



LEGAL UPDATE

Miguel Rodriguez

General Counsel

ACPE # 0130-9999-23-325-L03-P&T

Learning Objectives

- Discuss the ongoing impact of the Supreme Court's *Rutledge vs. PCMA* decision on the legislative landscape.
- Discuss ongoing lawsuits and court decisions related to state PBM reforms.
- Explain American Pharmacies' involvement in amicus briefs & alliances in defending state reforms in court.
- Describe the Federal Trade Commission's investigation of PBM activities and potential outcomes.



Interpretation and Enforcement of State PBM Reform Laws



Congratulations, You've Passed PBM Reform...



- Court Interpretation (ERISA Preemption?)
- Rulemaking
- Complaints
- Enforcement



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- Court Interpretation
 - Rulemaking
 - Complaints
 - Enforcement



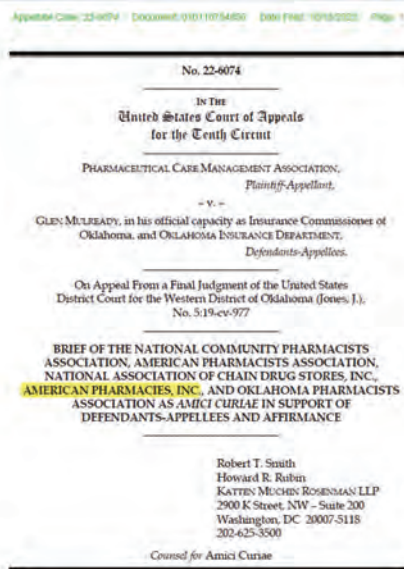
Example: Anti-Steering Laws

- Passed in several states including Texas, Minnesota, Oklahoma and Tennessee
- Prohibit a PBM from steering patients to their own mail order pharmacy
- Protects patient choice

Court Interpretation: ERISA Preemption

- ERISA plans are the health plans operated by large companies and make up the vast majority of patients.
- *PCMA v Rutledge*: US Supreme Court held that states can enforce laws regulating PBMs even when the PBMs are processing claims of ERISA plans.
- *PCMA v Wehbj*: 8th Circuit Court of Appeals held North Dakota PBM reforms were not preempted by ERISA.
- *PCMA v. Mulready*: District court held Oklahoma anti-steering laws are not preempted by ERISA.
- PCMA did not appeal Oklahoma's steering to affiliated pharmacy law; that part of the law stands.

Court Interpretation: *PCMA v Mulready* Appeal



PCMA appealed to the 10th Circuit Court of Appeals the following parts of the Oklahoma law:

- Permitting pharmacies to join preferred networks
- Setting network access requirements
- Prohibiting steering through discounted cost-sharing
- Prohibiting termination of a pharmacy from a network solely because the pharmacy is on probation with the state pharmacy board.

American Pharmacies filed amicus joined by NCPA, APhA, NACDS and OPhA

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT CHATTANOOGA

MCKEE FOODS CORPORATION,
Plaintiff,
v.
STATE OF TENNESSEE,
Intervenor,
BFP Inc., d/b/a THRIFTY MED PLUS
PHARMACY,
Defendant.

Case No. 1:21-cv-279
Judge Arday
Magistrate Judge Lee

MEMORANDUM OPINION AND ORDER

Before the Court are the Intervenor-Plaintiff State of Tennessee's Motion to Dismiss for Lack of Jurisdiction (Doc. 27), Plaintiff McKee Foods Corporation's Motion for Summary Judgment (Doc. 33), Defendant BFP Inc.'s Motion to Dismiss for Lack of Jurisdiction (Doc. 37), and Defendant BFP Inc.'s Motion to Stay Discovery Pending Resolution of Pending Dispositive Motions (Doc. 52). These motions have been fully briefed and the Court recently heard oral argument. The motions are now ripe for review.

For the reasons below, Defendant's Motion to Dismiss for Lack of Jurisdiction (Doc. 37) is **GRANTED** and the remaining motions are **DENIED** as moot.

