

# SB 2008 SCA001 – Oppose Pharmaceutical Care Management Association

# Comments and Concerns Respectfully Submitted on April 26, 2021

PCMA member companies to participate in the stakeholders meeting include: Centene; CVS Caremark; Express Scripts; Humana; OptumRx; Prime Therapeutics; MagellanRx;

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans—with health coverage through large employers, health insurers, labor unions, and federal and state-sponsored health programs.

In 2019 over 135 million¹ prescription drug claims were processed in Illinois for commercial payers, Medicaid and Medicare. Nearly every one of those claims processed flawlessly within seconds providing access to life saving medications for you constituents on behalf of the employers of Illinois, the state of Illinois and the Medicare program. PCMA members processed 84% of those claims.

PBM's manage prescription drug benefits on behalf of health insurers, Medicare Part D, large employers and other payers. We are the only entity in the drug supply chain whose role is to reduce costs for our clients, employers, unions plans, and government sponsored programs and we have concerns that this bill limits our ability to reduces costs and in some cases will in fact requires us to raise costs.

HB2008 will increase costs for Illinois families, small business and individuals \$1 Billion the first year. Mandating what all private employers, that provide health insurance for their employees in Illinois, both big and small, must reimburse a small segment of the business community, is the worst case of government picking winners and losers. But this bill doesn't just do that with reimbursement it does it with every aspect of the bill. From telling a private business how it should pay for the services it is purchasing for its employees, to where it should purchase those services, restricting the quality it can demand from its venders and even if and how it is allowed to look for waste, fraud and abuse. By requiring a PBM to take on a fiduciary role, a role federal courts have struck down and the Department of Labor says PBMs cannot function in, this law will force PBMs to make plan design changes that will increase costs without any correlating increases in patient care.

PCMA, on behalf of our member companies, appreciate the opportunity to submit the following outline of issues in the SB2008.

<sup>&</sup>lt;sup>1</sup> Number of Retail Prescription Drugs Filled at Pharmacies by Payer | KFF



#### **Issue 1: Generic Substitution**

(Page 2, Lines 13-24)

- Substitutions of generic drugs are already allowed in current law, as they should be. However, there are instances when a patient should continue to utilize a brand name drug over a generic so an immediate substitution should not be required.
- The second sentence of this section deals with formulary changes, which are also addressed in current law (215 ILCS 134/25) and should continue to be led by the insurer's physician-led pharmacy and therapeutics committee.
- This language should be removed from the bill.

#### **Issue 2: Unfair Deceptive Practices**

(Page 3, Line 9)

- This section adds pharmacy audit guidelines to an "unfair or deceptive practice."
- The Department of Insurance currently has regulatory powers over PBMs, which would include audit practices if added to the PBM section. Adding violations as an unfair or deceptive practice are overreaching and unnecessary.
- This language should be removed from the bill.

#### **Issue 3: Pharmacy Benefit Manager Contracts**

(Page 4, Lines 13)

- This section amends the Pharmacy Benefit Manager article, which applies to any PBM licensed in Illinois, per the current statutory definition, under commercial, government and Medicaid plans.
- The definitions in the current law were just negotiated and enacted in July. The new laws should be implemented and tested before changing definitions. There agreement by all parties on the definitions of maximum allowable cost and pharmacy benefit manager in PA 101-452.
- The maximum allowable cost definition should stand as is and this language should be removed from the bill.

#### **Issue 4: Pharmaceutical Product Definition**

(Page 5, Lines 24-26)

- This section amends the definition of "pharmaceutical product" and expands coverage and applicability of PBM laws beyond medication to devices and vaccines, beyond the scope of PBM contracts.
- This section does not appropriately reflect existing PBM contracts and should be removed from the bill

#### **Issue 4: Pharmacy Acquisition Cost**

(Page 6, Lines 6-8)



- The section defines "pharmacy acquisition cost" and only includes the amount invoiced to the pharmacy business by a wholesaler. It does not take into consideration the amount actually paid by the pharmacy business such as discounts, any negotiated price by contract, any reduction for bulk buying, any reduction for timely payment, etc.) Acquisition cost should refer to the cost paid by the pharmacy business, not just invoiced by a wholesaler. Wholesalers could easily invoice any amount, driving up costs.
- The language should be amended to more accurately reflect the amount paid for prescription drugs in the marketplace such as pharmacy acquisition costs is "net of all discounts, rebates, chargebacks, and other adjustments to the price of the drug."

#### **Issue 5: Spread Pricing Definition**

(Page 7, Lines 6-12)

- This section defines spread pricing. Spread pricing is the term used for one of the methods for which plan payors pay PBMs for the services provided in managed prescription drug benefits.
- PBMs can either be paid by administrative fees, retaining any savings incurred (or "spread pricing"), or a sharing model of rebates and fees. Plans and clients choose the pricing model that best fits their needs to compensate for PBM services. If spread pricing is not allowed to be utilized, compensation will instead be incurred through higher administrative fees. Pharmacists also utilize spread pricing when they purchase items (box of tissues) at one price but sell them at another price the difference in that cost is "spread pricing."
- This section interferes with private contracts between employers, health plans, union plans and PBMs and should be removed the bill.

#### **Issue 6: Third Party Payer Definition – ERISA Implications**

(Page 6, Lines 13-16)

- This section defines "Third-party payer". By defining a "Third-party payer" and then using the term throughout the bill, the provisions of the bill and the costs of the bill have been extended to the self-insured market. Insert Rutledge explanation.
- The U.S. Supreme Court ruled in December 2020 that ERISA did not preempt Arkansas Act 900.
   The Court's reasoning rested on its long-standing precedent in New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.<sup>2</sup> The Court in Rutledge deemed Act 900 "merely a form of cost regulation".
- Rutledge did not change existing law regarding the scope of ERISA preemption. ERISA
  preemption principles that prevent states from regulating plan design or central matters of plan
  administration remain intact, regardless of the outcome in Rutledge. Rutledge was narrowly
  tailored to the Arkansas law at issue in the case, because it was simply a "cost regulation."

<sup>&</sup>lt;sup>2</sup> "Travelers" 514 U.S. 645 (1995)



Further, *Rutledge* reinforced the principle that laws directed at third parties, rather than plans themselves, may be preempted, by rejecting without discussion the argument that only plans may invoke ERISA preemption.<sup>3</sup>

- The Employee Retirement Income Security Act of 1974 (ERISA)<sup>4</sup> established a federal regulatory framework that governs both insured and self-insured "employee welfare benefit plans"<sup>5</sup> and retirement plans sponsored by employers, labor unions, and certain other entities. ERISA preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."<sup>6</sup>
- This definition expands the scope of the legislation and should be removed from the bill.

