the full payments on to pharmacies. Thus, there is a "spread" between the amount that the health plan pays the PBM and the amount that the PBM reimburses the pharmacy. Bills regulating spread pricing stop or limit PBMs from retaining the difference in those payments that exceed the total charges submitted by a network pharmacy.[19] Auditors in Kentucky, New York, Ohio, Pennsylvania, Texas and West Virginia have taken significant actions to more closely examine this pricing model. This practice extends beyond the private insurance market. In 2018, Ohio conducted an audit of its Medicaid MCOs who contract their prescription benefit plans to PBMs. The Attorney General's report identified a total spread of $224.8 million, representing 8.9 percent of total spend. Further, the PBMs charged the state a spread of more than 31 percent for generic drugs which comprised more than 86 percent of all prescriptions. Legislation in this area is still progressing to date. Both New York and Louisiana have passed bills prohibiting spread pricing in their Medicaid programs, while states such as South Dakota and Maine recently passed legislation requiring more transparency on spread policy.[20] PCMA has yet to file a case against any of these new regulations.

PHARMACY AUDIT STANDARDS AND LEGISLATION

Audits of pharmacies by pharmacy benefit managers (PBMs) are a common practice to help identify and mitigate fraud, waste, and abuse. Audits also serve to ensure compliance with regulatory and contractual requirements between pharmacies and PBMs. Pharmacists have begun to push back on these inspections, citing unfair auditing practices resulting in stiff penalties and fees. In response, recent legislative measures often referred to as Fair Pharmacy Audit Acts or Pharmacy Audit Bill of Rights, have been enacted in over 40 states, including Tennessee. The model Pharmacy Audit Bill of Rights sets several standards for acceptable audit practices. Such standards include the amount of notice a PBM must give a pharmacy prior to an audit, who is authorized to conduct an audit, the frequency of audits, and restrictions on penalties for errors found during audits. Specifically, clerical or record-keeping errors cannot, in and of themselves, constitute fraud.[21]

Many such statutes also outline registration requirements for PBMs.[22] As of early 2020, fourteen states have enacted registration requirements for pharmacy benefit managers, including Tennessee. The registration requirements that have been adopted by these fourteen states require that a PBM be licensed and registered with the state. While the application requirements vary by state, they typically include organizational information, a certificate of good standing, professional qualifications, background information, financial statements, a surety bond and/or proof of insurance coverage, a detailed business plan, and any existing contracts with payers or pharmacies.[23]

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[19] National Academy for State Health Policy, Comparison of State Pharmacy Benefit Managers Laws https://nashp.org/comparison-state-pharmacy-benefit-managers-laws/#footnote1
[20] PBM Watch http://www.pbmwatch.com/pbm-legislation.html
[21] Arkansas Pharmacist Association, Provisions of the PBM Audit Bill
https://apa.memberclicks.net/assets/documents/2011%20audit%20bill.pdf
[22] Benedette, D. The 4 Policy Changes Hitting Pharmacies. Drug Topics Journal. August 2018. 162 (8)
https://www.drugtopics.com/article/4-policy-changes-hitting-pharmacies
[23] National Law Review, New Laws in 2019 Regulating Pharmacy Benefit Managers https://www.natlawreview.com/article/new-laws-2019-regulating-pharmacy-benefit-managers

MAXIMUM ALLOWABLE COST (MAC)

The measures described above have largely avoided legal challenges primarily because they stop short of specific price restrictions. Conversely, the ERISA Preemption case currently before the Supreme Court (PCMA V. Rutledge) focuses on a 2015 Arkansas law regulating pharmacy reimbursement for drug costs. Specifically, the law stipulates new requirements for updates to Maximum Allowable Cost limits and MAC cost appeal procedures.

MAC List Constuction

A Maximum Allowable Cost (MAC) list refers to a payer or PBM-generated list of products that includes the upper limit or maximum amount that a plan will pay for generic drugs and brand name drugs that have generic versions available ("multi-source brands"). In the absence of regulatory measures, PBMs have significant discretion in the design, scope, and application of multiple MAC lists.[24] MAC lists have been implicated as a means of deriving profits largely from independent pharmacies, plan sponsors, and consumers. The lack of transparency surrounding MAC pricing and the use of multiple MAC lists in each contract can contribute to spread pricing practices and allows PBMs to privilege some contracts, such as PBM-owned pharmacies, over other non-affiliated retail pharmacies.

Several states have recently passed legislation or have legislation pending that is designed to provide clarity on PBM derivations of MAC pricing, in some cases standardizing how products are selected for inclusion on MAC lists. Maine's most recent legislation requires the carrier of the PBM under contract to use a single MAC list for all its pharmacy contracts and allows only specific types of drugs to be included on that single list.

MAC Pharmacy Appeals

Legislation regulating MAC lists often include sections that require PBMs to provide procedures by which pharmacies may comment on and appeal MAC price lists or rates. In Tennessee, this requirement is included under section 56-7-3108 "Appeal by Pharmacy of Cost of Particular Drug or Device on Maximum Allowable Cost List". Tennessee's statute states "A pharmacy benefits manager or covered entity shall establish a clearly defined process through which a pharmacy may contest the listed maximum allowable cost for a particular drug or medical product or device" 56-7-3108(a) and "If a pharmacy's appeal is determined to be valid … the pharmacy benefits manager or covered entity shall provide reimbursement to the appealing pharmacy".[25] This legislation follows national trends in this area. However, recent litigation suggests there may be future legal challenges to such requirements.

MAC-Related Legal Challenges

In 2014, PCMA filed suit against an Iowa law, which regulated how PBMs establish generic drug pricing. PCMA v. Gerhart reviewed three subsections of Iowa's law requiring PBMs to (1) provide information regarding their pricing methodologies to Iowa's insurance Commissioner at the Commissioner's request; (2) limited the types of drugs to which a PBM could apply MAC pricing and the sources from which a PBM could obtain pricing information; and (3) allow for MAC list appeals. The appeal process noted here would allow for potential retroactive payments to pharmacies for incorrect pricing. In 2015, the District Court of the Southern District of Iowa held that this regulation was not preempted by ERISA. However, after PCMA's appeal, the 8th Circuit reversed the lower court's finding, holding unanimously that the Iowa law impermissibly interfered with ERISA plans operating in Iowa.[230]

Following PCMA's win in Iowa, the organization filed another suit against a 2015 Arkansas law regulating pharmacy reimbursement for drug costs, new requirements for pharmacy benefit managers' updates to

[24] National Community Pharmacists Association http://www.ncpa.co/pdf/leg/mac-one-pager.pdf
[25] TN 56-7-3108 (e) (1)

MAC limits, and administrative appeal procedures. PCMA contended that this law was preempted by both ERISA and Medicare Part D. PCMA further claimed that the law was unconstitutional.[26] The district court held that (1) the law was preempted by ERISA, (2) was not preempted by Medicare Part D, and (3) was not unconstitutional. The state and PCMA appealed the ERISA and Medicaid Part D rulings, respectively. On review, the 8th Circuit ruled in favor of PCMA stating that ERISA superseded the Arkansas law to regulate PBMs.[27] The 8th Circuit also reversed the district court's Medicare Part D ruling, finding in PCMA's favor. Arkansas filed a writ of certiorari following this ruling. In early January 2020, the U.S. Supreme Court confirmed it would take up the case. Specifically, the Supreme Court reviewed the 8th Circuit's ruling on Arkansas's MAC statute (Ark. Code Ann. 17-92-507) to determine "whether the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001 et seq., preempts a State's regulation of the rates at which pharmacy benefit managers reimburse pharmacies" in contravention of the Court's precedent that ERISA does not preempt rate regulation in Maine (as discussed in the next section of this brief). The US Solicitor General submitted a brief in favor of Arkansas and other states seeking to regulate their PBMs.[28] As noted above, SCOTUS held 8-0 on December 10th that the Arkansas law was not preempted by ERISA.[29]

Following PCMA. v. Rutledge, PCMA filed two additional cases in North Dakota (8th Circuit) and Oklahoma (10th Circuit). In 2017, PCMA v. Tufte targeted two North Dakota bills that regulated PBM reimbursement to pharmacies for prescription drugs and how much PBMs may claim as profit. In 2019, the Patient's Right to Pharmacy Choice Act of Oklahoma barred the use of higher reimbursement rates for PBM-owned pharmacies and banned PBMs from preventing pharmacies from disclosing cost information to consumers.[30] Later in 2019, PCMA filed a second suit in the District Court of Oklahoma – PCMA v. Mulready – claiming the law weakens competition among pharmacies. In addition, PCMA claims the law limits the ability of PBMs to offer cost-saving and quality assurance initiatives within the State.[30] This case is still pending in the district court of Oklahoma. It is likely that both cases will consider the opinions provided in the December 10th SCOTUS decision in their rulings.

