November 12, 2020

Commissioner John F. King
Office of Insurance and Safety Fire Commissioner
Administrative Procedure Division
Two Martin Luther King, Jr. Drive
704 West Tower, Floyd Building
Atlanta, Georgia 30334

Re: Pharmacy Benefits Managers Regulation

Dear Commissioner King,

Thank you for the opportunity to offer comment regarding the proposed regulation of Pharmacy Benefits Managers ("PBMs"). More importantly, thank you for your leadership in prioritizing the promulgation of these regulatory updates. As you and your team are likely aware, PBM regulations have not been updated since 2011 despite the fact that reigning in problematic PBM practices have been a focus of the General Assembly via legislation passed and signed into law including:

2015 – HB 470

- MAC Pricing protections and improvements to audit bill of rights passed into law.

2017- HB 276/SB 313

- The Pharmacy Patient Protection Act passed into law prohibiting, amongst other things, gag clauses, copay claw-backs, retaliation, recouping money outside the audit process, and restrictions on home delivery.

2019- HB 323

- Updates to Pharmacy Patient Protection Act passed into law including strengthening anti-mandatory mail order; prohibitions on steering, data mining, charging fees/fines in connection with audits, making false statements, and expanding protections to other dispensers including oncologists.

2020- HB 946/SB 313

- Material update to PBM licensure, oversight, and penalties; anti-steering law strengthened, transparency requirements added along with new patient protections including copay accumulator; protections extended to other dispensers; and a surcharge on PBMs that engage in steering or continue to engage in charging pharmacies point of sale or retroactive fees.

Despite the foregoing efforts to reign in practices including steering patients to PBM affiliated pharmacies, imposing mandatory mail order requirements, retroactive fees, and underwater reimbursements persist. We believe these proposed regulations represent an important step towards holding PBMs accountable for violations of the law and more importantly, to protecting patients and providers from practices that the General Assembly has overwhelmingly rejected as contrary to the public policy of this state.

Comments

Rule 120-2-97-.02 (Scope and Purpose): The addition to the stated purpose of the Regulation to include to "protect the interest of the enrolled public," may seem innocuous to some but it is consistent with the actions of the General Assembly to protect the public. Indeed, the Pharmacy Patient Protection Act, which was passed in 2017 and strengthened in 2019 and again in 2020 is, at its core, an effort to protect patients and dispensers from PBM abuses. In addition, in 2020, the General Assembly unequivocally weighed in on the practices of steering and imposing point of sale and retroactive fees finding that:

> These practices have resulted in harm, including increasing drug prices, overcharging insureds and payors, restricting insureds' choice of pharmacies and other dispensers, underpaying community pharmacies and other dispensers, and fragmenting and creating barriers to care, particularly in rural Georgia and for patients battling life-threatening illnesses and chronic diseases.

This addition, which can also be found in R. 120-2-33-.02, dealing with the regulation of HMO's, sets the tone for the revisions and regulations that follow, protecting the interest of the public from prohibited PBM practices.

Rule 120-2-97-.03 (License, application, issuance, renewal, net worth, probationary license); **Rule 120-2-97-.05** (Annual Renewal); **Rule 120-2-97-.06** (Examination by Commissioner; on-site visits; access to records; and expenses); **Rule 120-2-97-.08** (Penalties, Commissioner actions and reimbursements): These rules are belt and suspenders building blocks to the robust oversight the General Assembly contemplated in HB 946 and SB 313. The new law provides for these very increases in licensure, renewal, and fines; adds fraud and violation of rules as a basis for not issuing or renewing a license; and increases authority to access records, conduct financial examinations, compliance audits, and investigate complaints. In addition, these bills contemplate the ability of the Commissioner to access records. These rules set forth the powers of the Commissioner to oversee and enforce PBMs as contemplated by the law and thus are critically important.

Rules 120-2-97-.07 (Forms; reports, and required documentation):

While the undersigned believe PBM regulation could be more expansive – such as having stand-alone rules promulgated for practices such as MAC pricing reimbursements, patient steering, mandatory mail order, and copay accumulator – we are fully supportive of the proposed revisions to Rule 120-2-97-.07. In particular, these changes will provide a uniformity to investigations of complaints and provide investigators with the material information necessary to reach a determination with regard to whether a violation of the law occurred.

By way of example, Georgia MAC pricing law is detailed and nuanced, and this rule would require the production of material information, including but not limited to, identification of methodologies and sources used in determining a drugs reimbursement price, reason for denial of a MAC appeal, and the pricing history of the drug in question for the day of reimbursements and the five days prior (which is a touchtone of the law itself). This information is what is needed for a proper investigation.

Similarly, with regard to patient steering, a PBM would be required to produce communications with patients who believe they have been steered as well as communications to non-affiliate pharmacies/dispensers including on-screen rejections when a dispenser attempts to fill a claim for a patient but that claim is denied. This type of information is vital for proper investigation of complaints and ensures that every investigation will begin on the same footing.

As to the reporting provisions pertaining to NADAC and the surcharge for PBMs engaged in steering or fees, this rule effectuates and is true to the law.

Additional Comment and Conclusions

As previously indicated, these proposed rules are an important step to protecting Georgians from PBM practices that the General Assembly has determined should be stopped. Understanding that the provisions of HB 946 and SB 313 are sweeping in their scope, these rules center punch several of the core issues set forth in the new law and provide a mechanism for transparency, investigation, and enforcement. As such, we thank you and respectfully request that you proceed with adoption of these rules.

At some point in the future, we do think it is worth considering adding requirements that PBMs annually submit information reflecting compliance with Section 3 of the legislation dealing with physicians employed or contracted with pharmacy benefits managers; and also providing for required records to be provided by PBMs to assist investigators in connection with complaints that a PBM has failed to apply copay assistance when required by law. The copay issue featured prominently during the legislative session with patient groups and providers, including oncologists, emphasizing how harmful copay accumulator practices can be to sick patients who are on specialty medications and need all of the help they can get in paying for their life saving medications.

We again thank you for your leadership and work in promulgating these rules and respectfully urge you to enact them as written.

Sincerely,

Georgia Pharmacy Association
Medical Association of Georgia
Georgia Society of Clinical Oncology

LIMITED SCOPE EXAMINATION OF PHARMACY BENEFIT MANAGERS

July 27, 2020

Prepared for the:

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EXECUTIVE SUMMARY

Health insurers utilize the services of Pharmacy Benefit Managers ("PBMs") to manage prescription drug benefits on their behalf. While PBMs were originally designed to reduce administrative costs in administering a prescription drug program, PBMs have grown and now have substantial profitmaking ability through price spreading and rebates.

Amid concerns about PBM practices, the state of Arkansas passed the 2018 *PBM Licensure Act* which authorizes the Arkansas Insurance Commissioner ("Commissioner") to license and regulate the activities of PBMs. Subsequently, the Arkansas Insurance Department ("AID") issued Rule 118: *Pharmacy Benefits Managers Regulation* which licenses and regulates the activities of PBMs. Additionally, the Arkansas State Legislature passed Act 994 of 2019 which explicitly prohibited spread pricing as of July 24, 2019. Additional guidance surrounding this was provided in AID Bulletin No. 7-2019.

In 2019 the Commissioner engaged Lewis & Ellis, Inc. ("L&E") and its subcontractors, Ideal Health Strategies ("IHS") and Regulatory Insurance Advisors, LLC, ("RIA"), (collectively the "auditors" or "examiners") to perform a limited scope market conduct examination to review spread pricing[1] and other reimbursement activities of PBMs providing prescription coverage for state funded health plans issued through either the Arkansas Works ("AR Works") program (Arkansas Works Act of 2016, Ark. Code Ann. §§ 23-61-1001 et seq) or the Provider-led Arkansas Shared Savings Entity (PASSE) system created by Act 775 of 2017. The PBMs subject to the examination were Optum Rx, CVS/Caremark, and Express Scripts, Inc. (ESI)

The differential pricing analysis showed that National Chain pharmacies were reimbursed more (defined as greater than 5% difference) than Regional Chain and Independent Pharmacies for the same drug product unit (i.e. tablet, capsule).

The spread pricing analysis showed that one of the three PBMs being audited, ESI, was employing significant spread pricing practices during the audit time frame. Specifically, ESI was charging the health benefit plan an estimated 15.26% more than was being paid to the pharmacies.

[1] "spread pricing" is defined in AID Rule 118 to mean "the model of prescription drug pricing in which the pharmacy benefit manager charges a health benefit plan a contracted price for prescription drugs although the contracted price may differ with the amount the pharmacy benefits manager pays the pharmacist"

The Direct and Indirect Remuneration (DIR) or "clawback" analysis showed that both CVS Caremark (9.71%) and ESI. (4.55%) assessed DIR or "clawback" fees to the pharmacies during the audit timeframe. OptumRx's clawback pricing could not be evaluated.

While the report focuses on several pharmaceutical pricing practices, it does not provide a complete picture of pharmacy costs and PBM compensation. There are a number of additional factors that impact PBM revenues and pharmacy reimbursements that were either outside of the scope of this report or unavailable due to the lack of PBM response. These additional factors include rebates, additional insurer fees, and pharmacy fees.

PURPOSE & SCOPE

BACKGROUND AND SCOPE

Health insurers utilize the services of Pharmacy Benefit Managers ("PBMs") to manage prescription drug benefits on their behalf. PBMs offer a variety of services, including but not limited to claim adjudications; customer service or call centers; clinical services such as prior authorizations; drug utilization reviews; and mail-order and specialty pharmacies.

PBMs provide many cost-cutting measures to health insurers, e.g. by establishing pharmacy networks. These networks give PBMs purchasing power, allowing them to negotiate discounted prescription coverage for insurers and their customers. PBMs can also negotiate manufacturer rebates directly with the pharmaceutical company to further reduce prescription drug costs. These services allow PBMs to generate revenue through several approaches, including administration and service fees charged to insurers for processing prescriptions, through operation of their own mail-order and specialty pharmacies, and on the margin between the amount charged to insurance plan sponsors and the amount paid out to pharmacies for a prescription.

While PBMs were originally designed to reduce administrative costs in administering a prescription drug benefit program, PBMs have grown and now have substantial profitmaking ability through price spreading and rebates, which are payments negotiated directly with pharmaceutical manufacturers. It can be difficult for health insurers to oversee compliance with prescription benefit programs outsourced to PBMs in part because they are not subject to industry-wide regulation. Exact terms of the financial arrangements for pharmacy services are obscured in part by the sheer number of entities involved in every transaction including insurers, PBMs, pharmacies, wholesalers, manufacturer, and by the contract provisions that keep most of the transactional details confidential. These issues result in a lack of transparency in the expenditure of Arkansas's dollars spent on public pharmaceutical programs.

Therefore, amid growing concerns about PBM practices, the state of Arkansas passed Act One (1) and Act Three (3) of the Second Extraordinary Session of 2018 by the Ninety-First (91st) Arkansas General Assembly, "*An Act To Create The Arkansas Pharmacy Benefits Manager Licensure Act*," (hereafter, the "PBM Licensure Act") which authorizes the Arkansas Insurance Commissioner ("Commissioner") to license and regulate the activities of pharmacy benefits managers ("PBMs").

The PBM Licensure Act was amended by Act 994 of 2019. On August 18, 2018, AID issued a rule licensing and regulating the activities of PBMs in AID Rule 118: "Pharmacy Benefits Managers Regulation".