#### **Issue 7: MAC Lists Restrictions**

(Page 7, Lines 20-26 & Page 8, Line 1)

- This section imposes additional MAC restrictions, which were very closely reviewed, negotiated and agreed upon by all stakeholders in 2019 and are now being implemented – making significant changes already without allowing fair implementation and review of the effectiveness of PA 101-452 restrictions would undermine the entire sponsor lead stakeholder negotiations.
- PA 101-452 also already allows for a MAC appeals process creating unnecessary redundancies.
- PBMs do not have access to a pharmacy business' acquisition cost and therefore would not know when the 7-day window would begin as required in this section. The law already requires MAC information to be updated and published every 7 calendar days.
- It is to soon to enact additional MAC restrictions when the recently negotiated provisions are just now being implemented; therefore these provisions should be removed from the bill.

#### **Issue 8: MAC Appeals**

(Page 8, Lines 21-26& Page 9, lines 1-7)

- PA 101-452 currently requires a MAC appeals process as negotiated and agreed upon by all stakeholders. This new language now includes "pharmaceutical products," including devices – not under the purview of PBMs.
- The language is redundant; current law already allows appeals if the reimbursement is below the
  acquisition cost amount paid to the pharmacy business and therefore should be removed from
  the bill.

#### **Issue 9: Pharmaceutical Wholesaler Drug Cost Information**

(Page 9, Lines 22-26 & Page 10, Lines 1-14)

<sup>&</sup>lt;sup>3</sup> See Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312, (2016) (holding Vermont law regulating ERISA third-party plan administrator preempted by ERISA).

<sup>&</sup>lt;sup>4</sup> 29 U.S.C. § 1001 et seq.

<sup>&</sup>lt;sup>5</sup> Id. § 1002(1).

<sup>&</sup>lt;sup>6</sup> 29 U.S.C. § 1144(a).



- Pharmacy businesses asked for PBMs to provide the name and national drug code number for appeals during negotiations for PA 101-452. They are now reverting back to their original request that the wholesaler information be only from wholesalers in Illinois when pharmacy businesses certainly are not restricted to only purchasing their drugs from wholesalers in Illinois.
- This section highlights the fact that pharmacy businesses most often do not purchase drugs on their own; they use pharmacy service administrative organizations (PSAOs) to purchase drugs for them in a cooperative-type deal. These PSAOs, ironically, are owned by drug wholesalers, meaning they are contracting with pharmacies to buy drugs from themselves. PSAO operations should be licensed and regulated with the State of Illinois, like PBMs, to provide more transparency to the drug price contracting relationships.
- The Department of Insurance recommends PSAO licensure in its insulin pricing report. PCMA
  has provided PSAO transparency practices language to staff and has included that language in
  the appendix of this document.
- We recommend this section be removed from the bill and an additional section added that will
  provide transparency to a critical component of the drug supply chain.

#### **Issue 10: Green Book (Approved Animal Drug Products)**

(Page 11, Lines 21)

- Negotiations on PA 101-452 specifically identified and agreed on sources i.e. the Orange book.
   The insertion of the term "green book" doesn't seems illogical sense it identifies veterinarian drugs.<sup>7</sup>
- This words "green book" should be removed from the bill.

#### **Issue 11: Pharmacists Scope of Practice**

(Page 12, Lines 9-26)

- This provision includes an expansion of pharmacists' scope of practice, allowing pharmacists to counsel the patient on alternative treatments other than the prescription given by the patient's physician and share information on insurance plan contract provisions.
- This expansion of the scope of practice from dispensing of medicine to the practice of medicine seems inappropriate and should be removed from the bill.

#### **Issue 12: Disclosure of Proprietary Contract Terms**

(Page 12, Lines 25-26 & Page 13, Line 1-19)

 These provisions allowing pharmacy business owners to disclose private contract information to any state and federal officials were also negotiated in 2019. Private agreed-upon contracts with proprietary information should not be allowed to be given out and unprotected.

<sup>&</sup>lt;sup>7</sup> https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book



- The Department of Insurance already has regulatory authority over PBMs as granted in PA 101-452.
- PA 101-452 includes transparency provisions between the PBM, regulators, and plan sponsors.
- Disclosure of proprietary private contract terms could cause unforeseen market disruptions
  and are unnecessary since there are regulatory protections in place; therefore these provisions
  should be removed from the bill.

#### **Issue 13: Gag Clause**

(Page 14, Lines 1-4)

 There are provisions for prohibiting gag clauses incorporated into state law in PA 101-452 and gag clause prohibitions in federal law.

This section is redundant and unnecessary and should be removed from the bill.

#### **Issue 14: Pharmacy Reimbursement**

(Page 14, Lines 5-13)

- This section prohibits PBMs from reimbursing any pharmacy less than the amount reimbursed to a PBM affiliate, which does not take into account the cost savings of utilizing pharmacy networks AND requires that reimbursement to pharmacies (independent and chain) be at least the amount of the NADAC price, which does not provide any incentives for pharmacies to purchase drugs at a lower cost or any incentives for manufacturers to negotiate lower costs.
- This provision alone will greatly increase drug costs and insurance premiums for every consumer

   as well as Medicaid spending only to the benefit of pharmacy business owners, including big
   chain pharmacies and for this reason this section should be deleted from the bill.

#### **Issue 15: Pharmacy Reimbursement**

(Page 14, Lines 14-25)

 This section requires the pharmacy business owners and chain pharmacies to be reimbursed at NADAC plus a dispensing fee that equals the Medicaid fee-for-service rates which today is \$8.85.

• Enacting this single provision will increase the costs of dispensing drugs in Illinois over \$500 million in the first year,<sup>8</sup> a 300% increase for Illinois patients, employers, labor unions and health plans. Over the next 5 years these increased costs could be in excess of \$2.5 billion.

<sup>&</sup>lt;sup>8</sup> **Methodology:** A \$2 dispensing fee was assumed for all prescription fills,1 increased costs for dispensing fees is the difference between all prescriptions filled with a \$2 dispensing fee and all prescriptions filled with a \$8.85 dispensing fee. Count of prescription fills was held constant at 2019 levels. Given trends of year-on-year increasing prescription utilization, this is likely an underestimation of costs associated with increasing the dispensing fee to \$8.85 per prescription.