FIDUCIARY DUTY

Requiring PBMs to act as a fiduciary to consumers is one of the furthest reaching measures working its way through state legislatures. These measures require PBMs to act in the best interest of plan sponsors, pharmacies and/or the consumers they serve. According to Bloomberg Law, such regulations would require PBMs to disclose their agreement terms with drug manufacturers, disclose any actual or potential conflicts of interest, and share all cost savings derived from these agreements.[31]

PCMA's first legal challenge was brought against Maine's Unfair Prescription Drug Practices Act (UPDPA) under PCMA v. Rowe. Passed in 2003, UPDPA required PBMs to disclose payments received from pharmaceutical manufacturers and pass discounts received on to their clients. PBMs were also required to serve as a fiduciary for their clients. The 1st Circuit Court of Appeals held that the law was

[26] Ballotpedia, Rutledge v. Pharmaceutical Care Management Association https://ballotpedia.org/Rutledge_v._Pharmaceutical_Care_Management_Association#cite_note-scotusblog-2
[27] Nessel, J. Supreme Court to Rule on States' Right to Regulate Pharmacy Benefit Managers. Pharmacy Times, January 2020. https://www.pharmacytimes.com/news/supreme-court-to-rule-on-states-right-to-regulate-pharmacy-benefit-managers
[28] Leslie Rutledge, Attorney General of Arkansas, Petitioner v. Pharmaceutical Care Management Association https://www.supremecourt.gov/DocketPDF/18/18-540/124444/20191204153422611_18-540%20Rutledge.pdf
[29] PCMA v Rutledge. SCOTUS Opinion, full text. 18-540 Rutledge v. Pharmaceutical Care Management Assn. (12/10/2020) (supremecourt.gov)
[30] Gu, A. Legal Challenges Against State PBM Laws May Culminate in Supreme Court Review. Source on Healthcare, November 2019. https://sourceonhealthcare.org/legal-challenges-against-state-pbm-laws-may-culminate-in-supreme-court-review/
[31] Graham, T. and Patel, A. INSIGHT: Exclusive Benefit—An Analysis of PBMs as Potential ERISA Fiduciaries. Bloomberg Law, October 2019. https://news.bloomberglaw.com/employee-benefits/insight-exclusive-benefit-an-analysis-of-pbms-as-potential-erisa-fiduciaries

constitutional and not preempted by ERISA. PCMA requested Supreme Court review but was denied, upholding Maine's law.

The following year, PCMA challenged the District of Columbia's PBM Law, Title II of the Access Rx Act of 2004. This law "required PBMs to act as fiduciaries, disclose the content of their contracts with pharmacies/manufacturers, and pass on any payments/discounts received from pharmacies or manufacturers". The District Court found that ERISA preempted the law in full. PCMA v. the District of Columbia was eventually heard by the Court of Appeals of the D.C. Circuit. The circuit court, affirming the lower court decision, struck down key provisions of the law based on ERISA preemption. These conflicting rulings of nearly identical statutes have helped push the ERISA preemption issue to the SCOTUS.

Since PCMA's first cases, several states have gone on to implement – or are in the process of implementing – fiduciary duty legislation of their own. Nevada's 2017 law specifies that a PBM has a fiduciary duty to a third party when the PBM has contracted with an entity to manage that party's pharmacy benefits plan.

> "Pharmacy benefit manager has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party and shall notify the third party in writing of any activity, policy or practice of the pharmacy benefit manager that presents a conflict of interest that interferes with the ability of the pharmacy benefit manager to discharge that fiduciary duty."[32]

As of January 1, 2020, Minnesota's law states that a PBM has a fiduciary responsibility to the health care carrier. In Utah, a new bill states that a PBM has a fiduciary responsibility to the insurer and requires PBMs to report information about rebates and administrative fees to the Utah Insurance Department. California signed legislation into law in late 2018 that requires PBMs to have a fiduciary responsibility to their health plan clients.[33]

In 2015, Express Scripts Holding Co. stated that fiduciary rules such as those described above "could have a material adverse effect upon our financial condition, results of operations and cash flow". Opposition also states that the fiduciary standard on firms would infringe on the current federal stance on regulating the financial sector.[34]

THE MAINE APPROACH

In July 2019, Gov. Janet Mills enacted four new laws to control the cost of prescription drugs. These new laws impose stricter requirements on PBMs, provide updates to the drug transparency program, establish a review board for drug affordability, and provide support for the state to move forward with a wholesale drug importation program.[35] We focus on the first portion, stricter requirements for PBMs, below.

Maine's recent legislation creates a well-defined fiduciary duty responsibility and requires PBMs to hold a license from the Superintendent of the Bureau of Insurance.[36] Maine was also the first state to enact legislation that shifts the responsibility from the PBM to the contracting plan sponsor. Specifically, Maine requires carriers to be held responsible for monitoring all activities carried out by the contracted PBM if

[32] Nevada SB 539 May 16, 2017 https://www.leg.state.nv.us/Session/79th2017/Bills/SB/SB539.pdf
[33] PBM Watch http://www.pbmwatch.com/pbm-legislation.html
[34] Hopkins, J. Fiduciary Rule Revival: Should it apply to PBMs? Benefits Pro, May 2018. https://www.benefitspro.com/2018/05/17/fiduciary-rule-revival-should-it-apply-to-pharmacy/?slreturn=20200230132451
[35] Lanford, S. and Hensley-Quinn, M. Maine Forges New Ground and Enacts Comprehensive Drug Package. National Academy for State Health Policy, July 2019. https://nashp.org/maine-forges-new-ground-and-enacts-comprehensive-drug-package/
[36] Ibid.

the PBM manages the prescription drug benefits.[37] Maine intends this legislation to lead to better enforcement and monitoring of responsibilities. With respect to fiduciary duty, the law states:

> *"A carrier that contracts with a pharmacy benefits manager to perform any activities related to the carrier's prescription drug benefits is responsible for ensuring that, under the contract, the pharmacy benefits manager acts as the carrier's agent and owes a fiduciary duty to the carrier in the pharmacy benefits manager's management of activities related to the carrier's prescription drug benefits."*[38]

As noted earlier in this report, Maine's recent legislation requires the carrier of the PBM under contract to use a single MAC list for all its pharmacy contracts and allows only specific types of drugs to be included on that single list.[39] That same legislation also requires the use of PBM negotiated rebates to lower health plan premiums or reduce costs for individuals,[40] and stipulates that PBM compensation is classified as an administrative cost incurred by the carrier.[41]

By regulating the carriers and not the PBMs directly, Maine has successfully avoided ERISA preemption disputes to date.

KEY TAKEAWAYS

From existing legislation, associated litigation, and the published best practices described in the previous section of this report, we note the following key points:

- Transparency, accountability, and consumer cost containment are the most common goals of both enacted and model legislation in this area.
- Tennessee has already implemented several of the best practices observed in other states regarding PBM operations.
- Legislation that has commonly triggered legal challenges include specific PBM pricing controls and changes that may impact Employee Retirement Income Security Act (ERISA) plan administration, which is governed by federal law.
    - The December 10, 2020 US Supreme Court decision may limit the success of future cases challenging State law based on ERISA preemption.
    - Maine has avoided ERISA preemption challenges to date by regulating the carriers that contract with PBMs rather than regulating the PBMs directly.
- Anti-claw back legislation has gained traction across the country, prohibiting PBMs from charging a copayment that exceeds the submitted pharmacy charges for a given drug.
    - Tennessee's recently passed anti-gag clause legislation will provide valuable data to inform the impact of anti-claw back legislation should the State choose to pursue such a path in the future.
- Clarifying and regulating the use of Maximum Allowable Cost (MAC) lists in PBM operations continues to gain traction nationally even as legal challenges to some models persist.
- As part of broader legislation addressing prescription drug cost and PBM practices, Maine established a Drug Affordability Review Board.

[37] Ibid.
[38] Maine SP466-LD1504 http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0466&item=4&snum=129
[39] Lanford, S. and Hensley-Quinn, M. Maine Forges New Ground and Enacts Comprehensive Drug Package. National Academy for State Health Policy, July 2019. https://nashp.org/maine-forges-new-ground-and-enacts-comprehensive-drug-package/
[40] Ibid.
[41] Maine SP466-LD1504 http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0466&item=4&snum=129

MARKET ANALYSIS

In this section, we discuss the results of two Tennessee-specific analyses. The first subsection describes Tennessee's prescription drug sales and utilization relative to national and peer state data. The second subsection summarizes responses received from Tennessee carriers and PBMs, including contracting terms and common practices employed across the market.

MARKET SCAN: DRUG COSTS ACROSS STATES

Tennessee ranks number two across all states for overall per capita retail drug sales. The difference in sales is largely driven by the private market and Medicare. As noted in the Methodology, Figure 1 below compares per capita sales in Tennessee with neighboring states as well as states that show a similar prevalence of chronic health conditions.

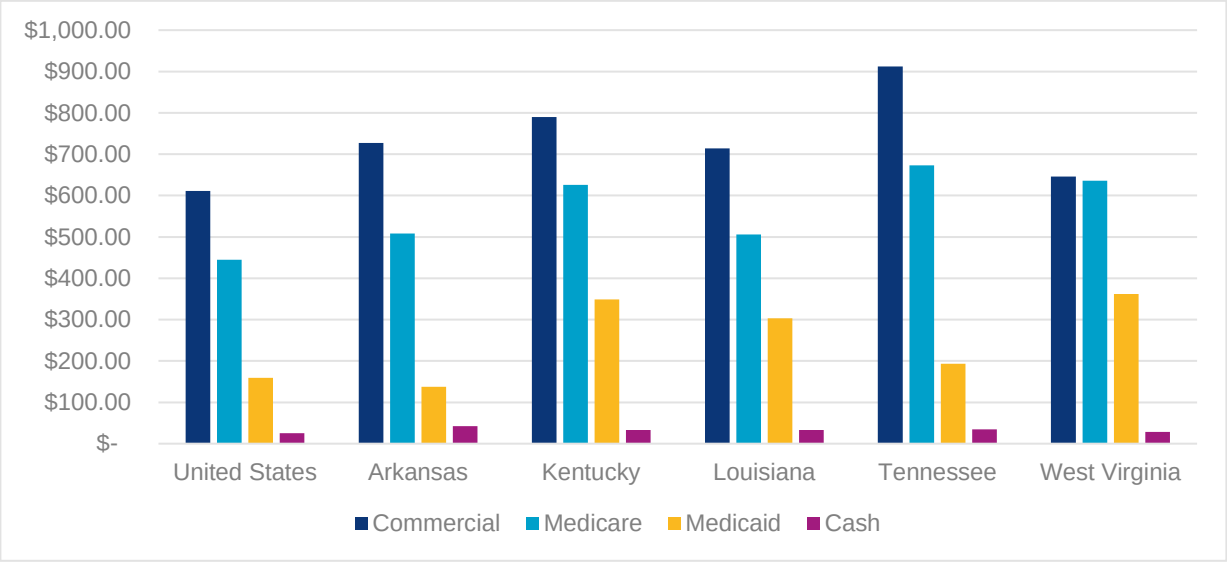

Figure 1. Per Capita Retail Drug Sales

Though Tennessee demonstrates a higher per capita cost relative the rest of the country, Tennesseans show similar or lower per capita utilization than the identified peer states, as illustrated in Figure 2.