Pursuant to the PBM Licensure Act and AID Rule 118, in 2019 the Commissioner engaged Lewis & Ellis, Ideal Health Strategies, and Regulatory Insurance Advisors to perform a limited scope market conduct examination to review spread pricing and other reimbursement activities of PBMs providing prescription coverage for state funded health plans issued through either the Arkansas Works ("AR Works") program (Arkansas Works Act of 2016, Ark. Code Ann. §§ 23-61-1001 et seq) or the Provider-led Arkansas Shared Savings Entity (PASSE) system created by Act 775 of 2017.

This examination is authorized to be conducted under the following Arkansas Code and Arkansas Insurance Department (AID) rules:

- Ark. Code Ann. § 23-61-201 for health insurance issuers.
- Ark. Code Ann. § 23-76-122 for health maintenance organizations.
- AID Rule 117, Section 7 (A)(7) for PASSE organizations, and
- Ark. Code Ann. § 23-92-508 and AID Rule 118, Section 8 for PBMs.

The Health Plans and their contracted PBMs included in this examination are defined in Table 1 below.

Table 1. Arkansas Health Plans and PBMs Examined

Arkansas Health Plan	Program	PBM
Arkansas Total Care	PASSE	CVS Caremark
Celtic Insurance Company d/b/a/ Arkansas Health & Wellness	Arkansas Works	CVS Caremark
Empower Healthcare Solutions	PASSE	CVS Caremark
QCA Health Plan	Arkansas Works	OptumRx
QualChoice Life and Health Insurance Company	Arkansas Works	OptumRx
Summit Community Care	PASSE	Express Scripts (ESI)
USAble Mutual Ins Co d/b/a/ Arkansas Blue Cross Blue Shield	Arkansas Works	CVS Caremark

LIMITS ON DISTRIBUTION AND UTILIZATION

This report has been prepared for the use of the AID regarding the financial examination of health insurers and PBMs specifically participating in either the Arkansas Works or PASSE programs. A review of ERISA plans, Commercial Markets and comparable markets was not performed. The data and information presented is not appropriate for any other purpose.

Any user of this report must possess a certain level of expertise in health insurance, pharmacy services, actuarial science, and/or financial examinations, so as not to misinterpret the data presented. Any distribution of this report should be made in its entirety. Any third party with access to this report acknowledges, as a condition of receipt, that the authors do not make any

representations or warranties as to the accuracy or completeness of the material. Any third party with access to these materials cannot bring suit, claim, or action against the authors, under any theory of law, related in any way to this material.

CONFIDENTIALITY OF REVIEW & RELIANCES

Examination records of AID are considered confidential and privileged under §§ 23-61-207, 23-61-107, 23-61-103(d), provisions which are applicable to both health insurers under examinations, and PBMs, pursuant to Rule 118, Section 8, and Ark. Code Ann. § 23-92-508.

The auditors were required to share and access data, records, work papers and other information, from this limited scope examination. The auditors agreed to accept the same restrictions limiting the disclosure of any of the above referenced data, records, and information as are applicable to AID.

The term "confidential data" includes all working papers, recorded information, documents, and copies produced by, obtained by, or disclosed to the Commissioner or any other person during this examination.

The auditors certified that they would use the confidential data received pursuant to this Agreement for the sole purpose of the examination and not for any other purpose, and in no event shall the auditors disseminate or communicate the confidential data in any form to any other person or entity, other than to AID.

The auditors certified that they would not use or disclose any confidential data with any of its personnel or departments that are not directly engaged in the examination.

The auditors certified that any claims data or rebate information received in the course of the examination shall only be disclosed to persons within its organization who: (1) are required to protect and otherwise not disclose or use the confidential data except as provided in the examination; and (2) need to know the confidential data.

Confidential data was held in the strictest confidence at all times and will not be divulged to any party other than the auditors, including but not limited to, other employees, officers, directors or agents of the auditors, and will not be used for any purpose other than the examination.

The auditors' work was based upon data and information obtained through the AID, the insurers, the PBMs, and Pharmacies. The auditors did not perform a complete audit of the data provided. The auditors relied upon the above parties to attest to the accuracy of the information provided. The auditors did review the data for overall appropriateness. If there were any material inaccuracies in the data provided, the conclusions reached in this report may be invalid.

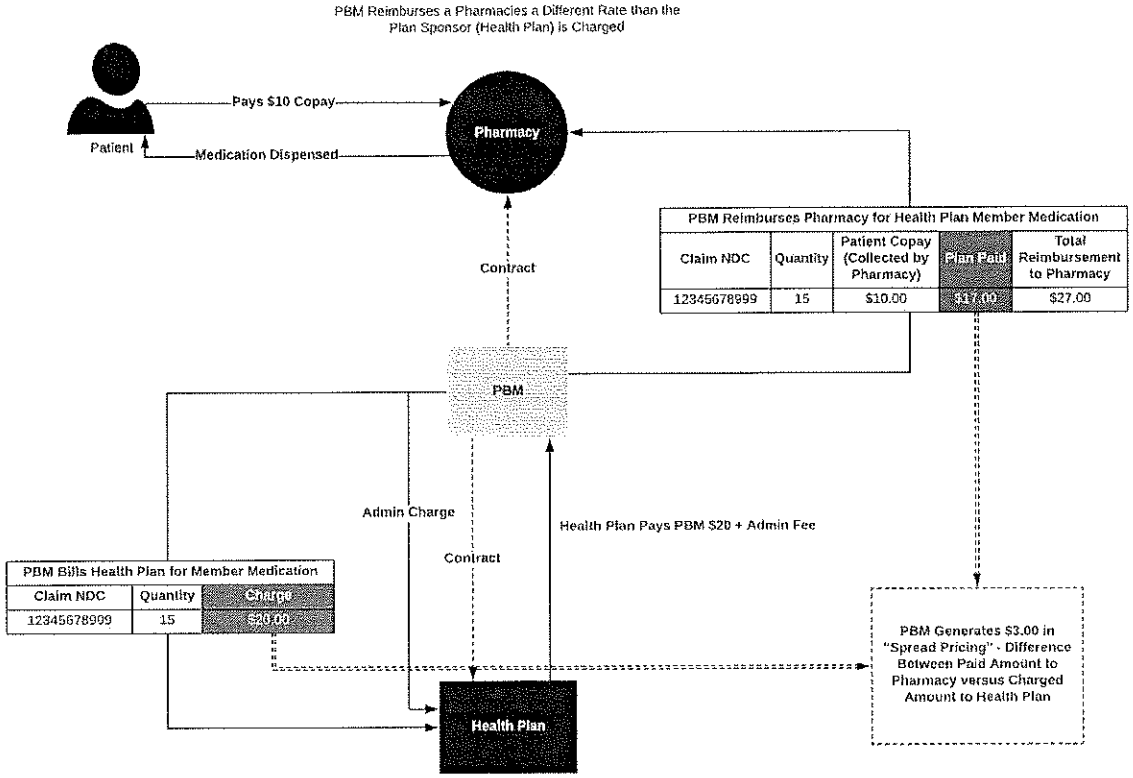
As examiners appointed by you pursuant to Ark. Code Ann. § 23-61-201 et seq, L&E and its subcontractors Ideal Health Strategies (IHS) and Regulatory Insurance Advisors, LLC (RIA) shall have immunity from liability for any statements made or conduct performed in good faith while carrying out the provisions of the examination statutes stated above.

DEFINITIONS OF PBM PRICING PRACTICES EVALUATED

SPREAD PRICING

Spread pricing is the PBM practice of charging the health plan a certain amount for a prescription but reimbursing the pharmacy at a lower rate and retaining the difference ("spread") as profit. Figure 1 provides an illustration of PBM spread pricing.

Figure 1: PBM Spread Pricing Example

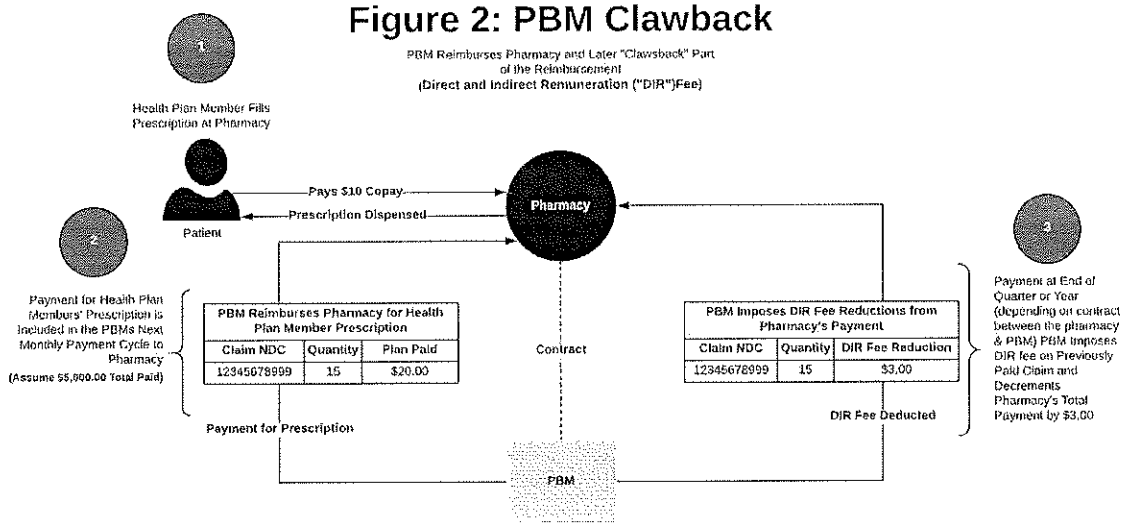


DIRECT AND INDIRECT REMUNERATION (DIR) OR "CLAWBACK" FEES

Direct and Indirect Remuneration (DIR) or "clawback" are retroactive fees assessed by the PBMs on the dispensing pharmacy after the prescription is dispensed. DIR fees can be in numerous forms (e.g. service fees, network access fees, administrative fees, reconciliation fees, etc.) that are often unclear to pharmacies who are forced to accept the PBMs DIR fees in the pharmacy network agreement.

DIR fees are difficult for the pharmacy to quantify and reconcile due to the lack of transparency in the pharmacy's agreement with the PBM. Most pharmacies are unable to accurately reconcile DIR fees back to the original prescription claim to ensure DIR fees were imposed correctly per the contract because the PBMs do not provide claim-level reporting to pharmacies for the DIR fees [2]. DIR fees are often assessed months after the point of sale and add to the PBM profit at the cost of the pharmacies. Figure 2 provides an illustration of PBM DIR/Clawback fees.