Data: Commercial market prescriptions is the number of prescriptions filled at retail pharmacies in Illinois using commercial group and nongroup insurance in 2019 from Kaiser Family Foundation "Number of Retail Prescription Drugs Filled at Pharmacies by Payer." This count



- Dispensing fees should be negotiated in contract.
- Illinois subsidizes Critical Access Pharmacies with an annual \$10 million in state funding (\$30 million total to date).
- The dispensing fee provision will alone is estimated to cost Medicaid an another \$210 million annually – with 68% of that money going straight to corporate pharmacies.
- NADAC listings do not accurately reflect overall marketplace acquisition costs or realities of the competitive marketplace. NADAC reflects the average drug costs as voluntarily reported by pharmacies. These self-reported prices typically exclude purchase discounts and other net price reductions pharmacies can receive. NADAC is not comprehensive and does not even include all drugs. NADAC pricing can incentivize and reward inefficient purchasers. All stakeholders in the health care system have a responsibility to help lower costs of health care, including pharmacies.
- We have included the entire analysis in the appendix of this document.
- This provision will increase the costs of dispensing drugs in Illinois over \$500 million the first year for Illinois families, employers, union plans and health plans and should be removed from the bill.

#### **Issue 16: Fees Prohibition**

(Page 14, Lines 26 & Page 15, Line 1-5)

- Pharmacy benefit managers (PBMs) maintain robust information technology systems to allow them to administer benefits for employers, health plans, and many government programs across the country—serving more than 266 million people. PBMs also contract with pharmacies to enable patients to fill prescriptions through their chosen benefit plan.
- Pharmacies agree to certain fees in their contractual arrangements with PBMs. These are not unlike fees paid by retailers to credit card companies in exchange for the risk of consumer fraud and for immediate payment for purchases, or the fees that banks charge consumers for ready access to cash through ATMs.
- Pharmacies freely enter into contracts with PBMs, agreeing to pay these fees in return for access to PBM services that enhance their own business practices; therefore this section should be removed from the bill.

#### **Issue 17: Accreditation and Credentialling Prohibition**

(Page 15, Lines 6-10)

does not include prescriptions filled at other types of pharmacies and is likely an undercount of the total number of prescriptions filled in Illinois using commercial insurance. Prescriptions filled using commercial insurance also includes ones covered by some government programs including Children's Health Insurance Program (CHIP), Veterans Administration (VA) and Indian Health Service, which are not covered by this bill; however, the populations covered by these types of insurance are small. Total Number of scripts filled in Illinois in 2019 for the full insured, self-insured, and non-group prescriptions were 73,619,807.



- This provision prohibits PBMs from having accreditation or credentialing standards beyond those standards required by the State Board of Pharmacy.
- This provision is an especially dangerous provision for patient safety. First, credentialing
  pharmacies ensures that patients receive high quality services while reducing the risk of
  fraud/abuse. Credentialling includes far more than ensuring that the pharmacists has a license
  with the Board to practice, it also includes ensuring there is liability insurance, provider billing
  numbers, and other standards require to transact business.
- Accreditation is higher standard often required when dispensing specialty drugs. The third-party
  independent accrediting organizations ensure that the highest standards of patient care are
  consistently being met when dispensing complex, high costs drugs for complicated disease
  states. Accreditation for specialty pharmacies is much like requiring board certification for a
  specialty practice of medicine. There is a distinct difference in the general practice of medicine
  and an oncology practice.
- Medicaid must be able to require IMPACT registration as part of their credentialling process.
- The provisions of this section will put Illinois patient's safety at risk and should be removed from the bill.

#### **Issue 18: Delivery**

(Page 15, Lines 11-13)

- PBMs do not want to prohibit a pharmacy business from offering prescription delivery services, however, the term "prescription delivery service" needs to be defined so that it does not include large mail-order facilities, which are reimbursed differently than traditional bricks and mortar facilities.
- PCMA would be happy to discuss the issue trying to be addressed here and the appropriate language to address the issue.

#### **Issue 19: Billing Standards**

(Page 15, Lines 14-18)

• We are unclear the issue this language is trying to solve for and would like further explanation.

#### **Issue 20: Spread Pricing Prohibition**

(Page 15, Lines 19-20)

- This section prohibits spread pricing. Spread pricing is the term used for one of the methods for which plan payors pay PBMs for the services provided in managed prescription drug benefits.
- PBMs can either be paid by administrative fees, retaining any savings incurred (or "spread pricing"), or a sharing model of rebates and fees. Plans and clients choose the pricing model that best fits their needs to compensate for PBM services. If spread pricing is not allowed to be utilized, compensation will instead be incurred through higher administrative fees. Pharmacists also utilize



- spread pricing when they purchase items (box of tissues) at one price but sell them at another price the difference in that cost is "spread pricing."
- Plan payors should determine the contract model that best meets their pharmacy care service needs. Spread pricing is not a guaranteed profit for PBMs. PBMs take a risk in order to meet their clients' needs for a traditional network. PBMs may take a loss on some claims when the amount reimbursed to the pharmacy is greater than the plan amount. This risk incurred by the PBM gives the plan payor cost predictability by providing a price-certain for prescription drug benefit payments to pharmacies. Due to some clients' financial situations, they may need this predictability to be able to offer such benefits to their members.
- The debate on traditional networks is not being led by consumers or plans for health care
  accessibility or affordability purposes; rather pharmacies are pushing this agenda because they
  perceive that they are likely to receive larger margins in profit in a pass-through network.
- Eliminating a market based contracting term between two sophisticated parties does nothing to improve the patient's care and should be removed from the bill.

#### **Issue 21: Any Willing Pharmacy**

(Page 16, Lines 20-26 & Page 17, Lines 1-11)

- The section requires a PBM to expand any willing pharmacy provisions.
- This provision negates the costs savings from developing pharmacy networks
- According to the Federal Trade Commission AWP requirements significantly reduce providers' incentive to engage in price competition.<sup>9</sup>
- Academic analysis concluded that AWP legislation leads to less competition and higher prices for consumers while providing no compensating benefits.<sup>10</sup>
- Another academic analysis specific to state AWP laws found that such legislation "is associated with increased pharmaceutical expenditures."
- This provision allows pharmacies not registered in Medicaid's IMPACT to fill Medicaid
  prescription and allows pharmacies already flagged by the OIG for Medicaid fraud to fill
  prescriptions. (Chicago is a heat zone for Medicaid fraud.)
- The provisions may allow a pharmacist to choose not to fill Medicaid prescriptions (Medicaid lockout), which is not helpful for Medicaid patients needing medication. Other points require copayment parity among all plan enrollees without taking into consideration preferred contracts with pharmacy networks, which help keep insurance costs down for consumers. Provisions

<sup>&</sup>lt;sup>9</sup>"Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs,"," FTC letter to CMS, Mar. 7, 2014.