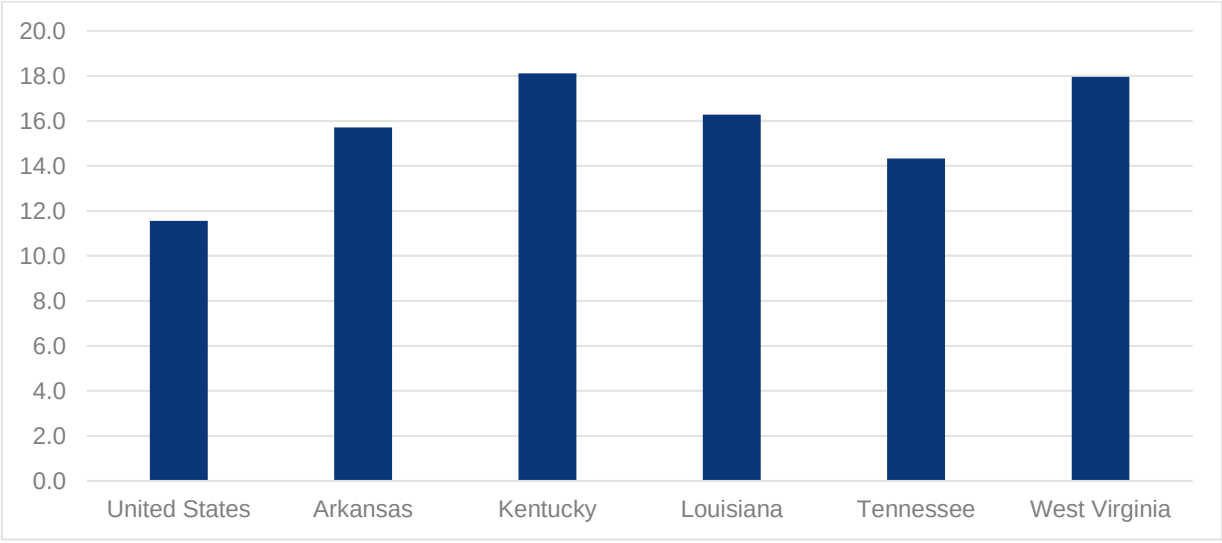

Figure 2. Per Capita Pharmacy Prescriptions

As expected from the above two indicators and illustrated in Figure 3, the straight-line average price per prescription is higher in Tennessee for each type of coverage relative to comparison states.

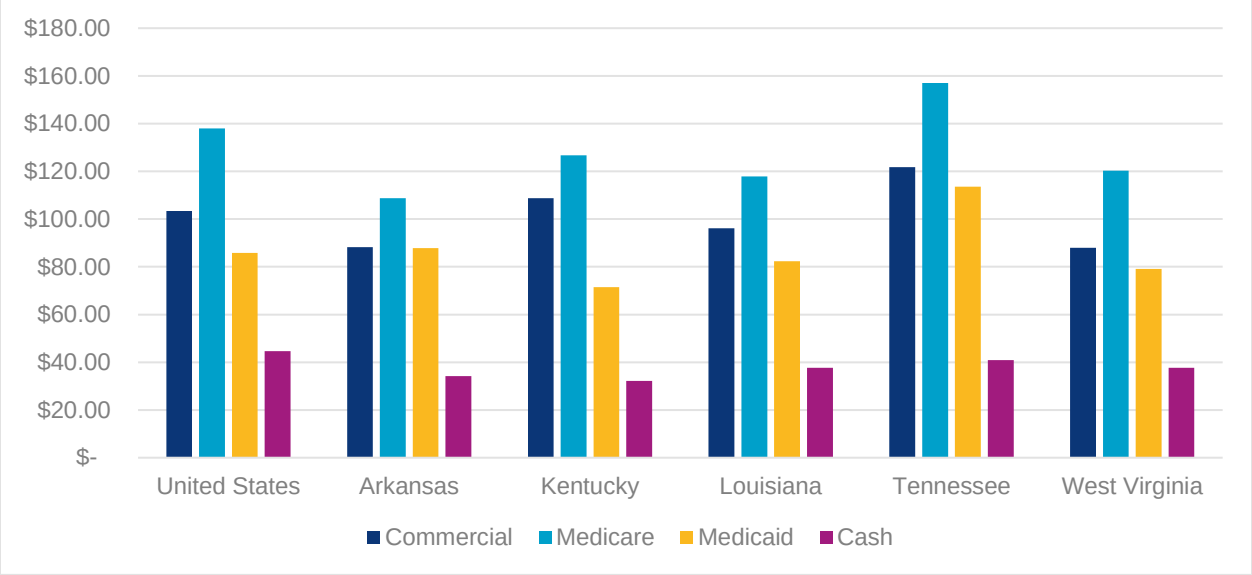

Figure 3. Average Price Per Prescription

While still roughly 33 percent higher than the national average, economic differences may partially explain the higher costs in Tennessee relative to comparison states. Figure 4 demonstrates that retail sales as percent of GDP is lower than three of the four comparison states included in the analysis.

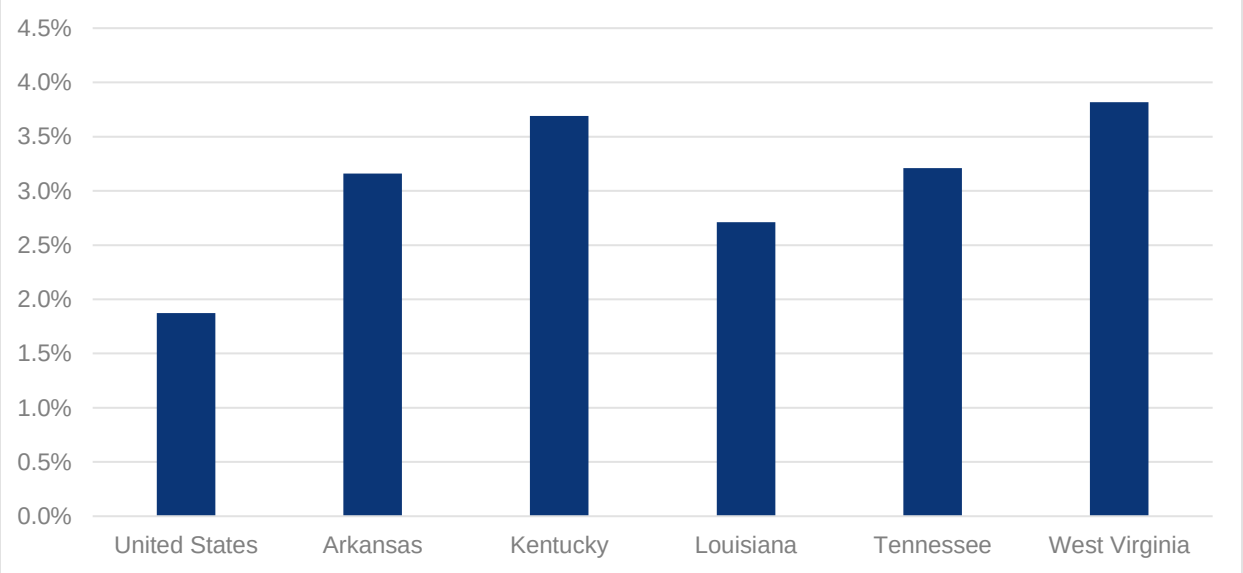

Figure 4. Per Capita Retail Drug Sales as a % of GDP

PBM RESPONSE SUMMARY

PBM responses varied in the level of detail and examples provided. However, after completing follow-up with each PBM, all points on the checklist provided in Appendix C were addressed. Below is a summary of key trends and outliers across the request's major themes.

Formulary Management

Of the respondents who manage formulary development directly, all stated that formularies and utilization management practices are reviewed at least annually, if not quarterly or monthly. All also delegate responsibility for clinical review to a formal Pharmacy and Therapeutics (P&T) Committee or other similar entity consisting of clinicians, specialists, and pharmacists and basing their determinations on prevailing clinical guidelines. Most respondents also provide drug utilization reviews aimed at increasing patient safety and improving appropriate utilization.

We note that a subset of six active PBMs contract out formulary management to a third party. As the State examines the applicability of additional policies, any actions related to formulary design or management must appropriately consider the responsibilities of such third-party vendors.

Accountability

Most respondents specified audit rights for their clients within their contracts, though there is variation in the notice required, allowable lookback period, and number of audits allowed in a contract term. Likewise, most of the respondents include language that allow or require plan sponsors to hire an independent party to complete such audits. One PBM added that they conduct annual market checks to ensure ongoing competitiveness of their terms.