Figure 2: PBM Clawback



DIFFERENTIAL REIMBURSEMENT

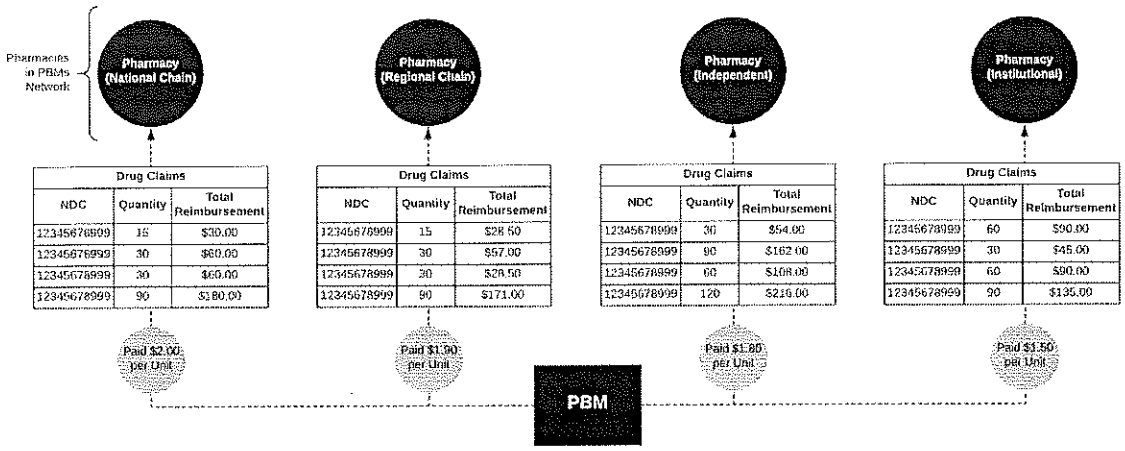
For the purposes of this audit, "differential reimbursement" refers to differences in reimbursement rates from the PBM to the pharmacies. The analysis compares the reimbursement of drugs down to the drug unit cost level (i.e. individual drug tablet, capsule, mg, etc.) between national, regional and independent pharmacies, as well as differences between pharmacies affiliated with the PBM, specifically CVS Caremark, and non-PBM affiliated pharmacies.

The purpose of the differential reimbursement analysis was to determine if the PBMs were providing reimbursement to certain pharmacies at higher reimbursement rate versus other pharmacies. Figure 3 provides an illustration of differential reimbursement.

[2] Direct and Indirect Remuneration (DIR) Performance and the Impact on Pharmacies Serving Medicare Part D Beneficiaries. A White Paper by INMAR Intelligence® February 2019, Revised July 2019. A White Paper by Inmar Intelligence, commissioned by NACDS (National Association of Chain Drug Stores). Accessed June 2020, https://www.nacds.org/pdfs/government/2019/DIR-Whitepaper.pdf.

Figure 3: PBM Differential Reimbursement Example

PBM Reimburses a Pharmacies a Different Rate for the Same Product



Drug Claims

NDC	Quantity	Total Reimbursement
12345678999	15	$30.00
12345678999	30	$60.00
12345678999	30	$60.00
12345678999	90	$180.00

Drug Claims

NDC	Quantity	Total Reimbursement
12345678999	15	$28.50
12345678999	30	$57.00
12345678999	30	$28.50
12345678999	90	$171.00

Drug Claims

NDC	Quantity	Total Reimbursement
12345678999	30	$54.00
12345678999	90	$162.00
12345678999	60	$108.00
12345678999	120	$216.00

Drug Claims

NDC	Quantity	Total Reimbursement
12345678999	60	$90.00
12345678999	30	$45.00
12345678999	60	$90.00
12345678999	90	$135.00

AUDIT PROCEDURES

DATA COLLECTION

Beginning in July 2019, data was requested from the Arkansas sponsored health plans and the PBMs that provide prescription benefit management to the health plans as detailed in Table 1.

The data requested included:

HEALTH PLAN

- PBM contracts and amendments.
- All pharmacy claims.
    - These claims were requested from the health plans, but provided, directly or indirectly, by the PBMs

PHARMACY BENEFIT MANAGERS (PBM)

- Complete and unredacted PBM management agreements, amendments, and appendices.
- A listing of all reimbursement agreements with pharmacies in the State of Arkansas.
- Complete and unredacted copies of all pharmaceutical rebate agreements between the PBM and pharmaceutical manufacturers.
- A complete set of pharmacy claims for all Arkansas health plans for the audit timeframe of January 1 through June 30, 2019. This time frame was chosen because the AID assumed oversight of the PBMs on January 1, 2019.
- The pharmacy paid claims tape for each Arkansas health plan.
- A copy of actual paid claims tape report to support pharmacy payments for the month of March 2019.
- Pharmacy claims processing information for all Arkansas health plans.
    - Bank Identification Number (BIN)
    - Processor Controller Number (PCN)
    - Group #/Group ID

Pharmacies

A sample of 100 Arkansas pharmacies were chosen to receive the pharmacy data request. The data requested was for March 2019. This shortened timeframe was chosen to assist the pharmacies with the management of the volume of data requested. It was also determined that by reviewing a truncated timeframe, the information would still lead to confirmation of spread

pricing and clawback disparities. The pharmacies are not under the oversight of the AID, so any data submitted by the pharmacies was voluntary.

The 100 pharmacies were sent a letter requesting pharmacy claims processing data specific to the information above. The purpose of the pharmacy data request was to acquire the pharmacies claim system level data so that it could be compared to the data provided by the PBMs. Beginning February 20, 2020, a letter was sent to the pharmacies requesting the following data:

- Claims level detail for each of the Arkansas sponsored insurance companies (carriers or PASSE entities) that were processed by the pharmacy during the month of March 2019. Key data points that were requested included:
    - Processing information (BIN/PCN/Group ID) to identify the PBM that covered the claim.
    - All payment information (e.g. patient copay, amount paid by carrier, total received by the pharmacy, dispensing fee paid to pharmacy).
    - Any retroactive fees (DIR, etc.) assessed on the pharmacy by the PBM.
- Unredacted copies of pharmacy contracts with each of the PBMs evaluated by the audit, namely CVS Caremark, OptumRx and Express Scripts.
- The name and contact information for the pharmacy contact person.

The data received or omitted from the Health Plans and the PBMs included:

HEALTH PLANS

- Arkansas Blue Cross Blue Shield (CVS Caremark)
    - Provided PBM contracts and amendments
    - Provided full set of claims, but data set was provided to health plan by CVS Caremark
- Empower (CVS Caremark)
    - All data was provided by CVS Caremark
- Centene
    - All data was provided by CVS Caremark
- QualChoice (Optum Rx)
    - Provided PBM contracts and amendments
    - Provided full set of claims, but data set was provided to health plan by OptumRx

- Summit (Express Scripts)
    - All data provided by Express Scripts

PHARMACY BENEFIT MANAGERS

- CVS Caremark
    - Provided copies of PBM agreements with health plans (BCBSAR, Empower, Centene)
    - Provided a list of reimbursement agreements with pharmacies in the State of Arkansas
    - Provided complete and unredacted copies of all agreements between the PBM and pharmaceutical manufacturers regarding rebates. However, these were not provided until May 28, 2020 (requested in July of 2019)
    - Provided a complete set of pharmacy claims for all Arkansas health plans for the audit timeframe of January 1 through June 30, 2019
    - Provided pharmacy paid claims tape for each Arkansas health plan
    - Provided a copy of actual paid claims tape report to support pharmacy payments for the month of March 2019
    - Provided processing information for all Arkansas health plans
    - Processing information (BIN/PCN/Group ID) for CVS Caremark plans:
        - Arkansas BCBS
            - 004336/ADV/RX3961
            - 004336/-/RX3956
        - Centene
            - Ambetter – 004336/-/RX5448
            - Arkansas Total Care – 004336/MCAIDADV.RX5476
        - Empower
            - 004336/ADV/RX2798
- OptumRx
    - Provided copies of PBM agreements with health plan, however all specialty pricing was redacted from contracts and amendments
    - Provided a list of reimbursement agreements with pharmacies in the State of Arkansas
    - Provided copies of agreements between the PBM and pharmaceutical manufacturers regarding rebates. These documents were uploaded May 26, 2020 (Requested in July of 2019). Due to timing, these documents have *not* been reviewed for completeness.
    - Provided a complete set of pharmacy claims for all Arkansas health plans for the audit timeframe of January 1 through June 30, 2019.

  - Did *not* provide pharmacy paid claims tape for each Arkansas health plan.
  - Provided a copy of actual paid claims tape report to support pharmacy payments for the month of March 2019.
  - Provided processing information for all Arkansas health plans.
  - Processing information (BIN/PCN/Group ID) for OptumRx plans:
    - QualChoice
      - 005947/-/QCAQHP
      - 005947/-/QCA

- Express Scripts
  - Provided copies of PBM agreements with health plan (Summit), however all specialty pricing was redacted from contracts and amendments.
  - Provided a list of reimbursement agreements with pharmacies in the State of Arkansas.
  - ESI did *not* provide any manufacturer rebate agreements stating that there are no rebates for PASSE entities.
  - Provided a complete set of pharmacy claims for all Arkansas health plans for the audit timeframe of January 1 through June 30, 2019. However, this data was *not* provided in the format (24 data fields) or with the terminology requested. Rather, the claims were submitted in a set with 284 individual data fields using ESI terminology, which added complexity to the audit due to having to identify the data fields relevant to the analysis.
  - Provided pharmacy paid claims tape for each Arkansas health plan.
  - Did *not* provide a copy of actual paid claims tape report to support pharmacy payments for the month of March 2019.
  - Provided processing information for all Arkansas health plans. However, the spreadsheet provided had 123,872 individual BIN/PCN/Group ID combinations. Upon discussion with one of the pharmacies in our subset, auditors were informed that there was only one BIN/PCN/Group ID combination relevant to the State funded plan.
  - Processing information (BIN/PCN/Group ID) for ESI plans:
    - Summit
      - 020107/NS/WPKA

PHARMACY SUBSET

- Thirty-six (36) of the 100 pharmacy companies (representing 51 pharmacies), to whom data requests were sent provided meaningful responses (claims and/or contracts) to the data request.

- Pharmacies that responded to the data request represented a mix of independent pharmacies and regional pharmacy chains. *No* national chains responded to the request.
- Summary of responses provided:
    - Claims data - 51 pharmacies provided claims data with PBM payment information
    - DIR/Clawback data - Only one regional pharmacy chain was able to provide DIR/Clawback data
        - Multiple pharmacies contacted the auditors stating that the PBMs had locked the pharmacies out of accessing this information on their access portals.
    - PBM Contracts - Only 10 pharmacy companies provided copies of their PBM contract
        - Several pharmacies contacted the auditors stating that the PBMs had instructed them that their contracts were proprietary and that they were not allowed to share the contracts with auditors under threat of contract termination.

DATA NORMALIZATION

Data files from PBMs by carrier were uploaded to a secure Citrix ShareFile site for the auditors to analyze. All claims data sets were converted to Excel spreadsheets, if necessary. Claims data from each PBM were converted into a standard and consistent data layout and formatting.

Negative claims (reversals and rejections) were removed along with the matched positive claims to net only fully adjudicated claims. For the Optum claims set, a large number of reversed claims did not have an equal number of positive (e.g. processed) claims. As an example, RX number 129140 had 20 reversals at the same pharmacy on 3/8/2019, but no positive processed claim in the data set. This did not affect our analyses as there were net positive claims to match the pharmacy data set. However, this does affect the overall summary of net claims. After data normalization was performed, the individual pharmacy claims sets were combined into a single claims data set.

For the purposes of the differential pricing analysis, pharmacies in the PBM data set were classified as either an Independent (I), National Chain (N), or a Regional Chain (R).