<sup>&</sup>lt;sup>10</sup> Klick, Jonathan and Wright, Joshua D., "The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures," Am. L. & Econ. Rev. 192 (2015)

<sup>&</sup>lt;sup>11</sup> Durrance, C., "The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures," Atlantic Economic Journal, 2009.



- would restrict PBMs' ability from offering patients lower copayments or higher supply of drugs to limit copay amounts harmful to patient affordability and accessibility to medication.
- This cost of expanding any willing provider rules, restricting the use of national accreditation standards and pharmacy networks could increase costs in Illinois \$4.8 billion over the next 10 years.<sup>12</sup> These costs include \$2.6 billion for the self-insured group market, \$1.8 billion for the fully insured group market and \$400 million for the direct purchase market.
- We have included our full analysis in the appendix of this document.
- The expansion of the any willing provider rules, restricting the use of national accreditation standards and pharmacy networks along with the fiduciary requirements in this legislation could increase costs in Illinois \$670 million in excess drug spending the first year and therefore should be removed from the bill.

#### **Issue 22: Differential Copays**

(Page 17, Lines 12-22 & Page 18, Lines 1-9)

- This section will prevent a health plan, employers or union plan from using a preferred network.
- Pharmacies offer deep discounts, or a lower dispensing fee to participate in a more exclusive network due to increased volume of business.
- Legislation that prevents PBMs from creating preferred networks for retail and mail-order pharmacies negatively impacts the performance of formulary management and utilization management costing Illinois families and employers.
- Preferred pharmacies offer lower copays/cost sharing than non-preferred pharmacies in the network which mean savings for your constituents
- Non-preferred pharmacies in the network offer regular copay/cost sharing
- Consumers can CHOOSE either preferred or non-preferred pharmacies.
- The provisions in this section removes flexibility for the employer or union plan, the ultimate payer who should have the right to make the decision how they want to structure their benefit and therefore should be removed from the bill.

#### Issue 23: Anti-Mail Order Provisions

(Page 17, Lines 23-26)

- This section prohibits an employer from determining that the use of mail order may be in the best interest of his employees and the only affordable option for his small business.
- One of the many tools that employers and other PBM clients use to provide significant cost savings and convenience for their enrollees are mail-service pharmacies. Mail-service pharmacies can contain the increasing cost of prescription drugs due to their unmatched

<sup>&</sup>lt;sup>12</sup>**Methodology:** The methodology used to create these cost projections was that used by Visante in the April 2020 paper "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools."



- efficiency and lower over-head costs compared to retail pharmacies. During this unprecedented global pandemic Illinois should not be limiting safe, affordable access to life saving medications.
- The provisions in this section removes flexibility for the employer or union plan, the ultimate
  payer who should have the right to make the decision how they want to structure their benefit
  and therefore should be removed from the bill.

#### **Issue 24: Pharmacy Network Participations**

(Page 18, Lines 10-12)

- This language would allow pharmacies to exclude Medicaid from its contact.
- Contracts between PBMs and Pharmacies often include all lines of business and pay a uniform rate regardless of the plan a member is enrolled in.
- IAMHP sees no public policy benefit to allow pharmacies to exclude Medicaid members <sup>13</sup> and therefore this language should be removed from the bill.

#### Issue 25: Marketing Material, Data and Record Transfer Provisions

(Page 18, Lines 19-26 & Page 19, Line 1-18)

- These sections prohibit including provider names on any materials unless all providers are included, prohibits transferring information for the purpose of transferring patients, prohibits transferring records to or from an affiliate for any commercial purpose or presenting a claim for payment pursuant to a referral from an affiliate.
- These provisions interfere with private contracts and should be removed from the bill.

#### **Issue 26: Fiduciary Requirements**

(Page 20, Lines 17-25 & Page 21, Lines 1-6)

- This section includes a requirement that a PBM have a fiduciary responsibility. The Illinois Pharmacy Association proposed this language in 2019 to HB 465, but the language was removed.
- According to the Department of Labor (DOL), PBMs "who have no power to make any decisions
  as to plan policy, interpretations, practices or procedures, but who perform [certain]
  administrative functions for an employee benefit plan...are not fiduciaries of the plan."<sup>14</sup>
- PBMs do not deal in plan assets or have fiduciary status in contracts with insurers. PBMs
  perform functions within a framework of policies. The plan sponsor has the final say on all plan
  designs.
- A fiduciary is generally a person who holds a legal or ethical relationship of trust with another
  party, such as a financial advisor or an asset manager. State and federal law (including ERISA)
  govern certain fiduciary relationships and generally require the fiduciary to act for the sole

<sup>&</sup>lt;sup>13</sup> Statement from IAMHP: IAMHP strongly opposes this provision as it could have an adverse impact on Medicaid members.

<sup>14 29</sup> CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.



- benefit and interest of the beneficiary.
- A PBM is a provider of pharmacy benefit management and pharmacy care services to multiple clients. A PBM is acting on its own behalf, not acting on behalf of plan clients, when engaging in administration and operation of its pharmaceutical care services (such as negotiations with pharmaceutical manufacturers and network pharmacies and managing the formulary).
- PBMs do not exercise discretionary authority over a plan administration or plan assets. Rather,
  PBMs serve in an administrative and ministerial, non-discretionary function for clients pursuant
  to the PBM services contract. PBMs do not make decisions about whether the plan should offer
  pharmaceutical benefits or the scope or design of those benefits as such decisions are the plan
  sponsor's role.
- Requiring a PBM to act as a fiduciary will increase health care costs in Illinois \$6 billion dollars over the next 10 years.<sup>15</sup>
- We have included our full analysis in the appendix of this document.
- This section will increase the costs for the self-insured group market \$3.2 billion, the fully insured group market \$2.3 billion and the direct purchase market \$500 million over the next 10 years and therefore should be removed from the bill.

#### **Issue 27: Audit Provisions**

(Page 21, Line 8 – Page 27 Line 13)

- This section contains a list of restrictions on PBM network pharmacy audits that PBMs conduct
  on pharmacies to ensure that reimbursements are accurate. PCMA and the Illinois Pharmacy
  Association previously worked on an audit bill and provisions of those negotiations are now law.
- Several provisions would undermine the purpose of the audit. Just two examples include page 21, line 22, the definition of misfill incorporates any mistake, which is the purpose of auditing, to collect moneys erroneously paid out and page 26 lines 2-9 requires recoupment if the intent to fraud can be proven.
- Extrapolation must be allowed to calculate penalties and charge-back amounts to adequately collect moneys reimbursed in error.
- PCMA is willing to work on audit provisions again, but those negotiations will likely need separate
  meetings. Any audit guidelines should focus on on-site audits and not include concurrent audits
  which occur daily to catch errors at the time of dispensing.
- PCMA has provided alternative audit standards language based on industry practices previously
  to staff and has provided that language again in the appendix of this document.