Most PBMs answered affirmatively that they offer measurable and auditable performance guarantees in some contracts. However, those guarantees vary significantly across contracts and, in some cases, are only incorporated on specific client request.

Pricing

Respondents most often cited Medispan as the single source of Average Wholesale Pricing (AWP). In reference to AWP, three PBMs mentioned employing First Databank when pricing is not available in Medispan. One PBM references “multiple sources” for AWP.

Contract language provided by respondents did not indicate any specific protections against drug manufacturer price inflation outside of concerns that may be addressed by fraud, waste, and abuse practices.

HEALTH PLAN CARRIER RESPONSE SUMMARY

There was less variation observed among carrier responses compared to PBM responses. Trends and variances in two major themes are summarized below.

Oversight

All responding carriers stated that the PBM contracts grant them audit and transparency rights, with one carrier adding that they have open access to the PBM’s records. All carriers also stated that they have audited their PBMs in the last five years, and all require monthly and/or quarterly reporting from their PBMs. Reported information may include performance data, utilization, and/or rebate data.

All but two carriers noted that they set specific parameters for formularies, prescription drug lists, and the pharmacy coverage requirements. The remaining two carriers noted that they allow the PBMs to develop such standards but reserve the right to change them as needed.

Compensation and Cost Containment

While carriers described varying payment models across their existing contracts, all indicated that their contracts include separate administrative fees for certain value-added services. Three carriers stated that their contracts require dollar-value rebate guarantees from their PBMs, while an additional three stated that 100 percent of rebates are passed through to the carrier.

Carrier responses also indicated a variety of cost-containment guardrails, including annual guarantees on drug discount rates and dispensing fees, minimum discount rates, and performance targets. Carriers also commented that fraud, waste, and abuse standards allow them to remove certain drugs from the formulary or add prior authorizations and/or quantity limits as needed.

ALIGNMENT WITH BEST PRACTICES AND MODEL POLICY

The following subsection connects the best practices described in earlier sections of this report to Tennessee PBM and carrier responses.

Network Adequacy

Responding PBMs identified standards for their pharmacy networks that aligned with best practices. According to the Pharmaceutical Care Management Association (PCMA), a best practice for PBMs is to "provide patients 24-7 access to pharmacists or other clinicians".[42] Most PBMs offered clients access to pharmacists and/or clinicians, some providing 24/7 call center operations. A subset of PBMs noted that they have adopted limited retail and specialty pharmacy networks to improve discounts for plan sponsors.

PBM Transparency

Tennessee enacted anti-gag clause legislation to prohibit such practices in PBM contracts. Gag clauses prohibit pharmacies contracted with PBMs from informing their consumers that the drug they are purchasing has different cost options available. Anti-gag clause laws have improved transparency among pharmacies, PBMs, and consumers. Responding PBMs allow clients to negotiate contract terms, including rebate arrangements, which is a best practice noted by the PCMA[42].

Milliman identified the inclusion of performance guarantees as a best practice for PBM contracts, specifically "performance guarantees should be measurable and auditable to allow the PBM account teams to track, measure, and clearly explain the guarantees to all stakeholders…Best-in-class language regarding missed performance guarantee payout allocation should state that the health plan has the right to allocate the full at-risk payout amount across its choice of performance guarantees."[43] As noted in the previous section, responding PBMs have established performance guarantees that are both measurable and auditable. However, such guarantees are not standard and often only included on client request.

Pricing

Maximum Allowable Cost (MAC) refers to a payer or PBM-generated list of products defining the maximum amount that a plan will pay for generic drugs as well as brand name drugs for which generic versions are available. Tennessee's MAC law allows pharmacies to appeal a PBM's MAC list and receive retroactive reimbursement for any pricing difference. Several PBMs stated that they maintain consistency in the MAC lists they provide to their clients. Notably, MAC list standards varied for each PBM, with some updating more frequently than others, varying client to client, and potentially using multiple MAC lists for the same client.

All PBMs referenced nationally recognized sources for AWP (Medispan or First Databank), and some PBMs provide guaranteed discounts and dispensing fee provisions, both of which were identified as best practices by Milliman[43]. PBM responses on pricing questions varied greatly, and some best practices were utilized more heavily than others.

[42] Pharmaceutical Care Management Association, infographic. https://www.pcmanet.org/wp-content/uploads/2017/04/PBM-Best-Practices_infographic_FINAL.pdf
[43] Anderson, B. and Callahan G. PBM Best Practices Series: Effective Contracting. Milliman White Paper. Published February 2020. https://milliman-cdn.azureedge.net/-/media/milliman/pdfs/articles/best-practices-effective-pbm-contracting.ashx

Audits

As noted in previous sections of this report, several legislative measures, including those in Tennessee, have been enacted outlining procedural requirements and limitations for pharmacy audits. Responding PBMs indicated that they allow independent auditors to intermittently review and confirm the PBM's contractual performance.

KEY FINDINGS

The market scan and carrier responses described above produced the following key findings:

- Prescription drug costs in Tennessee are markedly higher than both the national average and comparable peer states. This difference in price is only partially explained by differences in GDP among peer states.
- Rebates, the most cited source of both spread revenue and national debate on PBM transparency, do not pose significant risk in the Tennessee fully insured market. Carrier responses indicated either 100 percent pass through of rebate revenue or dollar value guarantees of such revenue from their PBM vendors, both policies aligning with industry best practices.
- MAC list policies provided through carrier and PBM responses leave open the possibility for spread revenue capture by PBMs on generic drugs.
- Audit rights provided under PBM contracts are largely robust and flexible in their application by clients.
- Performance guarantees vary greatly, most often included only on specific client request. This trend tends to disadvantage smaller clients, who may not be aware of – or have the negotiating power to stipulate – such guarantees.
- Contract language provided by most responding PBMs did not include mechanisms to protect clients against drug manufacturer price inflation.

RECOMMENDATIONS

Based on the findings described above, we recommend the four policies described in Table 3 for consideration by the Tennessee State Legislature. These policies seek to close remaining sources of spread revenue in the PBM model, improve accountability and reporting in the PBM-client relationship, and identify and mitigate factors outside of the PBM business model that may be contributing to Tennessee's higher than average consumer drug spend.

Table 3. Recommendations Summary

Policies External to PBM Operations		
Finding	**Goal**	**Recommendation**
Despite rebate pass-through and guarantee provisions, significant audit protocols, and relatively streamlined benchmarking, per capita drug spend and average drug price indicate higher costs than the national average as well as states with similar prevalence of chronic conditions.	Mitigate factors external to PBM operations that may contribute to high drug prices in Tennessee.	Establish a review board to examine drug affordability issues statewide and propose recommendations for future consideration.
Policies Related to PBM Operations		
Finding	**Goal**	**Recommendation**
MAC list standards varied for each PBM and from client to client. Some PBMs maintain multiple lists across clients and within client contracts, leaving open the possibility for spread revenue capture.	Mitigate opportunities for spread revenue across pricing schedules and create more transparent funds flow across entities.	Require carriers contracting with PBMs to stipulate the use of a single MAC list, which dictates both PBM reimbursement from the carrier and pharmacy reimbursement from the PBM.
Performance guarantees in PBM contracts vary greatly depending on the client. Most are only included if specifically requested by the client.	Expand applicability of performance guarantees, ensuring that plan sponsors of all sizes and levels of sophistication may access the same guarantees.	Require carriers contracting with PBMs to include performance guarantees in such contracts, with consistent checks and repercussions for not meeting those guarantees.
Specific terms providing plan sponsor protections against drug manufacturer price inflation were not identified in contract language provided by respondents.	Leverage PBM position to protect against drug manufacturer price inflation.	Require carriers contracting with PBMs to stipulate PBM programs that mitigate the financial risk of mid-year drug manufacturer price inflation as well as the introduction of high-priced new market entrants.

POLICY ANALYSIS

For each recommendation proposed above, this section defines the key policy and resource requirements needed for effective implementation.

BASELINE DATA AND ASSUMPTIONS

The baseline data below is intended to provide situational awareness regarding the current State-regulated market. Several of the factors illustrated below also informed the resource requirements and limitations described for each recommendation later in this section.

Kaiser Family Foundation reports that approximately three million Tennesseans received coverage through their employer. Based on the number of fully ensured enrollees reported to the Dept of Commerce and Insurance, roughly 13 percent of those individuals are covered under fully insured plans. The remainder receive coverage through self-insured plans. Such plans are governed by ERISA and associated regulations outside of the purview of State insurance regulation.

Table 4. Fully Insured Covered Lives* by Market

	2019	2020	2021
Individual	184,794	216,462	206,618
Small Group	129,198	192,930	182,837
Large Group	357,060	372,349	403,367
Total	**671,052**	**781,741**	**792,822**

*Enrollment reported by TN Dept of Commerce and Insurance

Premiums in Tennessee's individual market have declined over the last three filings, while small group and large group premiums have remained relatively constant.