An independent pharmacy was defined as a pharmacy that had 3 or less locations. A national chain was defined as a company with pharmacies equally distributed throughout the United States (e.g. CVS, Walgreens, Wal-Mart). A regional chain was defined as a pharmacy company not defined as a national chain with more than 3 locations in the state of Arkansas.

Claims from March 2019 were isolated from each of the PBM data sets for the Spread Pricing and DIR/Clawback Analysis.

DATA ANALYSIS APPROACH

During the audit analysis, it was discovered that a portion of claims information received from the health plans included claims that were outside the Arkansas Works plans. The auditors were able to obtain from the Arkansas All-Payer Claims Database (APCD) the percent of claims from each health plan that were applicable to Arkansas Works plans.

The APCD data was applied to the total data set of claims submitted by Blue Cross Blue Shield of Arkansas (CVS), Centene (CVS), Empower (CVS) and QualChoice (Optum) to estimate the actual number and total spend of AR Works claims. It should be noted that Summit (Express Scripts) participates in the PASSE program only and does not participate in AR Works.

While the auditors did not use the insurers' National Association of Insurance Commissioners (NAIC) Annual Statement data for the analysis, the NAIC statement information is available publicly and contains information regarding market penetration for pharmacy data.

DIFFERENTIAL PRICING

For each PBM data set, claims were calculated to the unit cost level for each drug product national drug code (NDC) (e.g. NDC 00597015230 - JARDIANCE TAB 10MG, Claim Quantity 90, Total paid = $1375.04, Calculated Unit Cost = 15.28 ($1375.04/90)) to accurately compare the amount paid to the pharmacy for each drug product. Claims for each drug vary by the quantity dispensed so the unit cost calculation normalizes the data for comparison of reimbursement across drugs and pharmacies.

The auditors categorized the pharmacies associated with each claim into "Pharmacy Type" categories to compare the reimbursement of the individual drug unit costs based upon the type of pharmacy. These categories were:

- National chain pharmacy.
- Regional chain pharmacy.
- Independent pharmacy.
- Specialty pharmacy, and
- Institutional pharmacy (e.g. hospital pharmacies and native American tribal pharmacies).

The focus of the differential pricing analysis was to compare the PBMs' reimbursement for each drug between national chain pharmacies, regional chain pharmacies, and independent pharmacies operating within Arkansas. Claims for specialty pharmacies and institutional pharmacies were excluded from the differential pricing analysis since the normal drug reimbursement for these types of pharmacies have inherent high volatility across pharmacies and by drug type.

Comparative analytics were completed based upon the pharmacy type (national chain pharmacies, regional chain pharmacies, and independent pharmacies) and the corresponding unit cost for each drug product dispensed across the pharmacies.

SPREAD PRICING

The individual PBM datasets from March 2019 were combined with the pharmacy data, matching claims based on prescription number, fill number and date filled. To identify the presence of "spread", the "total paid" to the pharmacy from the pharmacy claims data set was subtracted from the "total paid" to the pharmacy from the PBM claims data set. Any difference between the "total paid" numbers was defined as "spread".

Spread is reported both as a total amount, as well as the percentage of total paid of the claims in the matched data set. Percent of claims with spread pricing is also presented.

The pharmacy data set represents claims from a subset of pharmacies from a single month of the audit timeframe. The results from this subset analysis was extrapolated to estimate the total spread amount from January 1st through June 30th, 2019.

DIR/CLAWBACK

"DIR/Clawback Fees" was a data field in both the PBM and the Pharmacy data request. Claims with DIR reported were totaled and reported as the percentage clawed back compared to the total spent.

The pharmacy data set represents claims from a subset of pharmacies from a single month of the audit timeframe. The results from this subset analysis was extrapolated to estimate the total spread amount from January 1st through June 30th, 2019.

AUDIT RESULTS

DATA DEMOGRAPHICS

PBM DATA

The claims data submitted by the PBMs is summarized in Table 2 below.

Table 2. PBM Data Demographics (Claim Records)

PBM	CVS Caremark			OptumRx	Express Scripts
Health Plan	BCBSAR	Centene	Empower	QualChoice	Summit
Total Claims	1,626,536	705,177	144,476	318,724	110,003
Total Claims by Pharmacy Type					
Independent	490,998	196,380	55,121	73,001	40,757
Regional Chain	281,090	119,818	57,506	53,376	24,147
National Chain	833,393	380,040	29,865	184,860	42,096
Other	21,055	8,939	1,984	7,487	3,003

Claims from CVS Caremark-covered health plans accounted for most claims (85.16%) from Arkansas Works plans. Due to incomplete data, the reported claims were removed from the Express Scripts (6,207 claims) and OptumRx (70,208 claims).

PHARMACY DATA

The claims submitted by the pharmacies are summarized in Table 3 below.

Table 3. Pharmacy Data Demographics (Claim Records)

	All Plans	CVS Caremark			OptumRx	Express Scripts
		BCBSAR	Centene	Empower	QualChoice	Summit
Total Claims	32,257	16,600	5,427	3,470	3,901	1,730
Claims with Clawback Data	5,203	2,806	482	1,134	0	798

Fifty-one (51) pharmacies submitted a total of 32,257 claims for the timeframe of March 1st through March 31st, 2019. A small number of claims (1,129) were submitted by pharmacies that were from marketplace plans not part of Arkansas Works plans. These claims were excluded.

LIMITATIONS OF DATA:

- PBM Data.
  - There were zero DIR/Clawback fees reported by the PBMs for the audit timeframe.
- Pharmacy Data
  - Claims data received from the pharmacies represents a small sample size (1.7%) of the total audit claims data set.
  - No national chain pharmacies submitted claims data, so that section of retail pharmacies could not be evaluated.
  - Only one pharmacy company submitted DIR/Clawback data. That data set does not include any claims from OptumRx, so auditors are unable to evaluate DIR/Clawback results for OptumRx.

DIFFERENTIAL PRICING ANALYSIS RESULTS:

The results of the differential pricing analysis are summarized in Table 4 below. The analysis uses negative numbers to represent pharmaceutical pricing approaches that favor certain pharmacy types over another (e.g. favors National Chain Pharmacies over Independent Pharmacies).

Pharmacies participate in the PBMs pharmacy network by contractual agreement. The agreement defines the guaranteed average wholesale price (AWP) and maximum allowable cost (MAC) reimbursement rates in which the PBM will reimburse the pharmacy for claims submitted for PBM members. The PBMs agreements with pharmacies will vary in regard to the reimbursement rate guarantees based upon the number of pharmacies participating, estimated volume of PBM member claims processed and timing (i.e. when the agreement was signed). PBMs may apply different contractual language in the agreement with the pharmacy which allows the PBM to classify certain drug products differently (i.e. brand versus generic) and/or apply different MAC lists. Overall, the difference in reimbursement rates between pharmacies should be minimal, differing by only a few percentage points. The auditors consider differential reimbursement of 5% or greater to be material.

Table 4. Differential Pricing Analysis Summary

	CVS Caremark			OptumRx	Express Scripts
	BCBSAR	Centene	Empower	QualChoice	Summit
Independent vs National					
All Claims	-3.69%*	-3.69%*	-17.70%*	0.70%#	0.09%#
Brand Claims	-0.36%*	-0.36%*	-12.79%*	-12.74%*	-17.60%*
Generic Claims	-4.76%*	-4.76%*	-24.56%*	3.20%#	1.78%#
Specialty	-0.56%*	-0.56%*	-2.49%*	-20.51%*	N/A

*Independent Pharmacies were Paid Less than National Chains, # Independent Pharmacies were Paid More than National Chains

	CVS Caremark			OptumRx	Express Scripts
	BCBSAR	Centene	Empower	QualChoice	Summit
Independent vs. Regional					
All Claims	-0.30%*	-0.30%*	-8.86%*	-9.80%*	-18.86%*
Brand Claims	0.00%	0.00%	-26.44%*	-4.47%*	-2.63%*
Generic Claims	-0.54%*	-0.54%*	-5.20%*	-10.58%*	-20.18%*
Specialty	-2.89%*	-2.89%*	-1.38%*	-5.31%*	N/A

*Independent Pharmacies were Paid Less than Regional Chains, # Independent Pharmacies were Paid More than Regional Chains

	CVS Caremark			OptumRx	Express Scripts
	BCBSAR	Centene	Empower	QualChoice	Summit
Regional vs. National					
All Claims	-4.56%*	-4.56%*	-21.60%*	-4.66%*	-0.78%*
Brand Claims	0.58%#	0.58%#	-3.38%*	-8.99%*	-2.03%*
Generic Claims	-6.04%*	-6.04%*	-26.94%*	-3.84%*	-0.66%*
Specialty	-0.27%*	-0.27%*	-12.78%*	-6.26%*	N/A

*Regional Pharmacies were Paid Less than National Chains, # Regional Pharmacies were Paid More than National Chains

	CVS Caremark			OptumRx	Express Scripts
	BCBSAR	Centene	Empower	QualChoice	Summit
Independent vs. CVS-Owned					
All Claims	-0.71%*	-1.16%*	28.80%#	N/A	N/A
Brand Claims	-1.62%*	1.25%#	0.19%#	N/A	N/A
Generic Claims	-0.49%*	-1.73%*	33.34%#	N/A	N/A
Specialty	-0.44%*	-4.48%*	N/A	N/A	N/A

*Independent Pharmacies were Paid Less than CVS Pharmacies, # Independent Pharmacies were Paid More than CVS Pharmacies

For the BCBSAR and Centene plans (both CVS Caremark), the data set shows a small preference in pricing toward the National Chain and Regional Chain pharmacies over the Independent Pharmacies. The auditors consider the difference to be acceptable. However, the Regional Chain pharmacies were paid less (-6.04%) than National Chain pharmacies for generic claims which is considered material as the difference is greater than 5%.

For the Empower (CVS Caremark), QualChoice (OptumRx) and Summit (ESI) data sets, the pricing advantage to the larger pharmacy entities (i.e. National Chains) is much more pronounced versus Regional Chains and Independent Pharmacies. The auditors consider the difference to be material since it is greater than 5%.

Overall, the BCBSAR and Centene plans (both CVS Caremark) data sets demonstrated a small reimbursement difference based upon the pharmacy type which is considered normal and acceptable. The exception is Regional Chain pharmacies were paid less (-6.04%) than National Chain pharmacies for generic claims which is considered material as the difference is greater than 5%. Please refer to Table 4.

Empower (CVS Caremark), QualChoice (OptumRx), and Summit (ESI) almost always reimbursed national pharmacies at higher rates than the rates at which they reimbursed regional or independent pharmacies. Not only were national pharmacies reimbursed at higher rates, Table 4 illustrates that the difference in rates usually resulted in national pharmacies being compensated for the same drug at a rate often 5% higher, if not more than 5% higher, than the rate provided to regional or independent pharmacies.

The auditors also compared the reimbursement between Arkansas operating CVS Caremark owned pharmacies (CVS Pharmacies) versus Arkansas Independent Pharmacies to determine if CVS Caremark was reimbursing its' owned pharmacies more than locally owned and operated Arkansas pharmacies. The difference in reimbursement for the BCBSAR and Centene data sets

is considered acceptable. For the Empower data set the Independent Pharmacies were paid significantly more than the CVS Pharmacies.