#### **Issue 28: Transparency Provisions**

(Page 27, Line 15 - Page 28, Line 11)

<sup>&</sup>lt;sup>15</sup> **Methodology:** The methodology used to create these cost projections was that used by Visante in the April 2020 paper "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools."



- The section requires PBMs to give the Department quarterly reports on pharmaceutical drug rebate information.
- PA 101-452 mandates regulatory powers by the Department, including disclosures and exams, as well as mandates disclosures to plan sponsors.
- PCMA has previously provided alternative transparency language to staff and has included the alternative language in the appendix of this document.

#### **Issue 29: Network Adequacy Provisions**

(Page 28, Line 15 – Page 31, Line 1)

- The section requires PBMs to provide an adequate and accessible PBM network for prescription drug coverage and prohibits including mail-order pharmacy as part of network.
- PBMs must already file a network plan with the Department for review.
- PCMA believes that pharmacy networks should mirror a state regulated health insurance plan
  providers' network adequacy standards and employer sponsored plans should continue to
  determine the how they will structure their pharmacy network to meet the needs of their
  employees therefore this language should be removed from the bill.

#### **Issue 30: Medicaid Payment Requirements**

(Page 32, Lines 25-26 & Page 33, Lines 1-5)

- This section requires all Medicaid managed care organizations to reimburse pharmacies at the minimum of the NADAC listing and pay an additional professional dispensing fee set at the same rate as the Medicaid fee-for-service program.
- IAMHP has estimated that the increase in the dispensing fee alone will increase costs to the Medicaid program by approximately \$210 million. The change in ingredient cost will also increase costs significantly.
- Due to the increased costs this provision should be removed from the bill.

#### **Issue 31: Effective Date**

- The bill, without an effective date, would be effective January 1, 2022, which should be changed to January 1, 2023.
- Health plans for 2022 are being developed now and will be filed this spring. PBMs have just now worked with implementation of PA 101-452 on July 1, 2020.



# **APPENDIX**

### Senate Bill 2008

# Will Cost Illinois Patients, Employers, and Health Plans Over \$1 Billion Annually

# \$500 Million Dollars in Increased Dispensing Fees \$670 Million in Prescription Drug Costs

The core mission of pharmacy benefit managers (PBMs) is to reduce prescription drug costs for health plan sponsors so that consumers have affordable access to needed prescription drugs. PBMs offer a variety of services to their health-plan-sponsor clients and patients that improve prescription adherence, reduce medication errors, and manage drug costs.

#### Section 513b1 (I and n) Reimbursement Mandate:

Requiring PBMs to reimburse pharmacies at mandated levels of the National Average Drug Acquisition Cost (NADAC) plus a dispensing fee at least equal to the Medicaid fee-for-service rate of \$8.85 will cause spending on prescription drugs to soar.

Enacting just one component of the bill provision could cost the state of Illinois over \$500 million in

increased dispensing fee spending in the first year alone, a 300% increase for Illinois patients, employers, labor unions, and health plans. Over the next 5 years, these increased costs could be in excess of \$2.5 billion.

Mandating an \$8.85 dispensing fee on every prescription filled using commercial insurance will lead to skyrocketing costs year-over-year for the 7.3 million people in Illinois covered by commercial health insurance. Research also shows that mandating reimbursement at NADAC levels will cause drug spending to go up, 1 adding to the hundreds of millions of dollars in extra costs.

This bill amounts to a big government payout that goes to pharmacies. A 300% increase in fees that a pharmacy charges health plan sponsors to fill every prescription will end up costing Illinois employers and patients big money.

### Projected 1-Year and 5-Year Increases in Prescription Drug Dispensing Fee Spending in Illinois Commercial Insurance Market Due to Adopting Proposed Policy

	Fully Insured, Self- Insured, and Non- Group Prescriptions (2019)	1-Year Increased Costs	5-Year Increased Costs	
Increased Dispensing Fee Spending	73,619,807	\$504,295,678	\$2,521,478,390	

Methodology: A \$2 dispensing fee was assumed for all prescription fills,¹ increased costs for dispensing fees is the difference between all prescriptions filled with a \$2 dispensing fee and all prescriptions filled with a \$8.85 dispensing fee. Count of prescription fills was held constant at 2019 levels. Given trends of year-on-year increasing prescription utilization, this is likely an underestimation of costs associated with increasing the dispensing fee to \$8.85 per prescription.

Data: Commercial market prescriptions is the number of prescriptions filled at retail pharmacies in Illinois using commercial group and non-group insurance in 2019 from Kaiser Family Foundation "Number of Retail Prescription Drugs Filled at Pharmacies by Payer." This count does not include prescriptions filled at other types of pharmacies, and is likely an undercount of the total number of prescriptions filled in Illinois using commercial insurance. Prescriptions filled using commercial insurance also includes ones covered by some government programs including Children's Health Insurance Program (CHIP), Veterans Administration (VA) and Indian Health Service, which are not covered by this bill; however, the populations covered by these types of insurance are small.

<sup>&</sup>lt;sup>1</sup> The Menges Group. "Pennsylvania Medicaid MCO Prescription Drug Repricing: Cost Impacts of Using NADAC Payment Structure."

# Senate Bill 2008 Increases Costs Without Increasing Patient Care

The proposed Illinois legislation will seriously undermine the ability of PBMs to control drug costs, and as a result drug spending in Illinois will soar. Although some of the provisions are subject to interpretation, we estimate the bill provisions discussed below could cost the state of Illinois \$670 million in excess drug spending in the first year alone, and \$8.2 billion over the next 10 years.

SB 2008 will increase dispensing fees paid to pharmacies, expand Any Willing Provider (AWP) rules, restrict the use of national accreditation standards, preferred pharmacy networks, specialty pharmacies and mail-order pharmacies and would create a fiduciary mandate for PBM's.

Expanding AWP Rules and Restricting the Use of National Accreditation Standards and Pharmacy Networks Could Increase Costs \$4.8 Billion Over the Next 10 Years.

According to the Federal Trade Commission (FTC), AWP requirements significantly reduce providers' incentive to engage in price competition.<sup>2</sup> Academic analysis concluded that AWP legislation leads to less competition and higher prices for consumers while providing no compensating benefits.<sup>3</sup> Another academic analysis specific to state AWP laws found that such legislation "is associated with increased pharmaceutical expenditures." Legislation that prevents PBMs from creating preferred networks for retail and mail-order pharmacies will negatively impact the performance of formulary management, utilization and care management programs.