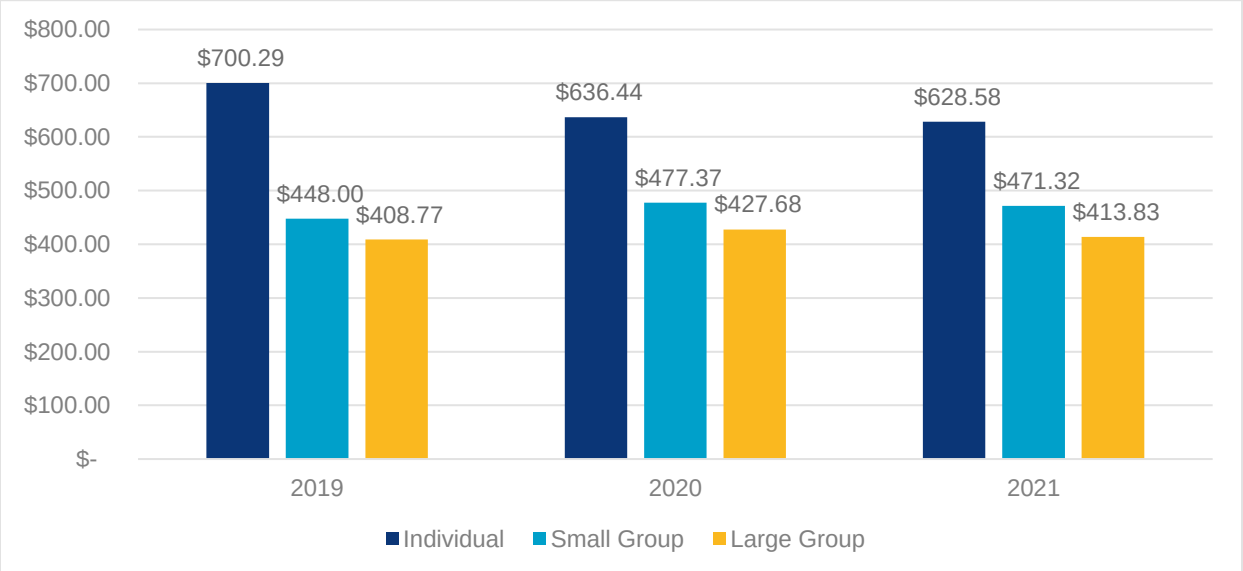

Figure 5. Weighted Average Premium by Market

During the last three filings, Tennessee has experienced modest market entry in the individual and small group markets and modest exit in the large group market.

Table 5. Comprehensive Health Plan Carriers by Market

	2019	2020	2021
Individual	5	5	6
Small Group	6	7	7
Large Group	12	10	9
Total	***23***	***22***	***22***

RECOMMENDATION #1- ESTABLISH REVIEW BOARD FOR DRUG AFFORDABILITY

Best Practices Summary

In 2019, Maine enacted major legislation impacting pharmaceutical pricing, which included establishment of a drug affordability review board.[44] Maine's drug affordability review board is comprised of five members with expertise in health care economics or clinical medicine. Individuals who are directly associated with payers may not be appointed to the board. Both the President of the Senate and the Speaker of the House appoint two members and one alternate board member each. The Governor appoints one member, one alternate board member, and names the Chair of the board. All members serve five-year terms.[45]

The review board is required to convene a public meeting every 12 weeks. During such meetings, the board is expected to review available prescription drug data, largely from public payors across the State, and provide recommendations based on their knowledge and expertise. Board recommendations may impact rebate negotiations, bulk purchasing arrangements, and formulary design decisions. The public may attend and provide comments or, alternatively, submit written comments on pending board decisions. Expert testimony is permitted during the review board meeting as well.[445]

Annual spending targets for public payors are determined by a related advisory board, which is a twelve-member council comprised of a variety of appointed representatives from diverse stakeholder groups. Members of the board and the advisory council are permitted legislative per diem and reimbursement for expenses.[45] The drug affordability review board then presents their recommendations in a report to the joint standing committee of the legislature.[45]

Policy Design

As described earlier in this report, Tennessee has experienced drug prices higher than peer states and the national average that are only partially explained by peer state economic differences. Additionally, our analysis of health plan and PBM contracting practices found that the most common sources of PBM-related price inflation have been mitigated in the Tennessee fully insured market. Establishing a drug affordability review board aims to identify factors external to the PBM focus of this report that may impact drug pricing across payers in Tennessee. Table 6 defines the key elements of policy design that would support implementation of a drug affordability review board in Tennessee.

[44] Lanford, S. and Hensley-Quinn, M. Maine Forges New Ground and Enacts Comprehensive Drug Package. National Academy for State Health Policy, July 2019. https://nashp.org/maine-forges-new-ground-and-enacts-comprehensive-drug-package/
[45] Maine SP466-LD1504 http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0466&item=4&snum=129

Table 6. Drug Affordability Review Board: Policy Design Areas and Considerations

Policy Area	Key Considerations
Applicable Authorities and Governance	Board may be established as a quasi-governmental entity or within the Department of Commerce and Insurance with members appointed by Executive and Legislative branches of Tennessee State government.

Key Requirements	• Board Membership: represents cross-section of clinical and health economic expertise
	• Charge:
	  ○ Establish parameters to define affordability for Tennessee consumers.
	  ○ Review drug prices for key cost drivers, which may include individual drugs or drug categories.
	  ○ Report findings and recommendations, which may include legislative action, plan guidance, employer guidance, etc.
	• Funding: may be funded by grants, PBM/health plan fee, etc. and operated in accordance with § 9-1-118 as applicable
	• Term Limits: may be limited to 5-year terms
	• Public Meetings and Record: defines requirements for open meetings and record disclosure in accordance with § 10-7-503
	• Conflict of Interest: establishes parameters to limit and disclose actual and perceived conflicts of interest and applicable repercussions

Oversight	Board may report to an appropriate legislative committee, such as the House Life and Health Insurance Subcommittee, regarding activity and findings on a semi-annual basis.
Additional Options	• Public employees' health plan may be directed to incorporate Board findings into their formulary design. • Insurance Dept may be required to disseminate Board findings as informational bulletin to carriers and registered PBMs. • Non-voting Board Member advisory roles may be added for Insurance Commissioner or designee, Public employee's health plan administrator or designee, patient advocates, employers, pharmacists, etc. • Additional funding may be sought in the future for external resources as needed
Timing	Board establishment: Appointments may be required within six months of establishing legislation. Additional milestones may include first convening, finalization of charter and objectives, confirmation of funding sources/endowments if applicable, etc. Sunset clause: Tennessee may choose to establish a sunset clause to provide an opportunity to evaluate the drug affordability review board's effectiveness before choosing to extend its lifespan.

Resource Requirements and Financial Implications

Reflecting the requirements of other State-appointed committees in Tennessee, the Drug Affordability Review Board would require, at minimum, funding allocations for travel reimbursement and per diem expenses.

In Maine, baseline funding is allocated under the Department of Administrative and Financial Services. However, the board is also in the process of establishing independent funding to support future review activities. The review board is allowed to receive funding and grants from other public and private sources.

Depending on the level of coordination and scope of responsibilities assigned through legislation, the State may also consider allocating a resource to oversee the operations of the review board. This resource would be dedicated to managing execution of review board tasks as well as coordinating communications with key stakeholders and State agencies. Estimated funding is provided in Table 7 below.

Table 7. Drug Affordability Review Board: Estimated Annual Funding

Financial Implications	
Per Diem	$223 per diem lodging per day $61 per diem meals per day
Expense Reimbursement	2d x $284 = $568 per member/per meeting
*Full Time Employee	Salary: $80,220[46] Fully loaded at 30% benefit rate: $104,286[+]
**Total Financial Implications	Without optional FTE: $18,176 With optional FTE: $122,462

*Optional
**Assumes eight (8) member board, quarterly meetings.
[+]Assumes benefit multiplier of 1.3.

As the Board progresses through their review efforts, they may find it useful or necessary to solicit support from external resources. If allowed under the establishing legislation (as described under Additional Options in Table 6 above), the Board may seek public or private sources of additional funding to cover such external needs.

Key Implementation Milestones

Table 8 below identifies the initial milestones to guide implementation of the Review Board, noting the parties responsible for achieving each milestone. Subsequent milestones would be set by the Board itself, reporting back to the identified Legislative oversight committee as required.

Table 8. Drug Affordability Review Board: Implementation Milestones

ID	Milestone	Responsible Parties
1	Establishing legislation enacted	State Legislature and Governor
2	Board Members appointed	State Legislature and Governor, as defined in legislation
2.1	*Optional: Job posting for Project Manager released*	Board Chair, Dept of Human Resources
3	Inaugural Board meeting held	Board Chair / Co-Chair
4	Charter and review procedure approved by Board	Board members
5	First review and recommendations reported to Committee	Board Chair

Limitations and Additional Considerations

While conducting external reviews of drug affordability will shed light on other factors that may be contributing to the high cost of prescription drugs, board recommendations will only hold weight to the extent that they are implemented. The State will have the most direct control over implementation within public, state-operated programs. However, whether such recommendations and public actions can influence the trajectory of other markets will largely depend on subsequent legislative action.

[46] US Bureau of Labor Statistics. Project Management Specialist: https://www.bls.gov/oes/current/oes_nat.htm

RECOMMENDATION #2 – REQUIRE SINGLE STANDARDIZED MAC LIST IN PBM CONTRACTS

Best Practices Summary

The goal of MAC pricing is to establish a fair reimbursement rate for all pharmacies and ensure that plan sponsors are not overpaying for medications. MAC pricing allows PBMs to routinely compare the acquisition costs for a given product. However, it is not uncommon for PBMs to employ multiple MAC lists, one that dictates plan sponsor reimbursement to the PBM and one or more other lists that provide different rates to contracted pharmacies, allowing PBMs to retain spread revenue.[47] Eliminating this spread improves the transparency of contracting practices and resulting revenue streams, allowing plan sponsors greater control over where their dollars are spent.