LIMITATIONS OF ANALYSIS

- Auditors were unable to obtain copies of contracts between PBM and pharmacy to assess whether pricing is in line with individual pharmacies contracted pricing.
- No "specialty" indicator on ESI claims to assess differences in pricing.
- For CVS Caremark and OptumRx data set, the number of matching specialty NDC's between pharmacy types was extremely small.

SPREAD PRICING ANALYSIS

The results of the spread pricing analysis are summarized in Table 5 below by health plan and PBM.

Table 5. Arkansas Works/PASSE PBM Analysis Summary – Pharmacy Data Set March 2019

PBM	CVS Caremark			OptumRx	Express Scripts
Health Plan	BCBSAR	Centene	Empower	QualChoice	Summit
Total Matched Claims - Pharmacy Data	13,342	4,995	2,910	1,522	1,542
Claims w/ Spread	63	14	4	1	1,290
Total $ Spread	$8,299	$593	$65	$2	$29,363
Total PBM Spend	$669,469	$1,304	$227,558	$4.94	$160,976
% Spread	**1.24%**	**45.45%**	**0.03%**	**47.77%**	**18.24%**
% of Claims w/ Spread	**0.47%**	**0.28%**	**0.14%**	**0.07%**	**83.66%**

Overall, the auditors did not see significant spread pricing practices with CVS Caremark or OptumRx plans.

Conversely, there was significant spread pricing found in the ESI-administered PASSE plan. More than 83% of claims in the pharmacy data subset showed spread pricing practices. This spread accounted for more than an 18% difference between the amount that the health plan was charged and the amount the pharmacy was paid.

These results were extrapolated to the full claims set from the six-month audit timeframe to provide an estimate of spread pricing over the entire audit period. The results are summarized in Table 6 below.

Table 6. Arkansas Works/PASSE PBM Analysis Summary - January 1st-June 30th, 2019

PBM	CVS Caremark			Optum	Express Scripts
Health Plan	BCBSAR	Centene	Empower	QualChoice	Summit
Total Claims in Data Set	1,626,536	705,177	144,476	248,516	106,637
Total Health Plan Spend	$133,285,068	$52,894,989	$13,089,025	$14,637,357	$11,793,275
Average $/RX	$81.94	$75.01	$90.60	$58.90	$110.59
% AR Works	66.00%	67.00%	67.00%	66.00%	100%
Approximate RX's – ARW	1,073,514	472,469	96,799	164,021	106,637
Total Health Plan Paid ARW	$87,968,145	$35,439,642	$8,769,647	$9,660,655	$11,793,275
Approximate Claims w/ Spread	5,069	1,324	133	105	89,210
Estimated Total Spread Amount	**$5,149**	**$45,146**	**$3.46**	**$6,347.34**	**$1,799,632**
Percent of Total Spend	**0.004%**	**0.085%**	**0.000%**	**0.043%**	**15.26%**

LIMITATIONS OF ANALYSIS

- Claims data received from the pharmacies represents a small sample size (1.7%) of the total audit claims data set.
- No claims were submitted by any national chain pharmacies.

DIR/CLAWBACK PRICING ANALYSIS

The results of the DIR/Clawback pricing analysis are summarized in Table 7 below.

Table 7. Arkansas Works/PASSE PBM Analysis Summary – Pharmacy Data Set March 2019

PBM	CVS Caremark			Optum	Express Scripts
Health Plan	BCBSAR	Centene	Empower	QualChoice	Summit
Claims w/ DIR Reported (>/ $0.05)	2,319	400	891	0	592
Total Clawbacks Assessed	$12,224	$2,951	$73,957	0	$3,748
Total PBM Spend on Claims w/ DIR Fees	$124,820	$30,841	$7,241	0	$82,436
% Clawback Assessed	9.79%	9.57%	9.79%	N/A	4.55%

Only one pharmacy submitted DIR/Clawback information. There were no claims covered by OptumRx in this pharmacy's claims dataset. Therefore, no DIR/Clawback analysis can be completed for OptumRx.

Both CVS Caremark and ESI assessed DIR/Clawback fees on the pharmacies during the audit timeframe. Across the 3 Arkansas Works plans, CVS Caremark's average DIR/Clawback fees were 9.72% of the total amount paid by the applicable health plan. ESI's average DIR fees averaged 4.55% over the sample period.

These results were extrapolated to the full claims set from the 6-month audit timeframe to provide an estimate over the entire audit period. The results are summarized in Table 8 below.

Table 8. Arkansas Works/PASSE PBM Analysis Summary - January 1st-June 30th, 2019

PBM Health Plan	BCBSAR	CVS Caremark Centene	Empower	Optum QualChoice	Express Scripts Summit
Total Claims in Data Set	1,626,536	705,177	144,476	248,516	106,637
Total Health Plan Spend	$133,285,068	$52,894,989	$13,089,025	$14,637,357	$11,793,275
Average $/RX	$81.94	$75.01	$90.60	$58.90	$110.59
% AR Works	66.00%	67.00%	67.00%	66.00%	100%
Approximate RX's - ARW	1,073,514	472,469	96,799	164,021	106,637
Total Health Plan Paid ARW	$87,968,145	$35,439,642	$8,769,647	$9,660,655	$11,793,275
Estimated Total Clawback	**$8,614,934**	**$3,390,666**	**$858,560**	**N/A**	**$536,124**

LIMITATIONS OF ANALYSIS

- Claims data received from the pharmacies represents a small sample size (1.7%) of the total audit claims data set. Only one pharmacy submitted DIR/Clawback data for analysis, which further reduced the sample size.
- No DIR/Clawback data was available for OptumRx plans so no analysis could be performed on that PBMs pricing practices.
- No claims were submitted by any national chain pharmacies.

CONCLUSIONS

The differential pricing analysis showed that National Chain pharmacies were reimbursed more (defined as greater than 5% difference) than Regional Chain and Independent Pharmacies for the same drug product unit (i.e. tablet, capsule).

The spread pricing analysis showed that one of the 3 PBMs being audited, Express Scripts Inc., was employing significant spread pricing practices during the audit time frame. Specifically, ESI was charging the health benefit plan an estimated 15.26% more than was being paid to the pharmacies.

The DIR/"clawback" analysis showed that both CVS Caremark (9.71%) and Express Scripts Inc. (4.55%) assessed DIR or "clawback" fees to the pharmacy during the audit timeframe. OptumRx's clawback pricing could not be evaluated.

While the report focuses on several pharmaceutical pricing practices, it does not provide a complete picture of pharmacy costs and PBM compensation. There are a number of additional factors that impact PBM revenues and pharmacy reimbursements that were either outside of the scope of this report or unavailable due to the lack of PBM response. These additional factors include rebates, additional insurer fees, and pharmacy fees.

ASOP 41 DISCLOSURES

The Actuarial Standards Board (ASB), vested by the U.S.-based actuarial organizations [3], promulgates Actuarial Standards of Practice for use by actuaries when providing professional services in the United States.

Each of these organizations requires its members, through its Code of Professional Conduct [4], to observe the ASOPs of the ASB when practicing in the United States. ASOP No. 41 provides guidance to actuaries with respect to actuarial communications and requires certain disclosures which are contained in the following.

1. IDENTIFICATION OF THE RESPONSIBLE ACTUARY

The responsible actuaries are:

- Dave Dillon, FSA, MAAA, MS, Senior Vice President & Principal at Lewis & Ellis, Inc.

The actuaries are available to provide supplementary information and explanation.

2. IDENTIFICATION OF ACTUARIAL DOCUMENTS

The date of this document is July 27, 2020. The date (a.k.a. "latest information date") through which data or other information has been considered in performing this analysis is April 28, 2020.

3. DISCLOSURES IN ACTUARIAL REPORTS

- The contents of this report are intended for the use of the Arkansas Insurance Department. Any third party with access to this report acknowledges, as a condition of receipt, that they cannot bring suit, claim, or action against L&E, under any theory of law, related in any way to this material.
- Lewis & Ellis Inc. is financially and organizationally independent from the PBMs under examination. L&E is not aware of anything that would impair or seem to impair the objectivity of the work.
- The purpose of this report is to assist the AID with the limited financial examination of Pharmacy Benefit Managers.
- The responsible actuary identified above is qualified as specified in the Qualification Standards of the American Academy of Actuaries.

[3] The American Academy of Actuaries (Academy), the American Society of Pension Professionals and Actuaries, the Casualty Actuarial Society, the Conference of Consulting Actuaries, and the Society of Actuaries.
[4] These organizations adopted identical Codes of Professional Conduct effective January 1, 2001.

- Lewis & Ellis has reviewed the data provided for reasonableness but has not audited it. L&E nor the responsible actuaries assume responsibility for items that may have a material impact on the analysis. To the extent that there are material inaccuracies in, misrepresentations in, or lack of adequate disclosure by the data, the results may be accordingly affected.
- L&E is not aware of any subsequent events that may have a material effect on the findings.

4. ACTUARIAL FINDINGS

The actuarial findings of the report can be found in the body of this report.

5. METHODS, PROCEDURES, ASSUMPTIONS, AND DATA

The methods, procedures, assumptions, and data used by the actuary can be found in the body of this report.

6. ASSUMPTIONS OR METHODS PRESCRIBED BY LAW

This report was prepared as prescribed by applicable law, statutes, regulations, and other legally binding authority.

7. RESPONSIBILITY FOR ASSUMPTIONS AND METHODS

The actuary does not disclaim responsibility for material assumptions or methods.

8. DEVIATION FROM THE GUIDANCE OF AN ASOP

The actuary does not believe that material deviations from the guidance set forth in an applicable ASOP have been made.

APPENDICES

APPENDIX 3. EXAMINER VERIFICATION

State of Texas)

)ss

County of Collin)

EXAMINER VERIFICATION

David Dillon being first duly sworn, upon his oath deposes and says; that he is an Examiner engaged by the Insurance Department of the State of Arkansas; that an examination was made of the affairs of:

Arkansas Health Plan	PBM
Arkansas Total Care	CVS Caremark
Celtic Insurance Company d/b/a/ Arkansas Health & Wellness	CVS Caremark
Empower Healthcare Solutions	CVS Caremark
QCA Health Plan	OptumRx
QualChoice Life and Health Insurance Company	OptumRx
Summit Community Care	Express Scripts (ESI)
USAble Mutual Ins Co d/b/a/ Arkansas Blue Cross Blue Shield	CVS Caremark

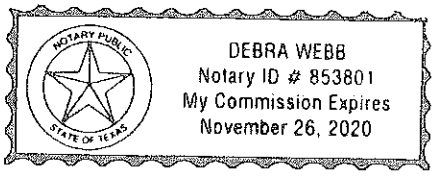
authorized under the laws of the State of Arkansas, pursuant to authority vested in a Certificate of Authority issued by Alan McClain, Insurance Commissioner of the State of Arkansas; that he was the Examiner of said examination and that the enclosed report of examination is a true and complete report.

David Dillon

Examiner in Charge

Subscribed and sworn before me this

27th Day of July, 2020.