When applied to specialty pharmacies, the consequences of AWP legislation is even greater. Because specialty drugs are dispensed in such low volumes and target rare conditions, it is infeasible for most retail drugstores to stock these medications and provide the specialized services patients require. States do not legally differentiate specialty pharmacies from traditional pharmacies, so essentially any licensed pharmacy can market itself as a specialty pharmacy. PBMs actively work with payers to identify specialty pharmacies that can best serve patient and healthcare provider needs. These payer-aligned specialty pharmacies must meet payers' terms and conditions to be included in preferred pharmacy networks. Terms and conditions focus on quality clinical care, performance, and cost-saving criteria. Qualified specialty pharmacies must also meet payer reimbursement rates to be included in networks. Of the roughly 64,000 pharmacies in the U.S., only about 400—less than 1%—are accredited as specialty pharmacies by the independent Utilization Review Accreditation Commission (URAC). In addition, PBMs utilize credentialing to evaluate a pharmacy's ability to implement plan design, encourage formulary compliance, and meet other contractual obligations.

#### Adopting Fiduciary Mandate Could Increase Costs \$6 Billion

According to the Department of Labor (DOL), PBMs "who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan...are not fiduciaries of the plan." <sup>1</sup> Imposition of a fiduciary mandate would create a conflict between PBMs' contractual obligations to their clients and the fiduciary duty to act "solely in the interest of plan participants." Fiduciary requirements will also create additional legal liability, leading to increased costs related to liability insurance.

#### Projected 10-Year Increases in Prescription Drug Spending In Illinois, 2022–2031 (Billions)

	Self-Insured Group Market	Fully-Insured Group Market	Direct Purchase Market	Total
Adopt fiduciary mandate	\$3.2	\$2.3	\$0.5	\$6.0
AWP, accreditation, and restricted use of pharmacy networks <sup>5</sup>	\$2.6	\$1.8	\$0.4	\$4.8
Maximum Costs – All Provisions <sup>6</sup>	\$4.4	\$3.1	\$0.7	\$8.2

Methodology: The methodology used to create these cost projections was that used by Visante in the April 2020 paper "Increased Costs Associated With Proposed State Legislation Impacting PBM Tools."

- 1. "Contract year 2015 policy and technical changes to the Medicare advantage and the Medicare prescription drug benefit programs,"," FTC letter to CMS, Mar. 7, 2014.
- 2. 29 CFR 2509.75-8 Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.
- 3. Klick, Jonathan and Wright, Joshua D., "The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures," Am. L. & Econ. Rev. 192 (2015)
- 4. Durrance, C., "The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures," Atlantic Economic Journal, 2009.
- 5. Includes Any Willing Provider (AWP), restrictions on pharmacy accreditation and mail-order. Illinois may already use some form of AWP. Estimated cost increases are based on comparing "with vs without AWP."
- 6. Numbers do not sum to totals due to some overlap in the effects of different types of legislation. For example, cost savings associated with utilization management are negatively affected by a fiduciary mandate, but also by Any Willing Provider applied to specialty pharmacies. We adjust the totals to avoid double counting of this cost impact.



# Proposed Senate Amendment to SB2008 Per Issue 9 of PCMAs Comments

### New Section in 215 ILCS 5 Article XXXIIC - Pharmacy Services Administrative Organizations

Sec. 513c1. Definitions. As used in this Article:

"Independent Pharmacy" means a pharmacy operating within the state that is under common ownership with not more than two other pharmacies.

"Pharmacy Benefit Manager" means a person, business, or entity, including a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager, that provides claims processing services or other prescription drug or device services, or both, for health benefit plans. (same def as used in 215 ILCS 5/513b1)

"Pharmacy Services Administrative Organization" or "PSAO" means an entity operating within the state that contracts with independent pharmacies to conduct business on their behalf with third-party payers. PSAOs may provide administrative services to pharmacies and negotiate and enter into contracts with third-party payers or PBMs on behalf of pharmacies. PSAOs may also provide other services, such as:

- a. Assistance with claims;
- b. Assistance with audits:
- c. Centralized payment;
- d. Certification in specialized care programs;
- e. Compliance support;
- f. Setting flat fees for generic drugs;
- g. Assistance with store layout;
- h. Inventory management;
- i. Marketing support;
- j. Management and analysis of payment and drug dispensing data; and/or
- k. Provision of resources for retail cash cards. "PSAO-pharmacy contract" means a contractual agreement between a PSAO and an independent pharmacy by which a PSAO agrees to negotiate with third-party payers on behalf of an independent pharmacy.

"Third-party payer" means any organization operating within the state that pays or insures health, medical, or prescription drug expenses on behalf of beneficiaries. $^{\rm ii}$ 

Sec. 513c2. Licensure requirements.

- (a) Beginning on July 1, 2022, to conduct business in this State, a pharmacy services administration organization must register with the Director. To initially register or renew a registration, a pharmacy services administration organization shall submit:
  - (1) A nonrefundable fee of \$500.
- (2) A copy of the registrant's corporate charter,

articles of incorporation, or other charter document.

(3) A completed registration form adopted by the

Director containing:

- $\mbox{(A)}$  The name and address of the registrant.
- $\ensuremath{(B)}$  The name, address, and official position of

each officer and director of the registrant.

- (b) The registrant shall report any change in information required under this Section to the Director in writing within 60 days after the change occurs.
- (c) Upon receipt of a completed registration form, the required documents, and the registration fee, the Director shall issue a registration certificate. The certificate may be in paper or electronic form, and shall clearly indicate the expiration date of the registration. Registration certificates are nontransferable.
- (d) A registration certificate is valid for 2 years after its date of issue. The Director shall adopt by rule an initial registration fee of \$500 and a registration renewal fee of \$500, both of which shall be nonrefundable. Total fees may not exceed the cost of administering this Section.
- (e) The Department may adopt any rules necessary to implement this Section.
- (f) No part of this Act shall be construed to require a third-party payer to enter into a contract with a PSAO.

Sec. 513c3. Examination.