This recommendation complements existing Tennessee legislation allowing pharmacies to appeal MAC related drug reimbursement, providing an additional layer of transparency specific to the plan sponsor.

Policy Design

Because settled and pending ERISA challenges question a State's ability to regulate PBM activity directly, this recommendation may be implemented by focusing on fully insured carriers' contractual agreements with their PBM vendors. As noted in prior sections of this report, Maine successfully averted legal challenges to their recent legislation by placing the onus on carriers to contractually adopt certain PBM requirements.

Table 9. Standardized MAC List: Policy Design Areas and Considerations

Policy Area	Key Considerations
Applicable Authorities and Governance	• State legislatures are vested with the authority to create, through the legislative process, new statutory requirements for non-ERISA insurance carriers and products. • The Department of Commerce and Insurance, Insurance Division is vested with the authority to regulate non-ERISA insurance carriers and products.

Requirements	• Operations:
	  ○ Require fully insured carriers operating in Tennessee to contractually require pass-through MAC list pricing with their PBM vendor.
	  ▪ Carriers must contractually require their PBM vendor to employ the same MAC list for their contracted pharmacies and the plan sponsor, passing through all revenue collected from the plan sponsor to the dispensing pharmacy.

Oversight	• Carriers may be required to demonstrate compliance with this requirement to the Department by providing standard contract language in the first year followed by attestations in subsequent years. The Department may conduct random and targeted market conduct exams to confirm compliance in future years. • The Department may report to the appropriate legislative committee, such as the House Subcommittee of Life and Health Insurance, regarding plan compliance with the requirement
Additional Options	• Carriers may be required to specify sourcing of MAC pricing, update protocols, or other disclosure and audit requirements.

[47] Calabrese, D. Am Health Drug Benefits. June 2008. 1(5). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115299/

Timing	• The Department may require up to one year to promulgate rules for insurance carriers to demonstrate compliance as well as establish policies and procedures to operationalize compliance review. • Carriers may require one plan year following the Department's dissemination of the policies and procedures to come into compliance.

Resource Requirements and Financial Implications

Key resource requirements for this recommendation, as well as all remaining recommendations in this report, are based on the State staff hours required to review and validate carrier compliance. As stated in the Assumptions section of this report, the Department of Commerce and Insurance reports six individual market carriers, seven small group carriers, and nine large group carriers, totaling 22 carriers subject to this requirement. However, we note that the timeframe for individual and small group first year contract reviews and subsequent year attestation reviews is limited to the form filing window each year. Large group reviews may be required at any time during the year.

Table 10 below estimates the annual cost associated with three operational workstreams. During the initial form filing submission, the Department may require up to an additional 200 hours to validate submitted contract language and may benefit from specific experience in pharmacy and formulary audit protocols. Once initial compliance has been confirmed, carriers may submit an attestation confirming their compliance as part of subsequent form filing processes. As directed by establishing legislation, the Department may then conduct targeted reviews of individual carriers to confirm ongoing and systemic compliance across all executed plan contracts.

Table 10. MAC List Compliance: State Resource Estimates

Financial Implications	First Year – Contract Language Review	Subsequent Years – Attestation Review	Targeted Review
Review Contract Estimated Time	4-8 hours per contract	N/A	16 hours per carrier
Receive and confirm completion of attestation	N/A	5-10 minutes per attestation	N/A
Review Attestation Language	N/A	30-60 minutes per attestation	N/A
Total # of Carriers	*22*	*22*	*5 annually*
Subtotal – All Carriers	88 - 176 hours	13 – 26 hours	80 hours
Reporting to the Oversight Committee	20 hours	12 hours	40 hours
Annual Additional Time Requirement	108 - 196 hours	25 – 38 hours	120 hours

Key Actions Required to Implement

Table 11 below identifies the initial milestones to guide implementation of standardized MAC lists among applicable carriers, noting the parties responsible for achieving each milestone. The first 12 months following enaction will focus on promulgating carrier rules and establishing internal policies and procedures to confirm compliance at the Department of Commerce and Insurance. Compliance processes will begin with the first form filing period for the next plan year.

Table 11. MAC List Compliance: Implementation Milestones

ID	Milestone	Responsible Parties
1	Establishing legislation enacted	State Legislature and Governor
2	Rules promulgated for validating carrier compliance	Dept Commerce and Insurance
3	Policies and procedures for validation established	Dept Commerce and Insurance
4	First year resources secured	Dept Commerce and Insurance
5	Carriers submit appropriate document during form review period	Applicable health plan carriers
6	Report to the oversight committee confirming first year compliance	Dept Commerce and Insurance

Limitations and Additional Considerations

ERISA limits the applicability of this recommendation to the fully insured market. As described earlier in this report, less than 800,000 covered lives are enrolled in such a health plan regulated by the State of Tennessee. As with any new State regulation, three potential impacts may occur:

1. The requirement to pass through MAC drug related revenues will likely trigger a renegotiation of administrative fees charged by the PBM. How these two reimbursement changes balance against each other will in part determine the impact on resulting cost.
2. Should the requirement positively impact cost for fully insured plan sponsors, the self-insured market may see consideration or adoption of similar contracting requirements, expanding the impact of this legislation beyond regulated carriers.
3. Conversely, if the requirement negatively impacts costs for plan sponsors, the market may see further migration toward self-insured products. While best practices research conducted during this study does not suggest such an impact, we cannot eliminate that possibility under the scope of this study.

RECOMMENDATION #3 – MANDATE PERFORMANCE GUARANTEES

Best Practices Summary

Incorporating PBM performance guarantees into plan sponsor contracts adds a layer of accountability and transparency to the health plan-PBM relationship. As described in a recent research brief of effective PBM contracting, PBM "performance guarantees should be measurable and auditable to allow the PBM account teams to track, measure, and clearly explain the guarantees to all stakeholders. Best-in-class language regarding missed performance guarantee payout allocation should state that the health plan has the right to allocate the full at-risk payout amount across its choice of performance guarantees. Not doing so allows the PBM to dilute the payout at risk, as some or most performance guarantees are easily achieved. Any customized performance guarantees should also be auditable and measurable."[48]

During our analysis of current Tennessee industry practices, most PBMs answered affirmatively that they comply with measurable and auditable performance guarantees in some contracts. However, those guarantees vary significantly across contracts and, in some cases, are only incorporated on specific client request.

[48] Anderson, B. and Callahan G. PBM Best Practices Series: Effective Contracting. Milliman White Paper. Published February 2020. https://milliman-cdn.azureedge.net/-/media/milliman/pdfs/articles/best-practices-effective-pbm-contracting.ashx

Policy Design

By requiring all fully insured health plan carriers to incorporate and report on PBM performance guarantees, this recommendation seeks to ensure that plan sponsors of all sizes and levels of purchasing power are aware of and may access the same guarantees.

Table 12. PBM Performance Guarantees: Policy Design Areas and Considerations

Policy Area	Key Considerations
Applicable Authorities and Governance	• State legislatures are vested with the authority to create, through the legislative process, new statutory requirements for non-ERISA insurance carriers and products. • The Department of Commerce and Insurance, Insurance Division is vested with the authority to regulate non-ERISA insurance carriers and products.

Requirements	• Operations:
	  ○ Require carriers contracting with PBMs to include in such contracts measurable and auditable guarantees that may be monitored at least annually by the plan sponsor
	  ○ Require reasonable repercussions for PBMs failing to meet contractual guarantees

Oversight	• Carriers may be required to demonstrate compliance with this requirement to the Department by providing standard contract language in the first year followed by attestation in subsequent years. • Carriers may also be required to provide evidence of PBM performance against contractual guarantees in subsequent years. • The Department may conduct random and targeted market conduct exams to confirm compliance in future years. • The Department may report to the appropriate legislative committee, such as the House Subcommittee of Life and Health Insurance, regarding both plan compliance and associated PBM performance.
Additional Options	• Allow underperformance in one area to be compensated by overperformance in another area.
Timing	• The Department may require up to one year to promulgate rules for insurance carriers to demonstrate compliance as well as establish policies and procedures to operationalize compliance review. • Carriers may require one plan year following the Department's dissemination of the policies and procedures to come into compliance.

Resource Requirements and Financial Implications

Oversight of this recommendation requires both validation of contract compliance and subsequent review of reported outcomes resulting from those contractual obligations. Though the three workstreams for this recommendation mirror those in Recommendation #2, we note that the hours required to effectively execute these workstreams are markedly higher. Targeted reviews will include both validation of the adoption of performance guarantees across executed contracts as well as validation that such guarantees have been met and reported by the PBM vendor.

Table 13. PBM Performance Guarantee Compliance: State Resource Estimates

Financial Implications	First Year – Contract Review	Subsequent Years – Attestation Review	Targeted Reviews
Data Request	1 hour per carrier	N/A	1.5 hours per carrier
Review Contract Language	4-8 hours per carrier	N/A	N/A
Scrub data	N/A	N/A	2-6 hours per carrier
Validate findings & complete report	N/A	N/A	15-25 hours per carrier
Receive and confirm attestation	N/A	0.5-2 hours	N/A
Total # Carriers	*22*	*22*	*5 annually*
Subtotal – All Carriers			
Report to the oversight committee	40 hours	12 hours	70 hours
Total Time Requirement	150-238 hours	23-56 hours	162.5-232.5 hours

Key Actions Required to Implement

Table 14 below identifies the initial milestones to guide implementation of PBM performance guarantees, noting the parties responsible for achieving each milestone. The first twelve months following enaction will focus on promulgating carrier rules and establishing internal policies and procedures to confirm compliance at the Department of Commerce and Insurance. Compliance processes will begin with the first form filing period for the next plan year. Targeted reviews may commence during the following plan year.