Debra Webb

Notary Public

State of Georgia, The Office of Insurance and Safety Fire Commissioner
Administrative Procedure Division

Hearing on New Rules and Regulations: November 19, 2020

Amending Regulation 120-2-97 entitled "Pharmacy Benefits Managers Regulation"

Public Comments

Capital Rx applauds and strongly supports the fundamental changes to health care and the pharmacy benefit market the State of Georgia has advanced in its proposed adoption of the Rules and Regulations of the Commissioner of Insurance, which amend regulation 120-2-97 entitled "Pharmacy Benefits Managers Regulation." Capital Rx is the fastest-growing pharmacy benefit manager (PBM) in America, and is encouraged by the Commissioner of Insurance and the State of Georgia's efforts to spur innovation, technology, transparency, and improve service for patients and consumers in the PBM marketplace.

In our view, and the growing opinion of other independent analysts, the State of Georgia has rightfully focused attention on reporting requirements for NADAC, the National Average Drug Acquisition Costs. NADAC is a well-established pricing reference file, and estimates the national average drug invoice price paid by independent and retail chain pharmacies. In contrast to other benchmarks, like Average Wholesale Pricing or "AWP," which represents a published price for a drug product based on data obtained from manufacturers, distributers and other suppliers, NADAC reflects actual purchasing trends occurring monthly across participating U.S. retail pharmacies. Increasingly, independent research is showing that AWP-based costs increase over time, whereas NADAC-based costs decline. The Kaiser Family Foundation in 2012 found NADAC to be 1-18% less than list price for the top 25 single source branded drugs (by sales), and 60- 93% less for the top 100 generic drugs. Our own audit, in collaboration with 3 Axis Advisors (3AA), shows the NADAC price index deflated drug costs for plans by 44% for a representative market-basket of generic drugs, while the AWP price index actually inflated them, by 1%.

Building on these factors, the proposed regulation under O.C.G.A. Section 33-64-9.1 (a)(2), correctly provides that a pharmacy benefits manager *should*, and shall annually file a NADAC report with the state and make it publicly available through their website. Neither of these requirements are cost or administratively prohibitive for Capital Rx, a smaller and newer PBM, and so we would anticipate these important regulations would not create any real financial or administrative burden on larger competitors.

We believe by establishing clear mechanisms for data access and transparency into NADAC, Georgia is spearheading a more robust and dynamic index, one which a greater number of consumers, plans, and patients can rely upon in a critical time. With prescription drug pricing and access to treatment paramount to our nation's future, Georgia's policy and regulatory efforts should be embraced by PBMs and are deserving of support.

For additional information, contact:

Josh Golden, Capital Rx
C: 404-862-3605
jgolden@cap-rx.com

COMMENTS – HEARING ON NEW RULES AND REGULATIONS OF COMMISSIONER OF INSURANCE – AMENDING REGULATION 120-1-97 ("PHARMACY BENEFITS MANAGER REGULATION")

TO THE COMMISSIONER OF INSURANCE:

I, **Representative Matt Hatchett**, hereby give the following comments on the importance of implementing and enforcing the following Pharmacy Benefits Managers ("PBMs") Regulation 120-1-97 ("Regulation") of the Commissioner of Insurance ("Commissioner"). The following comments are pursuant to the Commissioner announcing the proposed Regulations on October 19, 2020 with the required hearing taking place on November 19, 2020.

On August 5, 2020, House Bill 946 was signed into law almost unanimously with only one state senator opposing the bill. The purpose of the Regulation is to effectuate HB 946 and the regulation of PBMs under Title 33 – most notably under O.C.G.A § 33-64-11 (prohibited activities of PBMs).

HB 946 seeks to reduce the costs of prescription drugs for Georgia citizens by improving regulations and tightening regulatory loopholes for PBMs operating in Georgia. The law also seeks to reign in PBMs' abusive practices by putting Georgia patients first and by granting the Commissioner broad authority to enforce the law in order to give real meaning to HB 946 and § 33-64-11.

Thus, the Commissioner is correct in proposing the Regulation and should move forward with enforcement despite pleas by the parties opposing the Regulation. The Commissioner has interpreted the law and his authority correctly in the proposed Regulation; therefore, we encourage the Commissioner to continue to take PBM regulations seriously and enforce them within his broad grant of authority. We respectfully ask that none of the Regulations be watered down based on opposing comments since the General Assembly has already spoken on the matter.

HB 946's almost unanimous approval means that the bill was not a law that barely slipped through the legislative process. Rather, the overwhelming approval demonstrates widely accepted law that PBMs must follow. Instead, PBMs have been attempting to ignore Georgia PBM laws and find loopholes, such as arguing that they are not violating anti-steering laws since patients can technically go to a non-affiliated pharmacy if they are willing to pay the costs (which is really no choice at all due to the prohibitive costs of drugs in our nation).

The Commissioner's broad authority includes the authority to assess monetary penalties, place PBMs on probation, suspend a PBM's license if they violate the PBM regulations while on probation, and conduct financial examinations and compliance audits.

PBMs continue their abusive practices by utilizing their lobbying power to fight laws that are already on the books. These attempts undermine the legislative process and the Commissioner's authority, and are a blatant example of PBMs' self-dealing in placing their self-interests above patient care.

Aside from the Commissioner's broad authority to implement Title 33's regulation of PBMs, it is also necessary to understand PBM practices and define key terms that are central to these practices. Health insurers use PBMs' services to manage and administer prescription drug benefits on the insurer's behalf. PBMs were originally meant to reduce these administrative costs for insurers; however, PBMs have grown and have vertically integrated with insurance companies and corporate retail pharmacy chains in a way that has substantially increased these merged companies' profits.

The most concerning PBM practices are (1) steering patients to the PBM affiliated pharmacy, (2) charging patients co-pays which exceed the costs of the drug, (3) mandatory mail-order pharmacies, and (4) gag clauses prohibiting pharmacies from informing patients about cheaper drug alternatives. At the federal level, President Trump has also passed executive orders concerning these practices.

To see the harm that PBM practices have on patient care, we respectfully ask the Commissioner to reference the January 7, 2020 Joint Special Committee on Access to Quality Healthcare ("Committee") hearing where multiple patients and community pharmacists gave testimony on how PBM practices have interfered with the patients' needs for life-saving medication (click here to see the hearing video).

In addition, on February 27, 2020, the Committee held another hearing concerning PBMs' abusive practices where there was testimony about an infant who was forced to wait three weeks to get life-saving medication for pulmonary hypertension even though the infant needed the medication right away. The reason for the three week delay was because of steering as the PBMs required that the infant had to go to an affiliated-pharmacy if they wanted the medication covered by insurance. This is absolutely criminal and can make all the difference between life and death.

No Georgian should be deprived of necessary medication due to PBMs' self-dealing, especially when such self-dealing is a blatant disregard for Georgia law, which the PBMs are more than aware of. The PBMs' blatant disregard for the law is not a product of ignorance – it's a product of arrogance and disrespect toward Georgia patients and the legislature that has prohibited these abusive practices.

PBMs do not have the right to control the prescription drug market in Georgia, and the Commissioner's enforcement is necessary to preserve legislative integrity and the integrity of Georgia's healthcare system all together.

Although HB 946 is not effective until either January 1, 2021 or July 1, 2021 (depending on which subsection), § 33-64-11 is already in effect. Thus, the Commissioner should enforce the already effective PBM code sections referred to in the Regulations. For the foregoing reasons, we respectfully ask the Commissioner to enforce the Regulation as proposed and hold PBM's responsible for blatantly disregarding Georgia's PBM laws.

We would like to conclude with a link to a document (also attached to this letter) prepared for the Arkansas Insurance Department, which demonstrates that Georgia is not alone in fighting the abusive practices of PBMs (click here). The document reflects that nearby conservative-led states are also participating in the charge to fight the corporate takeover of healthcare in our country. Georgia is on the forefront of tackling PBM reform, and we therefore ask the Commissioner to weigh in and enact the Regulation as proposed in furtherance of § 33-64-11.

Matt Hatchett
Representative, District 150
Chairman, Georgia House Republican Caucus

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November 12, 2020

Mr. Gregg Conley
Administrative Procedure Division
704 West Tower, Floyd Building
2 Martin Luther King, Jr. Drive
Atlanta, Georgia 30324

RE: Comments to Department's Proposed Regulation 120-2-97, Pharmacy Benefits Managers Regulation

Dear Mr. Conley;

On behalf of the Pharmaceutical Care Management Association (PCMA), I am writing to provide comments on the Department's proposed rule 120-2-97, which implements HB 946/SB 313 and to provide notice that I intend to appear on behalf of PCMA at the November 19, 2020 public hearing.

PCMA is the national trade association representing America's pharmacy benefit managers ("PBMs"), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, state employee and retiree plans, and Medicare Part D plans.

We appreciate that since becoming Georgia's Fire and Safety Commissioner on July 1, 2019, Commissioner King has endeavored to clearly convey the legal requirements to the regulated entities under his jurisdiction.

PCMA shares that goal and submit these comments to facilitate the creation of a final rule that is clear, easily understood, and provides fair notice to PBMs regarding compliance. This letter provides PCMA's specific proposed revisions that accomplish the following:

1) Ensures that the proposed rule is reasonable and remains within the scope of the underlying statute as required by law;

2) Provides for notice, due process, and appropriate response time periods for the filing requirements set forth in the rule and statute; and

3) Confirms that existing laws such as ERISA, and the Georgia Open Records Act are acknowledged and followed.

PCMA appreciates the opportunity to share these comments and looks forward to working with the Department to finalize this rule.

Sincerely,

/s/ Mark Middleton
Mark M. Middleton

Re: 120-2-97 Pharmacy Benefit Managers Regulation

1. **120-2-97-.06(1):** This section should be drafted to be consistent with the statute that permits examinations and audits – but in the context of ensuring compliance with the law. Additionally, this section should also contain a direct reference regarding exempting the state health benefit plan and medical assistance program, which is explicitly stated in the new statute. The law states, regarding the Commissioner's authority to conduct financial examinations and compliance audits, "that such authority shall not extend to financial examination and compliance audits of pharmacy benefits managers' conduct in performing services on behalf of the state health benefit plan pursuant to Article 1 of Chapter 18 of Title 45 or the medical assistance program pursuant to Article 7 of Chapter 4 of Title 49. [HB 946, Lines 225-229].

    a. **PCMA Recommendation:** Revise 120-2-97-.06(1) as follows: The Commissioner or his or her designated representative is authorized to conduct financial examinations, compliance audits, and investigate complaints of the affairs of each pharmacy benefits manager ~~as often as is deemed necessary~~ to ensure compliance with the provisions of this chapter and the rules and regulations implemented pursuant to this chapter provided that such authority shall not extend to financial examination and compliance audits of pharmacy benefits managers conduct in performing services on behalf of the state health benefit plan pursuant to Article 1 of Chapter 18 of Title 45 or the medical assistance program pursuant to Article 7 of Chapter 4 of Title 49. Whenever the Commissioner shall deem it expedient, he or she shall examine, either directly or by use of an examiner duly authorized by him or her, the affairs, transactions, accounts, records, documents, assets, liabilities, of a pharmacy benefits manager and any other facts relative to its business methods, management, and dealings with a health plan or covered entity.

2. **120-2-97-.06(2):** This section should be clear that the information collected is relevant to ensuring compliance with the law.
    a. **PCMA Recommendation:** (2) Any pharmacy benefits manager being examined shall provide to the Commissioner or his or her designee convenient and free access, at all reasonable hours at their offices, to all books, records, documents and other papers relating to such pharmacy benefit manager's business affairs that are relevant to ensuring compliance with the law. In addition to on-site access to records, a pharmacy benefit manager shall, upon written request,

make its records available to the Commissioner or the Commissioner's designee, unless otherwise directed by the Commissioner.