- (a) The Director, or his or her designee, may examine a registered pharmacy services administrative organization.
- (b) Any pharmacy services administrative manager being examined shall provide to the Director, or his or her designee, convenient and free access to all books, records, documents, and other papers relating to such pharmacy services administrative organization's business affairs at all reasonable hours at its offices.
- (c) The Director, or his or her designee, may administer oaths and thereafter examine the pharmacy services administrative organization's designee, representative, or any officer or senior manager as listed on the license or registration certificate about the business of the pharmacy services administrative organization.
- (d) The examiners designated by the Director under this Section may make reports to the Director. Any report alleging substantive violations of this Article, any applicable provisions of this Code, or any applicable Part of Title 50 of the Illinois Administrative Code shall be in writing and be based upon facts obtained by the examiners. The report shall be verified by the examiners.
- (e) If a report is made, the Director shall either deliver a duplicate report to the pharmacy services administrative organization being examined or send such duplicate by certified or registered mail to the pharmacy services administrative organization's address specified in the records of the Department. The Director shall afford the pharmacy services administrative organization an opportunity to request a hearing to object to the report. The pharmacy services administrative organization may request a hearing within 30 days after receipt of the duplicate report by giving the Director written notice of such request together with written objections to the report. Any hearing shall be conducted in accordance with Sections 402 and 403 of this Code. The right to a hearing is waived if the delivery of the report is refused or the report is otherwise undeliverable or the pharmacy services administrative organization does not timely request a hearing. After the hearing or upon expiration of the time period during which a pharmacy services administrative organization may request a hearing, if the examination reveals that the pharmacy services administrative organization is operating in violation of any applicable provision of this Code, any applicable Part of Title 50 of the Illinois Administrative Code, a provision of this Article, or prior order, the Director, in the written order, may require the pharmacy services administrative organization to take any action the Director considers necessary or appropriate in accordance with the report or examination hearing. If the Director issues an order, it shall be issued within 90 days after the report is filed, or if there is a hearing, within 90 days after the conclusion of the hearing. The order is subject to review under the Administrative Review Law.
  - Sec. 513c4. Denial, revocation, or suspension of registration; administrative fines.
  - (a) Denial of an application or suspension or revocation of a registration in accordance with this Section shall be by written order sent to the

applicant or registrant by certified or registered mail at the address specified in the records of the Department. The written order shall state the grounds, charges, or conduct on which denial, suspension, or revocation is based. The applicant or registrant may in writing request a hearing within 30 days from the date of mailing. Upon receipt of a written request, the Director shall issue an order setting: (i) a specific time for the hearing, which may not be less than 20 nor more than 30 days after receipt of the request; and (ii) a specific place for the hearing, which may be in either the city of Springfield or in the county in Illinois where the applicant's or registrant's principal place of business is located. If no written request is received by the Director, such order shall be final upon the expiration of said 30 days.

- (b) If the Director finds that one or more grounds exist for the revocation or suspension of a registration issued under this Article, the Director may, in lieu of or in addition to such suspension or revocation, impose a fine upon the PSAO as provided under subsection (c).
- (c) With respect to any knowing and willful violation of a lawful order of the Director, any applicable portion of this Code, Part of Title 50 of the Illinois Administrative Code, or provision of this Article, the Director may impose a fine upon the PSAO in an amount not to exceed \$50,000 for each violation.

Sec. 513c5. Failure to register.

Any PSAO that operates without a registration or fails to register with the Director and pay the fee prescribed by this Article is an unauthorized insurer as defined in Article VII of this Code and shall be subject to all penalties provided for therein.

#### (215 ILCS 5/513c6)

Sec. 513b6. Insurance Producer Administration Fund. All fees and fines paid to and collected by the Director under this Article shall be paid promptly after receipt thereof, together with a detailed statement of such fees, into the Insurance Producer Administration Fund. The moneys deposited into the Insurance Producer Administration Fund may be

transferred to the Professions Indirect Cost Fund, as authorized under Section 2105-300 of the Department of Professional Regulation Law of the Civil Administrative Code of Illinois.

Sec. 513c76

Notice and Disclosure Requirements

this subsection.

- (a) A PSAO-pharmacy contract shall include a provision that requires the PSAO to provide to the independent pharmacy a copy of any contract, amendments, payment schedules, or reimbursement rates within 3 calendar days after the execution of a contract, or an amendment to a contract, signed on behalf of the independent pharmacy.
- Each PSAO shall disclose to the Department the extent of any ownership or control of the PSAO by any parent company, subsidiary, or other organization that provides:

   A. Pharmacy services; or
   B. Prescription drug or device services. iii
   Each PSAO shall notify the Department in writing within 5 calendar days of any material change in its ownership or control relating to any company,

subsidiary, or other organization outlined in

- (c) Before entering into a PSAO-pharmacy contract, a PSAO shall furnish to an independent pharmacy a written disclosure of ownership or control in order to assist the independent pharmacy in making an informed decision regarding its relationship with the PSAO.
  - The written disclosure shall include the extent of any ownership or control by any parent company, subsidiary, or other organization that provides:
    - A. Pharmacy services; or
    - B. Prescription drug or device services.

A PSAO-pharmacy contract shall provide that the PSAO shall notify the independent pharmacy in writing within 5 calendar days of any material change in its ownership or control related to any company, subsidiary, or other organization outlined in this subsection.

(d) Before entering into a contract with a third-party payer, a PSAO shall furnish to a third-party payer a written disclosure of ownership or control in order to assist the third-party payer in making an informed decision regarding its relationship with the PSAO and the independent pharmacy or pharmacies for which the PSAO is negotiating.

The written disclosure shall include the extent of any ownership or control by any parent company, subsidiary, or other organization that provides:

- A. Pharmacy services; or
- B. Prescription drug or device services.
  A PSAO contract with a third-party payer shall provide that the PSAO shall notify the third-party payer in writing within 5 calendar days of any material change in its ownership or control related to any company, subsidiary, or other organization outlined in this subsection.

Sec. 513c8. Accounting.

- (a) A contract between a third-party payer and a PSAO, pursuant to which the third-party payer has the right or obligation to conduct audits of independent pharmacies, shall contain specific language that permits the third-party payer to audit the PSAO in connection with the third-party payer's audit of an independent pharmacy.
- (b) The PSAO-pharmacy contract shall provide that all remittances for claims submitted by a third-party payer on behalf of a pharmacy to the PSAO shall be passed through by the PSAO to the independent pharmacy within a reasonable amount of time, established in the PSAO-pharmacy contract, after receipt of the remittance by the PSAO from a third-party payer.
- (c) A PSAO that provides, accepts, or processes a discount, rebate, or product voucher, to reduce, directly or indirectly, a covered person's out-of-pocket expense for the order, dispensing, substitution, sale, or purchase of a prescription drug shall provide to the Department of Insurance an annual report, available for public audit, that includes:
  - a. An aggregated total of all such transactions, by pharmacy; and
    - b. An aggregated total of any payments received by the PSAO itself for providing, processing, or accepting any discount, rebate, or product voucher on behalf of an independent pharmacy.

Sec. 513c9. Wholesale and PSAO Services in a Single PSAO Contract.