Table 14. PBM Performance Guarantee Compliance: Implementation Milestones

ID	Milestone	Responsible Parties
1	Establishing legislation enacted	State Legislature and Governor
2	Rules promulgated for validating carrier compliance	Dept Commerce and Insurance
3	Policies and procedures for validation established	Dept Commerce and Insurance
4	First year resources secured	Dept Commerce and Insurance
5	Carriers submit appropriate document during form review period	Applicable health plan carriers
6	Report to the oversight committee confirming first year compliance	Dept Commerce and Insurance

Limitations and Additional Considerations

Again here, ERISA limits the applicability of this recommendation to the fully insured market, thus limiting the consumer population that may be positively impacted. Additionally, the impact that performance guarantees may have on the market directly depends on the robustness of such guarantees. Carriers and consumers may benefit from communication of sample guarantees and/or dissemination of guides for developing such guarantees.

RECOMMENDATION #4 – REQUIRE PROTECTION AGAINST MANUFACTURER PRICE INFLATION

Best Practices Summary

Best practices promote the inclusion of PBM programs to protect against drug manufacturer price inflation in plan sponsor contracts. Such programs may include establishment of a standard cost effectiveness evaluation process for all new market entrants, establishment of price inflation caps in conjunction with major manufacturers, implementation of utilization review triggers, etc. If appropriately designed, these mechanisms limit the plan sponsor's financial exposure in the event of mid-year manufacturer price increases.

Policy Design

As discussed under Recommendation 3, this recommendation similarly seeks to expand implementation of this best practice across the fully insured market, addressing specific and ongoing national concerns caused by unexpected price increases from drug manufacturers.

Table 15. Price Inflation Protections: Policy Design Areas and Considerations

Policy Area	Key Considerations
Applicable Authorities and Governance	• State legislatures are vested with the authority to create, through the legislative process, new statutory requirements for non-ERISA insurance carriers and products. • The Department of Commerce and Insurance, Insurance Division is vested with the authority to regulate non-ERISA insurance carriers and products.
Requirements	• Operations: ○ Require the carriers to include in their PBM contracts mechanisms in which PBMs protect against drug manufacturer price inflation, which may include but not limited to: ▪ Establishing a standard and rigorous cost effectiveness evaluation process for all new drugs to market before they may be added to formulary ▪ Requiring the contracted PBM to establish and demonstrate the existence of price inflation caps with drug manufacturers. ▪ Establishing mid-year procedures for utilization management review ○ Require savings resulting from price inflation protections to be passed through to the plan sponsor.
Oversight	• Carriers may be required to demonstrate compliance with this requirement to the Department by providing standard contract language in the first year followed by attestation in subsequent years. Carriers may also be required to provide evidence of the efficacy of price inflation protections • The Department may conduct random and targeted market conduct exams to confirm compliance in future years. • The Department may report to the appropriate legislative committee, such as the House Subcommittee of Life and Health Insurance, regarding both plan compliance and associated price inflation protection.
Additional Options	
Timing	• The Department may require up to one year to promulgate rules for insurance carriers to demonstrate compliance as well as establish policies and procedures to operationalize compliance review.

	• Carriers may require one plan year following the Department's dissemination of the policies and procedures to come into compliance.

Resource Requirements and Financial Implications

Validating compliance with this recommendation requires both contract level review and confirmation of associated outcomes. As such, targeted reviews in the third workstream should be guided by a data request specific to recent price inflation activity, demonstrating the protections put in place under the contract and the value of those protections.

Table 16. Price Inflation Protection Compliance: State Resource Estimates

Financial Implications	First Year – Contract Review	Subsequent Years – Attestation Review	Targeted Reviews
Review One Contract Estimated Time	4-8 hours per carrier	N/A	N/A
Data request	0.5 hours per carrier		4 hours per carrier
Scrub data	N/A	N/A	4-8 hours per carrier
Validate performance reviews/write report	N/A	N/A	10-30 hours per carrier
Receive and confirm attestation	N/A	0.5-2 hours per carrier	N/A
Total # Carriers	*22*	*22*	*5 annually*
Subtotal – All Carriers	99-187 hours		
Report to the oversight committee	40 hours	12 hours	50 hours
Total Financial Implications	139-227 hours	23-56 hours	140-260 hours annually

Key Actions Required to Implement

Table 17 below identifies the initial milestones to guide implementation of PBM performance guarantees, noting the parties responsible for achieving each milestone. The first 12 months following enaction will focus on promulgating carrier rules and establishing internal policies and procedures to confirm compliance at the Department of Commerce and Insurance. Compliance processes will begin with the first form filing period for the next plan year. Targeted reviews may commence during the following year.

Table 17. Price Inflation Protection Compliance: Implementation Milestones

ID	Milestone	Responsible Parties
1	Establishing legislation enacted	State Legislature and Governor
2	Rules promulgated for validating carrier compliance	Dept Commerce and Insurance
3	Policies and procedures for validation established	Dept Commerce and Insurance
4	First year resources secured	Dept Commerce and Insurance
5	Carriers submit appropriate document during form review period	Applicable health plan carriers
6	Report to the oversight committee confirming first year compliance	Dept Commerce and Insurance

Limitations and Additional Considerations

ERISA again limits the applicability of this recommendation to the fully insured market, thus limiting the consumer population that may be positively impacted. Additionally, the impact that price inflation protections may have on the market directly depends on the robustness of such protections. Carriers and consumers may benefit from communication of sample protections and/or dissemination of guides for developing such protections.

DISCUSSION AND SUMMARY OF RECOMMENDATIONS

State governments around the country are working to find the right balance of regulatory oversight to ensure that PBMs are operating transparently and responsibly. The regulations that have been most successful in meeting this goal while avoiding legal challenges include anti-gag clause, PBM registration, and oversight and audit laws that avoid specific pricing stipulations. In the future, however, we can expect states to continue to seek more proactive ways of regulating PBM pricing that help contain costs and ensure financial transparency.

The recently decided PCMA v Rutledge US Supreme Court case regarding ERISA preemption helps clarify the history of conflicting findings from lower court appeals and – given the 8-0 decision – appears to open the door for broader State regulation of PBM operations. Whether PCMA can successfully pivot strategies to block future legislation remains to be seen. In the near term, Maine's most recent approach, which focuses on regulating insurance carrier contracts rather than PBM actions, continues to offer a path forward for states intending to increase regulation and oversight of pharmacy management. This pathway offers two additional advantages. Strategically, by focusing on the fully insured market, the State may directly communicate with and monitor the outcomes for the carriers being impacted as their plans fall under State regulatory purview. Operationally, this approach directly leverages several existing processes guiding State insurance regulation, augmenting current workstreams rather than creating anew.

In the table below, we summarize the key policy considerations, resource requirements, and limitations of each recommendation described in this report. Given the overlapping expertise required to implement and effectively monitor Recommendations #2-4, we have collapsed the resource estimates to identify total additional State hours. Hiring a dedicated resource within the Insurance Division of the Department of Commerce and Insurance would provide the level of consistent support and internal expertise required to successfully implement such measures across all applicable markets.

Table 18. Recommendation Summary

Recommendation	Policy Considerations	Resources[49]	Limitations

#1 Drug Affordability Review Board	• Board Membership representing cross-section of clinical and health economic expertise
	• Charge:
	  ○ Establish parameters to define affordability.
	  ○ Review drug prices for key cost drivers.
	  ○ Report findings and recommendations.
	• Funding may be funded by grants, PBM/health plan fee, etc. and operated in accordance with § 9-1-118 as applicable
	• Term may be limited to five years
	• Public Meetings and Record: defines requirements for open meetings and record disclosure in accordance with TN Code 10-7-503.
		Expense allocation for Board members: Est. $18,176 annually. With optional FTE for project management: Est. $122,462 annually.	Board authority limited to providing recommendations. Implementation of such recommendations may require additional operational, or in some instances, legislative actions.

#2 MAC List Oversight	• Carriers must require PBM to employ the same MAC list for all contracted pharmacies and the plan sponsor. • Revenue collected against the acquisition cost must be passed through to the plan sponsor.	Estimated FTE requirement specific to form filing and market conduct activities: 0.4 – 0.7 FTE. New requirements in this area will likely require additional communications and technical support for carriers and impacted PBMs beyond the time needed to complete specific oversight activities. Fully loaded FTE: Est. $110,417[50]	• ERISA limits applicability to the fully insured market. • Pass-through requirement will likely trigger renegotiation of administrative fees charged by the PBM. ○ How MAC list revenues and administrative fees balance out will in part determine the overall cost impact of this requirement.
#3 PBM Performance Guarantees	• Require carriers to include measurable and auditable guarantees that may be monitored at least annually by the plan sponsor. • Require reasonable repercussions for PBMs failing to meet guarantees. • Carriers may be required to provide evidence of the PBM performance against guarantees.		• ERISA limits applicability to the fully insured market. • Impact depends on the robustness of contract terms. • Carriers and consumers may benefit from communication of sample protections and/or dissemination of guides for developing such protections.

#4 PBM Protections Against Drug Manufacturer Price Inflation	• Require carriers to include in PBM contracts mechanisms by which PBMs protect against manufacturer price inflation, which may include:
	  ○ Establishing a rigorous cost effectiveness evaluation process for all new drugs to market before they may be added to formulary
	  ○ Requiring the contracted PBM to establish and demonstrate the existence of price inflation caps with drug manufacturers.
	  ○ Establishing mid-year procedures for utilization management review
	• Require savings resulting from price inflation protections to be passed through to the plan sponsor.		