3. **120-2-97-.06 (3):** This section should be clarified to assure that the actual examination costs are reasonable.

    a. **PCMA Recommendation:** Revise sub-section (3) as follows: "A pharmacy benefits manager shall pay the reasonable fees and expenses of the examination whether conducted by the Commissioner or contracted examiner designated by the Commissioner…"

4. **120-2-97-.07 (2) and (2)(a) and (2)(b):** With the goal of staying compliant with this rule, we recommend extending the timeline for PBMs to submit all communications sent to an insured from five business days to fourteen calendar days. Not only is this in line with existing law regarding MAC appeals (O.G.C.A. 33-64-9) but is more feasible if a PBM were to be required to respond to multiple complaints. Therefore, we recommend revising Sub-section (2) to provide a 14-day response time.

    a. **PCMA Recommendation:** (2) A pharmacy benefits manager shall file all methodologies utilized in determining multi-source generic drug pricing reimbursement to pharmacies in this state within 30 days of their use and upon receiving a notice of complaint by the Commissioner in connection with O.C.G.A. § 33-64-9, a pharmacy benefits manager shall within ~~five business days~~ 14 calendar days.

5. **120-2-97-.07 (2)(a) and (2)(b):** These sub-sections should be deleted as being outside the scope of the statute. The corresponding statute states, "(a)(1) Any methodologies utilized by a pharmacy benefits manager in connection with reimbursement pursuant to Code Section 33-64-9 shall be filed with the Commissioner for use in determining maximum allowable cost appeals" [HB 946, Lines 274-278];

    2 (a): The information in subsection (2)(a), requiring the drug specific methodology for determining multi-source generic drug prices, is not contained within the statute. If PBMs are already required to file "any methodology" with the Department, then requiring additional drug specific methodologies is duplicative and unnecessary. Additionally, the corresponding statute does not contemplate the authority for the DOI to serve as the arbiter for appeals pursuant to O.G.C.A. 33-64-9.

    Furthermore, not only is subsection (2)(a) beyond the scope of the law, but it is also not clear as to how this would ensure compliance with any provision of the Chapter.

2 (b): This section states that a PBM must provide a complainant pharmacy with the National Drug Code of a product that may be purchased by the contracted pharmacies at a price at or below the maximum allowable cost. The price that a pharmacy pays for the pharmaceuticals it stocks in its stores is not known to PBMs as PBMs do not have any insight into the specific terms of a contract between an individual pharmacy and its wholesaler. Providing this type of information is impossible and would automatically make a PBM non-compliant for something with which it has no knowledge and cannot provide.

Moreover, the rule states that a PBM must provide documentation regarding the price of a specific drug for the preceding 5 days prior to the claim being adjudicated. The purpose of this requirement is not clear. The law already states that PBMs must update MAC lists every 5 days, making this requirement duplicative and unnecessary.

a. **PCMA Recommendation:** Strike subsections (2)(a) and (2)(b) from the rule and revise sub-paragraph (2) so that it conforms exactly with the relevant statutory language as follows:
"(2) A pharmacy benefits manager shall file all methodologies utilized in determining multi-source generic drug pricing reimbursement to pharmacies in this state within 30 days of their use, provided, however, that methodologies not otherwise subject to disclosure under Article 4 of Chapter 18 of Title 50 shall be treated as confidential and shall not be subject to disclosure...

~~(a) Identify the methodology and source or sources used to determine the multi-source generic drug price for the drug which is the subject of the complaint; and (b) Identify the reason for the denial of any pharmacy reimbursement appeal and produce relevant documentation in connection with the reimbursement price of the drug the day the claim at issue in the complaint was adjudicated and the preceding 5 days prior to the day the claim was adjudicated including source pricing records as well the national drug code of an equivalent drug product that could have been purchased by the complainant pharmacy at a price at or below the amount the pharmacy was reimbursed;~~

6. **120-2—97-.07(3)**: This section needs revision as the corresponding statue for the rule does not require a PBM to file an annual disclosure statement identifying all affiliate pharmacies holding a Georgia license or non-resident pharmacy. However, *O.C.G.A 26-4-119(f)* does require licensed pharmacies and permitted non-resident pharmacies to file disclosure statements with the Board of Pharmacy identifying all such affiliates. Requiring a duplicative disclosure statement is unnecessary and this information could likely be shared between the Department and the Board of Pharmacy.

Finally, the communications required by the PBM to submit to the Commissioner regarding a complaint is vague and much of it unnecessary to adequately respond to a complaint. With the goal to provide accurate and pertinent information regarding a

complaint, we request that the information requested of PBMs be more targeted to the specifics of a complaint rather than provide the Department with an 'information dump' that may be of no use.

a. **PCMA Recommendation:** (3) ~~A pharmacy benefits manager shall annually file a disclosure statement identifying all affiliate pharmacies holding a Georgia license or non-resident pharmacy and~~. Upon receiving a notice of complaint by the Commissioner in connection with steering or a mail order mandate in relation to a licensed pharmacy or permitted nonresident pharmacy that has filed an affiliate disclosure statement with the Board of Pharmacy pursuant to O.C.G.A 22-64-119(f), a pharmacy benefits manager shall provide within fourteen ~~five~~ business days: (a) Any requested ~~and all~~ communications specific to the issue in the complaint ~~sent to the insured within the previous 12 months advertising, marketing, promoting an affiliate pharmacy or the affiliate pharmacy of another pharmacy benefits manager; any communication ordering an insured to use an affiliate pharmacy benefits manager or indicating that an insured's costs will increase when using a non-affiliate pharmacy~~; and (b) Any and all communications sent to a non-affiliate pharmacy when an insured attempted to fill a prescription including any on-screen rejections or other messaging directing an insured to an affiliate pharmacy or affiliate of another pharmacy benefits manager.

7. **120-2—97-.07(4)(a)-(b).** This section needs revision to provide clarification regarding the NADAC report. The timeline of reporting in the rule as written omits reports for the months of April and August. Moreover, the timelines for when the reports are due for submission are inconsistent (45 days for the May 15th and September 15th reports and 15 days for the report due on January 15th.) These reports are incredibly complex and detailed. To ensure adequate time for compliance with this section and consistency within the rule, the timeline should be extended to February 15th. Finally, any changes to a public domain name to access NADAC reports should be extended to 14 days, which is consistent with MAC appeals and notifications contained in O.G.C.A. 33-64-9.

PCMA Recommendations: (a)The required NADAC report for the months of January through April ~~March~~ no later than June 15 ~~May 15~~, for the months May through August ~~July~~ no later than October 15 ~~September 15~~, and for the months of September through December no later than February 15 ~~January 15~~ of the following year; and (b) on or before March 1, the website domain name where the public can access the pharmacy benefits manager's NADAC reports. Any changes to the domain name thereafter shall be filed with the Commissioner within fourteen 3 calendar days of the change.

8. **120-2-97-.07(5)**. As drafted, this section appears to go beyond the scope of O.C.G.A. 33-64-10 (b)] which states that the annual report of rebates and other payments be "in connection with claims if administered on behalf of the health plan." [HB 946, Lines 327-333].

   Additionally, this portion of the rule does not consider the lag that occurs when reconciliating rebates associated with a given health plan. Negotiated rebates from drug manufacturers, whose value is calculated in part with utilization, are typically tabulated on a quarterly basis. To ensure accurate reporting, PCMA requests that the deadline be extended to April 1st. We are also concerned that the term "other payments" is not clearly defined in the rule or statute and request clarification on what the Department defines as "other payments". Finally, for the annual report form provided by the Commissioner we ask the Department for information regarding when the form will be available and if the Department will be seeking input from interested parties.

   a. **PCMA Recommendation:** "(5) As required by O.C.G.A. Code Section 33-64-10 (a), a pharmacy benefits manager shall, for each health plan client, annually, on or before the fifteenth ~~first~~ day of April ~~March~~, on a form provided by the Commissioner report all rebates and other payments it received in the preceding calendar year from pharmaceutical manufacturers in connection with claims if administered on behalf of the health plan."

9. **120-2-97-.07(7)(b)**. This section does not reference the confidentiality provision that is explicitly set forth in O.C.G.A. 33-64-12 (c)(1) and should be revised accordingly.

   a. **PCMA Recommendation;** (b) Annually, on or before March 1, file a report detailing all prescription drug claims it or its contracted pharmacy benefits manager administered for Georgia insureds on behalf of each health plan including the date each claim was administered, the amount the pharmacy was reimbursed for the claim, and the aggregate dollar amount it reimbursed pharmacies in the previous calendar year for prescriptions drugs for Georgia insureds on behalf of all its health plan clients. Such data shall be confidential and not subject to Article 4 of Chapter 18 of Title 50, relating to open records;

10. **120-2-97-.07(7)(c)-(d)** This section requires a PBM who has engaged in the practice of steering or has imposed a point of sale or retroactive fee, annually, on or before April 1,

a health plan and PBM must render to the state of Georgia, a surcharge of 10% of the aggregate dollar amount it or its contracted PBM reimbursed pharmacies in the previous calendar year for prescription drugs for Georgia insureds. Additionally, (d) notes that any and all claims administered for Medicare are exempt but does not recognize the exemption for ERISA and Federal Employee Health Benefit programs. As we noted above, it is imperative that the rule recognize claims in connection with both Medicare and ERISA plans.

Finally, it is unclear whether the 10% surcharge is due collectively from the health plan and PBM or whether each is responsible for the 10% surcharge. PCMA requests clarification.

a. **PCMA Recommendation:** (c) If it has engaged in the practice of steering or has imposed point of sale or retroactive fees, annually, on or before April 1, render to the state of Georgia, a surcharge equal to 10% of the aggregate dollar amount it or its contracted pharmacy benefits manager reimbursed pharmacies in the previous calendar year for prescriptions drugs for Georgia insureds. The Commissioner shall provide notice of that action to the pharmacy benefits manager, and the pharmacy benefits manager may invoke the right to an administrative hearing in accordance with Chapter 2 of this title." (d) Any and all claims administered pursuant to the Medicare program, or health coverage provided through an employee benefit plan under the Employee Retirement Income Security Act of 1974, 29 U.S.C. Sec. 1001 or the Federal Employees Health Benefit Act. 5 U.S.C Sect. 8901 et seq shall be exempt from reporting requirements and shall be exempt from the surcharge calculation. All other claims administered on behalf of a Georgia insured shall be subject to reporting and, when a pharmacy benefits manager has engaged in the practice of steering or has imposed a point of sale or retroactive fee, the surcharge.

11. **120-2-97-.07(8).** PCMA is concerned that five days to respond to a complaint is insufficient time to ensure a full and complete report to the Commissioner. PCMA requests that the time to respond be extended to 14 calendar days.

a. **PCMA Recommendation:** (8) upon receiving a notice of complaint by the Commissioner regarding an audit in connection with O.C.G.A. Code Section 26-4-118, a pharmacy benefits manager shall identify within fourteen calendar ~~five business~~ days, on a form provided by the Commissioner, the notice given to the pharmacy, the number of claims audited during the audit at issue, the number of

claims audited within the past 12 months, the number of audits of the pharmacy within the past 12 months, the discrepancies identified in the audit at issue, the basis for the denial of any internal appeal, and the basis for recoupment.