- (a) A PSAO that owns or is owned by, in whole or in part, any entity that manufactures, sells, or distributes prescription drugs, biologicals, and/or medical devices shall not, as a condition of entering into a PSAO-pharmacy contract, require that the independent pharmacy purchase any drugs and/or medical devices from the entity with which the PSAO has an ownership interest, or an entity with an ownership interest in the PSAO.
- (b) A PSAO that owns or is owned by, in whole or in part, any entity that manufactures, sells, or distributes prescription drugs, biologicals, and/or medical devices shall disclose to the Department of Insurance any agreement with an independent pharmacy in which the independent pharmacy purchases prescription drugs, biologicals, and/or medical devices from a PSAO or any entity that owns or is owned by, in whole or in part, the PSAO.

Sec. 513c10. Notice of Appeals

The PSAO-pharmacy contract shall provide that in the event of a dispute between an independent pharmacy and a third-party payer, the PSAO shall ensure and facilitate timely communication from the independent pharmacy to the third-party payer.

The PSAO-pharmacy contract shall provide that the PSAO shall forward any and all notices of appeals from the independent pharmacy to the third-party payer within 24 hours of an independent pharmacy filing an appeal, in a format specified by the third-party payer.

requirements)

<sup>&</sup>lt;sup>i</sup> Ibid. (Adapted)

ii Adapted from https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Third%20Party%20Payor.aspx iii Adapted from http://www.legis.nd.gov/cencode/t26-1c27-1.pdf?20150518100811 (North Dakota PBM disclosure

# Proposed Senate Amendment to SB2008 Per Issue 27 of PCMAs Comments

Illinois Insurance Code 215 ILCS 5/513b7 (new)

#### Pharmacy Audits.

Notwithstanding any other law, when conducting a pharmacy audit, an auditing entity shall:

- (1) not conduct an on-site audit of a pharmacy at any time during the first 3 business days of a month or the first 2 weeks and final 2 weeks of the calendar year or during a declared State or federal public health emergency;
- (2) notify the pharmacy or its contracting agent no later than 14 days before the date of initial on-site audit; the notification to the pharmacy or its contracting agent shall be in writing and delivered by means that allows tracking or delivery;
- 3) limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the pharmacy

benefit manager, except in cases of fraud;

- 4) use the written and verifiable records of a hospital, physician, or other authorized practitioner that are transmitted by any means of communication to validate the pharmacy records in accordance with State and federal law:
  - (5) limit the number of prescriptions audited to no

more than 250 prescriptions, provided that a refill does not constitute a separate prescription for purposes of this subparagraph, and

no more than one on-site audit per quarter of the calendar year, except in cases of suspected fraud;

- (6) provide the pharmacy or its contracting agent with a copy of the preliminary audit report within 60 days after the conclusion of the audit;
- (7) be allowed to conduct a follow-up audit on site if a remote or desk audit reveals the necessity for a review of additional claims;
- (8) provide the pharmacy or its contracting agent with the ability to provide documentation to address a discrepancy or audit finding if the documentation is received by the pharmacy benefit manager no later than the 30th day after the preliminary audit report was provided to the pharmacy or its contracting agent; the pharmacy benefit manager shall consider a reasonable request from the pharmacy for an extension of time to submit documentation to address or correct any findings in the report;
- (9) be required to provide the pharmacy or its contracting agent with the final audit report no later than 90 days after the initial audit report was provided to the pharmacy or its contracting agent;
- (10) conduct the audit in consultation with a pharmacist if the audit involves clinical or professional judgment;

- (11) not chargeback, recoup, or collect penalties from a pharmacy until the time period to file an appeal of the initial pharmacy audit report has passed or the appeals process has been exhausted, whichever is later, unless the identified discrepancy is expected to exceed \$25,000, in which case the auditing entity may withhold future payments in excess of that amount until the final resolution of the audit;
- (12) not compensate the employee or contractor conducting the audit based on a percentage of the amount claimed or recouped pursuant to the audit;
- (13) not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal law or regulation; any amount to be charged back or recouped due to overpayment may not exceed the amount the pharmacy was overpaid;
- (14) conduct a pharmacy audit under the same standards and parameters as conducted for other similarly situated pharmacies audited by the auditing entity.
- (aa) Except as otherwise provided by State or federal law, an auditing entity conducting a pharmacy audit may have access
- to a pharmacy's previous audit report only if the report was prepared by that auditing entity.

(bb) Information collected during a pharmacy audit shall be confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the covered entity for which a pharmacy audit is being conducted and with any regulatory agencies and law enforcement

agencies as required by law.

(cc) A pharmacy may not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required

document or record, including a typographical error or computer error, unless the error resulted in overpayment to the pharmacy.

- (dd) A pharmacy shall have the right to file a written appeal of a pharmacy audit report in accordance with the procedures established by the entity conducting the pharmacy audit.
- (ee) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.
- (ff) To the extent that an audit results in the identification of any clerical or recordkeeping errors, such as typographical errors, scrivener's errors, or computer errors, in a required document or record, the pharmacy shall

not be subject to recoupment of funds by the pharmacy benefit

manager unless the pharmacy benefit manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefit manager, a health plan managed by the pharmacy benefit manager, or a consumer.

- (gg) Any claim that was retroactively denied for a clerical error, typographical error, scrivener's error, or computer error shall be paid if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity. As used in this subsection, "clerical error" means an error that does not result in actual financial harm to the covered entity or consumer and does not include the dispensing of an incorrect dose, amount, or type of medication or dispensing a prescription drug to the wrong person.
- (hh) This Section shall not apply to:
- (1) audits in which suspected fraudulent activity or

other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements, or other investigative methods;

- (2) audits of claims paid for by federally funded programs; or
- (3) concurrent reviews or desk audits that occur within 3 business days after transmission of a claim and where no chargeback or recoupment is demanded.

# Proposed Senate Amendment to SB2008 Per Issue 28 of PCMAs Comments

#### New Section - Pharmacy Benefit Manager Reporting.

A pharmacy benefit manager shall report to the Director on an annual basis the following information attributable to patient utilization of prescription drugs covered by health insurers in this State:

- (1) the aggregate amount of rebates received by the pharmacy benefit manager;
- (2) the aggregate amount of rebates passed through to health care insurers;
- (3) the aggregate amount of rebates passed on to the enrollees at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount;
- (4) the aggregate amount paid by health care insurers to the pharmacy benefit manager for pharmacist services; and
- (5) the aggregate amount a pharmacy benefit manager paid for pharmacist services.

Information required to be reported under this Section is limited to health insurer carriers in this State. The report made to the Department required under this subsection is confidential and not subject to disclosure under the Freedom of Information Act.