[49] Annual cost is based on current dollars, not adjusted for inflation in future years.
[50] Based on current salary levels for Manager/Associate Director positions within the Department of Commerce and Insurance https://salary.app.tn.gov/public/searchsalary, and a 30% benefit load.

APPENDIX A. GLOSSARY OF COMMON PBM TERMS

Term	Definition / Explanation
Actual Acquisition Cost	The net cost paid by a pharmacy for a drug, which excludes the pharmacy's operating costs and associated dispensing fees.
Adjudication	The processing of a prescription drug claim for payment. Most claims are submitted electronically by the dispensing pharmacy to the PBM or insurance company.
Administrative Fee	Fee paid to a PBM by their client for specific services rendered. The fee may be charged on a per-drug or per-member basis. Per-member fees transfer a level of risk to the PBM in managing member utilization.
Average Wholesale Price (AWP)	A pricing benchmark reflecting the average price paid by pharmacies to purchase drugs from wholesalers.
Benefit Administration	The operation of drug benefit related processes, which may include implementing and maintaining coverage and exclusions, enforcing limits, and defining member cost sharing.
Claim	In the context of insurance coverage, a claim is a formal request to an insurance company for compensation. Claims are typically required to include several standard pieces of information describing the service provided.
Claw Back	In the event that the standard co-pay paid by a member exceeds the actual cost of the drug, a claw back occurs when the pharmacy is required to collect and send the excess the payment to the member's insurance company or PBM.
Client	A PBM's client is the health insurer, employer, or other managed care organization that has contracted the PBM to manage their drug benefit.
Co-insurance	A fixed percent of the drug cost that the consumer pays when filling a prescription.
Co-pay	A fixed dollar amount that the consumer pays when filling a prescription.
Deductible	An annual dollar amount that a member must pay out of pocket before their coverage begins. Though not as common in the fully insured market today, some plans require their members to pay a separate prescription drug deductible before their coverage begins.
Dispensing Fee	A fixed amount charged by a pharmacy to cover the costs associated with filling prescriptions for members.
Employee Retirement Income Security Act (ERISA)	In the context of health insurance, ERISA is a federal law that sets minimum standards for self-insured plans offered by an individual's current or former employer. (See definition of self-insured below.)
Fiduciary Duty	A person or entity is obligated to act in a way that benefits another person or entity.
Formulary	An approved list of drugs for which coverage is provided under a given plan. An open formulary provides a list of recommended drugs but will reimburse for any drug filled by a member (certain drugs, such as over the counter medication, may be excluded). A closed formulary will only cover drugs that are included on the list. No reimbursement is provided for non-formulary drugs unless specifically authorized by the PBM or PBM client. The tiered, or incented, formulary, subjects different drugs to different co-pay amounts to encourage use of more cost effective options.
Fully-Insured Health Plan	A consumer or employer pays a fixed amount to an insurance company, who then covers the cost of the member's health care according to the coverage terms.
Gag Clause	Contractual requirement prohibiting pharmacists from telling consumers when it would cost less to pay cash for a given prescription than to use their insurance.
Market Conduct Exam	An investigation conducted insurance regulators to determine whether an insurer has followed applicable laws relating to consumer products.

Maximum Allowable Cost (MAC)	The price schedule for generic drugs, which is usually benchmarked at 50–60% below AWP. PBMs either set MAC pricing internally or may use MAC pricing schedules established for, for example, Medicaid beneficiaries.
Medical Necessity	The determination of whether services or products may be justified as reasonable, necessary, and/or appropriate, based on evidence-based clinical standards of care.
Pass-Through Pricing Model	A model in which the PBM remits the same cost, including discounts and dispensing fees, charged by a pharmacy to the PBM client. The PBM does not retain any portion of the reimbursement provided by the client.
Rebate	A negotiated dollar amount paid by manufacturers to PBMs to offset the cost, and thus encourage the sale, of brand name drugs.
Self-Insured Health Plan	An employer directly covers the actual claims costs for their employees and dependents. The employer may use an insurance company or other third party to administer their plan, but the employer assumes the financial risk in this arrangement.
Spread Pricing Model	A model in which the PBM retains a portion of the pharmacy reimbursement paid by the client.
Usual and Customary Charges	The price a pharmacy charges to consumers who pay cash without using any insurance coverage.
Utilization Management	A system designed to contain drug costs and promote appropriate use of prescription drugs. Utilization management often encourages the use of generic drugs, brands for which the manufacturer have provided deep discounts, or drugs that pose fewer safety risks.

APPENDIX B. PBM AND CARRIER DATA REQUESTS

DATA REQUEST FOR PHARMACY BENEFIT MANAGEMENT LANDSCAPE REVIEW

INTRODUCTION

The Tennessee Department of Commerce and Insurance has contracted with Public Consulting Group, Inc. (PCG) to assess the current landscape of pharmacy benefit management and the role managers play in Tennessee's healthcare market. The Department asks that PBMs active in the Tennessee market respond to the questions below to support this analysis. This request is not an audit. All information collected will be kept anonymized and solely used for this assessment.

INSTRUCTIONS

PBMs are asked to complete the each of the sections below. The Department requests that PBMs submit their response **no later than March 23, 2020 to David Combs (David.Combs@tn.gov)** Should you have any questions regarding the request for information, please also direct them to David Combs.

Formulary Development Process

1. Describe the processes, strategies, and evidence (guidelines, Randomized Control Trials (RCTs), comparative effectiveness studies, etc.) used to determine scope of pharmacy coverage.
2. Describe the rules and process used to determine tier placement and any utilization management strategies i.e. prior authorization and step therapy.
3. How often are the guidelines and rules described in items (1) and (2) above reviewed and updated?
4. Please provide sample copies of P&T agendas, minutes, and review materials.

Plan Sponsor Contract Terms

1. Please provide a copy of standard contract language used in plan sponsor contracts.
2. Do your plan sponsor contracts typically include dollar-value or other guarantees with respect to manufacturer rebates?
3. What value-add services do you offer to plan sponsors? Do you charge separate administrative fees for any such services?
4. Please describe your process for developing the Maximum Allowable Cost (MAC) list including, but not limited to, the sources used to determine MAC, frequency of MAC updates, criteria used to place a drug or medical device on a MAC list.
5. What source(s) do you use to determine Average Wholesale Price (AWP)?
6. Does your pricing structure differ for mail order claims verses retail pharmacy claims? Please explain.

DATA REQUEST FOR PHARMACY BENEFIT MANAGEMENT LANDSCAPE REVIEW

INTRODUCTION

The Tennessee Department of Commerce and Insurance has contracted with Public Consulting Group, Inc. (PCG) to assess the current landscape of pharmacy benefit management and the role managers play in Tennessee's healthcare market. The Department asks that carriers respond to the questions below to support this analysis. This request is not an audit. All information collected will be kept anonymized and solely used for this assessment.

INSTRUCTIONS

Carriers are asked to complete the each of the sections below. The Department requests that carriers submit their response **no later than March 23, 2020 to David Combs (David.Combs@tn.gov)** Should you have any questions regarding the request for information, please also direct them to David Combs.

General Audit and Transparency Rights

1. Do your PBM contracts grant you any audit and transparency rights?
    a. If so, please describe.
    b. Have you audited your PBM in the last five (5) years?
    c. Do you require regular reporting from your PBM? Please describe.

PBM Contract Terms

1. Do your PBM contracts stipulate any requirements regarding the scope of pharmacy coverage and/ or rigor of formulary development? Please describe.
2. What reimbursement model do your PBM contracts employ? Does your PBM charge you separate administrative fees for value-add services? Please describe.
3. Do your PBM contracts include any form of rebate guarantee?
4. Do your PBM contracts include any guardrails related to cost containment?

APPENDIX C. PBM RESPONSE CHECKLIST TEMPLATE

Formulary Development
1. Perform drug utilization reviews to reduce drug-drug interactions, increase patient safety, and improve appropriate use.
2. Use independent clinical experts and specialists to develop formularies and clinical programs to help ensure patients have access to clinically appropriate treatments.
3. Formulary development process references nationally recognized clinical guidelines.
4. Formulary exclusions and utilization management practices are reviewed at least annually.
5. PBM maintains consistency in MAC lists.
6. PBM uses nationally recognized, single source for AWP.
Contracting Terms
1. Offer programs that facilitate timely patient appeals to help ensure appropriate medication use.
2. Provide clients with audit rights in their contracts.
3. Negotiate all client contractual terms, including rebate arrangements ranging from 100% pass-through to shared savings.
4. Offer network options that include high quality, credentialed pharmacies.
5. Provide clients with programs to protect against drug manufacturer price inflation.
6. Provide patients 24-7 access to pharmacists or other clinicians.
7. Guarantee financial terms and service levels.
8. Include guaranteed discounts and dispensing fee provisions.
9. Adopt limited retail and specialty pharmacy networks to improve discounts for plan sponsors.
10. Include clear and auditable language related to minimum pricing and rebate guarantees.
11. Create clear definitions and key terms to eliminate confusion and frustration.
12. Include performance guarantees that are measurable and auditable to allow the PBM account teams to track, measure, and clearly explain the guarantees to all stakeholders.
13. Include a termination clause that gives the plan sponsor the right to cancel without penalty.
14. Include auditing provisions that allow the health plan the right to choose and hire an independent auditor to intermittently confirm the PBM's contractual performance.
15. Define rebate terms clearly.