12. **120-2-97-.08(2) and (3)** allow the Commissioner to suspend licenses, issue cease and desist orders, order reimbursements, and levy fines. As in our recommendations in 120-2-97-.03 (6)(c) and 120-2-97-.07(7)(c), adding explicit language here regarding the right to lawful notice and to an administrative hearing is necessary. Also, HB 946 recognizes the need for an extension for the initial filings required under the new law. This automatic extension should be added to the rule.

    a. **PCMA Recommendation**: Revise Subsection (2) to read: In addition to all other penalties provided for under this title, the Commissioner shall have the authority to place any pharmacy benefits manager on probation for a period of time not to exceed one year for each and every act in violation of this chapter and may subject such pharmacy benefits manager to a monetary penalty of up to $2000.00 for each and every act in violation of this chapter. If the pharmacy benefits manager willfully acted in violation of this chapter the monetary penalty may be increased up to $10,000.00 for each and every act in violation (3) In the event a pharmacy benefits manager is in violation of the chapter while on probation, the Commissioner may suspend the license. If the Commissioner moves to suspend, revoke, or non-renew a license for a pharmacy benefits manager, the Commissioner shall provide notice of that action to the pharmacy benefits manager in accordance with the Department's rules, and the pharmacy benefits manager may invoke the right to an administrative hearing in accordance with the Rules and Chapter 2 of this title."

    b. **PCMA Recommendation:** Add a new subsection (3) to read: "If the Commissioner moves to suspend, revoke, or non-renew a license for a pharmacy benefits manager, the Commissioner shall provide notice of that action to the pharmacy benefits manager in accordance with the Department's rules, and the pharmacy benefits manager may invoke the right to an administrative hearing in accordance with O.C.G.A. 33-64-2 (c)(5) "

    c. **PCMA Recommendation:** After, re-numbering the previous subsections, add a new subsection (7) to read: Prior to July 1, 2021, a pharmacy benefits manager shall be granted an extension for up to six months for its initial filings if the pharmacy benefits manager certifies that it is in need of such extension.

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Finally, we would like to note that the rule should recognize that claims in connection with ERISA plans are exempt from the regulations laid out in this rule. The Employee Retirement Income Security Act of 1974 (ERISA)[1] established a federal regulatory framework that governs both insured and self-insured "employee welfare benefit plans"[2] and retirement plans sponsored by employers, labor unions, and certain other entities. Employer-sponsored health benefit plans are "welfare benefit plans" and thus subject to ERISA. ERISA does not cover governmental plans[3] or church plans.[4]

ERISA includes an express preemption provision, which preempts all state laws that "relate to" ERISA-governed employee benefit plans. Congress adopted this express preemption provision to establish a uniform federal regulatory scheme and protect ERISA plans from the administrative and compliance burdens of satisfying a patchwork of different state regulations.[5] The US Supreme Court has construed ERISA's broad preemption provision to supersede any state law that has a "reference to" or "connection with" ERISA-governed plans.[6]

PBMs serve as TPAs for ERISA-governed health benefit plans. In that capacity, PBMs perform the essential functions necessary to deliver prescription drug benefits to plan members. PBMs contract with health plans to establish pharmacy networks, administer pharmacy credentialing and performance requirements, and otherwise administer the prescription drug benefits provided by plans. PBMs in turn contract with pharmacies to provide access for plan members to a plan's prescription drug benefits. Such contracts necessarily include arrangements for how much PBMs will reimburse (on behalf of a plan) network pharmacies for any particular prescription drug covered by the plan.

A state regulation of the PBM-pharmacy relationship and/or the PBM-plan relationship has an impermissible "connection with" ERISA when it impermissibly dictates administrator choices pertaining to plan structure and administration. Georgia, by enacting a law that seeks to regulate the procedures surrounding health plan and pharmacy reimbursements, limiting plan pharmacy network options, and establishing other restrictions in contracting, has impermissibly dictated choices in plan structure and administration. Thus, the application of much of this law is preempted by ERISA.

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[1] 29 U.S.C. § 1001 *et seq.*

[2] *Id.* § 1002(1)

[3] *Id.* § 1003(1).

[4] *Id.* § 1003(2).

[5] *Id.* § 1144(a); *see, e.g., Fort Halifax Packing Co., Inc. v. Coyne*, 482 U.S. 1, 11-12 (1987).

[6] *Gobeille v. Liberty Mut. Ins. Co.*, 136 S. Ct. 936, 943 (2016).

COMMENTS – HEARING ON NEW RULES AND REGULATIONS OF COMMISSIONER OF INSURANCE – AMENDING REGULATION 120-1-97 ("PHARMACY BENEFITS MANAGER REGULATION")

TO THE COMMISSIONER OF INSURANCE:

I, Representative David Knight, hereby give the following comments on the importance of implementing and enforcing the following Pharmacy Benefits Managers ("PBMs") Regulation 120-1-97 ("Regulation") of the Commissioner of Insurance ("Commissioner"). The following comments are pursuant to the Commissioner announcing the proposed Regulations on October 19, 2020 with the required hearing taking place on November 19, 2020.

On August 5, 2020, House Bill 946 was signed into law almost unanimously with only one state senator opposing the bill. The purpose of the Regulation is to effectuate HB 946 and the regulation of PBMs under Title 33 – most notably under O.C.G.A § 33-64-11 (prohibited activities of PBMs).

HB 946 seeks to reduce the costs of prescription drugs for Georgia citizens by improving regulations and tightening regulatory loopholes for PBMs operating in Georgia. The law also seeks to reign in PBMs' abusive practices by putting Georgia patients first and by granting the Commissioner broad authority to enforce the law in order to give real meaning to HB 946 and § 33-64-11.

Thus, the Commissioner is correct in proposing the Regulation and should move forward with enforcement despite pleas by the parties opposing the Regulation. The Commissioner has interpreted the law and his authority correctly in the proposed Regulation; therefore, we encourage the Commissioner to continue to take PBM regulations seriously and enforce them within his broad grant of authority. We respectfully ask that none of the Regulations be watered down based on opposing comments since the General Assembly has already spoken on the matter.

HB 946's almost unanimous approval means that the bill was not a law that barely slipped through the legislative process. Rather, the overwhelming approval demonstrates widely accepted law that PBMs must follow. Instead, PBMs have been attempting to ignore Georgia PBM laws and find loopholes, such as arguing that they are not violating anti-steering laws since patients can technically go to a non-affiliated pharmacy if they are willing to pay the costs (which is really no choice at all due to the prohibitive costs of drugs in our nation).

The Commissioner's broad authority includes the authority to assess monetary penalties, place PBMs on probation, suspend a PBM's license if they violate the PBM regulations while on probation, and conduct financial examinations and compliance audits.

PBMs continue their abusive practices by utilizing their lobbying power to fight laws that are already on the books. These attempts undermine the legislative process and the Commissioner's authority, and are a blatant example of PBMs' self-dealing in placing their self-interests above patient care.

Aside from the Commissioner's broad authority to implement Title 33's regulation of PBMs, it is also necessary to understand PBM practices and define key terms that are central to these practices. Health insurers use PBMs' services to manage and administer prescription drug benefits on the insurer's behalf. PBMs were originally meant to reduce these administrative costs for insurers; however, PBMs have grown and have vertically integrated with insurance companies and corporate retail pharmacy chains in a way that has substantially increased these merged companies' profits.

The most concerning PBM practices are (1) steering patients to the PBM affiliated pharmacy, (2) charging patients co-pays which exceed the costs of the drug, (3) mandatory mail-order pharmacies, and (4) gag clauses prohibiting pharmacies from informing patients about cheaper drug alternatives. At the federal level, President Trump has also passed executive orders concerning these practices.

To see the harm that PBM practices have on patient care, we respectfully ask the Commissioner to reference the January 7, 2020 Joint Special Committee on Access to Quality Healthcare ("Committee") hearing where multiple patients and community pharmacists gave testimony on how PBM practices have interfered with the patients' needs for life-saving medication (click here to see the hearing video).

In addition, on February 27, 2020, the Committee held another hearing concerning PBMs' abusive practices where there was testimony about an infant who was forced to wait three weeks to get life-saving medication for pulmonary hypertension even though the infant needed the medication right away. The reason for the three week delay was because of steering as the PBMs required that the infant had to go to an affiliated-pharmacy if they wanted the medication covered by insurance. This is absolutely criminal and can make all the difference between life and death.

No Georgian should be deprived of necessary medication due to PBMs' self-dealing, especially when such self-dealing is a blatant disregard for Georgia law, which the PBMs are more than aware of. The PBMs' blatant disregard for the law is not a product of ignorance – it's a product of arrogance and disrespect toward Georgia patients and the legislature that has prohibited these abusive practices.

PBMs do not have the right to control the prescription drug market in Georgia, and the Commissioner's enforcement is necessary to preserve legislative integrity and the integrity of Georgia's healthcare system all together.

Although HB 946 is not effective until either January 1, 2021 or July 1, 2021 (depending on which subsection), § 33-64-11 is already in effect. Thus, the Commissioner should enforce the already effective PBM code sections referred to in the Regulations. For the foregoing reasons, we respectfully ask the Commissioner to enforce the Regulation as proposed and hold PBM's responsible for blatantly disregarding Georgia's PBM laws.

We would like to conclude with a link to a document (also attached to this letter) prepared for the Arkansas Insurance Department, which demonstrates that Georgia is not alone in fighting the abusive practices of PBMs (click here). The document reflects that nearby conservative-led states are also participating in the charge to fight the corporate takeover of healthcare in our country. Georgia is on the forefront of tackling PBM reform, and we therefore ask the Commissioner to weigh in and enact the Regulation as proposed in furtherance of § 33-64-11.

David W. Knight

David W. Knight
Representative, District 130
Chairman, Appropriations: Higher Education

Georgia House of Representatives

RX PREFERRED
BENEFITS

Pharmacy Benefits Management
340b Administration
Hospice PBM

Dear Commissioner King,

RxPreferred is in full support of the proposed regulations promulgated pursuant to Chapter 64 of Title 33.

In Georgia, RxPreferred administers prescription drug benefits on behalf of local governments as well as commercial customers. RxPreferred is different than several of the larger PBMs as RxPreferred administers prescription drug benefits with a transparent model. RxPreferred does not engage in the practice of spread pricing, and passes back all rebates, discounts, and other revenues to plan sponsors.

Just as Rx Preferred's model increases transparency while at the same time lowering costs for clients and insureds, so too will these proposed regulations increase transparency in an industry that is sorely lacking the same. Traditional PBM's operate in a non-transparent manner, purposely making it difficult or impossible to determine the actual cost of a prescription drug. Traditional PBM's do this by utilizing spread pricing, failing to pass manufacturer rebates back to plan sponsors, or steering patients to PBM owned pharmacies. These conflicting interest strategies ultimately increase cost to patients and plan sponsors, which include governmental payors.

I am confident that traditional PBM's special interests will seek to weaken your proposed regulations, but RxPreferred believes these regulations should be adopted.

RxPreferred applauds Georgia for recognizing the common malpractice in the PBM industry and the need to create regulations to address the lack of transparency with traditional PBM models.

Health Regards,

Edward Reynolds

Edward Reynolds

Chairman

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