I. FACTUAL BACKGROUND

For the reasons below, Defendant

is **GRANTED** and the remaining motions

- For the reasons below, Defendant's Motion to Dismiss for Lack of Jurisdiction [Doc. 37] is **GRANTED** and the remaining motions are **DENIED** as moot.

- McKee Foods continues to raise legal costs by dragging Thrifty Med Plus through a pointless appeal.
- Please contribute to Thrifty Med Plus Pharmacy's (Greg and Julie Bohannon) Legal Defense Fund.
- Go to the Tenn. Pharmacists Ass'n Website Pharmacy Practice Preservation Fund (PPPF) page

Tennessee Pharmaceutical Association
A Division of Tennessee Health Institute

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PPPF Thrifty MedPlus Pharmacy Support

View Info

\$500.00

0 ▼

This is a suggested minimum amount and can be changed.

Proceed

What is a suggested donation amount you would like to donate?

PPPF Thrifty MedPlus Pharmacy Support

>

\$500.00

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What is a suggested minimum amount you would like to donate?

PPPF Thrifty MedPlus Pharmacy Support

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What is a suggested maximum amount you would like to donate?

PPPF Thrifty MedPlus Pharmacy Support

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This is a suggested minimum amount and can be changed.

OK Cancel

- Court Interpretation
- **Rulemaking**
- Complaints
- Enforcement

Rulemaking

- State and Federal regulators use rulemaking to clarify and add detail to the laws passed.
- The public is invited to comment on draft agency rules.
- Often regulators delay enforcement until the rulemaking has been completed.
- American Pharmacies consistently provides comments, where appropriate, to agency rules.



Rulemaking

- The National Association of Insurance Commissioners (NAIC) draft white paper on state PBM regulation

Draft 4/16/23
Comments are being requested on this draft by June 3, 2023. Comments should be sent only by email to John Matthews at jmatthews@naic.org.

GUIDE TO UNDERSTANDING PHARMACY BENEFIT MANAGER AND ASSOCIATED STAKEHOLDER REGULATION

NAIC White Paper Draft as of April 16, 2023

Drafted by the Pharmacy Benefit Manager Regulatory Issues (B) Subgroup

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June 3, 2023

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

RE: COMMENTS ON DRAFT PBM WHITE PAPER

Dear Chair Egan and members of the PBM Regulatory Issues (B) Subgroup:

With the support of the undersigned organizations, the National Community Pharmacists Association (NCPA), appreciates the opportunity to provide written comments on the draft white paper titled "Guide to Understanding Pharmacy Benefit Manager and Associated Stakeholder Regulation." NCPA has been supportive of the white paper process as a means to deliver into pharmacy benefit manager (PBM) role as middlemen in the drug supply chain and their impact on drug formulary creation, consumer access to community pharmacy services, and drug pricing. With the feedback we share below, we believe a strengthened final version of the white paper can help the nation's insurance commissioners and their staff to better understand the role of PBMs and put them in a better position to enforce existing or future laws to protect consumers from certain PBM practices and conflicts of interest.

Characterization of Relationships Among Key Players in Pharmaceutical Ecosystem

We appreciate the structure of the white paper to include description of the key players in the pharmaceutical ecosystem. While we recognize the need to be balanced in these descriptions, we believe the white paper does not adequately characterize the asymmetrical relationship between PBM and community independent pharmacies on the distribution chain. In the Vertical Integration and Consolidation section, the white paper correctly points to the competitive disadvantage independent pharmacies face compared to PBM-affiliated pharmacies when it comes to contracting. We believe it is important for policymakers to also recognize the broader challenges of a small business attempting to negotiate terms with Fortune 50 companies. For all practical purposes, such contracts are "take it or leave it." With vertical integration both upstream and downstream, there is a need to level the playing field between community pharmacies and PBM-affiliated pharmacies to protect patients from paying too much at the counter and to address conflicts of interests among vertically integrated companies. The vertical integration of PBMs into monoliths with an affiliated upstream insurance provider and downstream group purchasing organizations, mail-order, specialty, and retail pharmacies has only increased the pressures for PBMs to displace independent pharmacies and their patients to their own affiliated pharmacies.¹ This

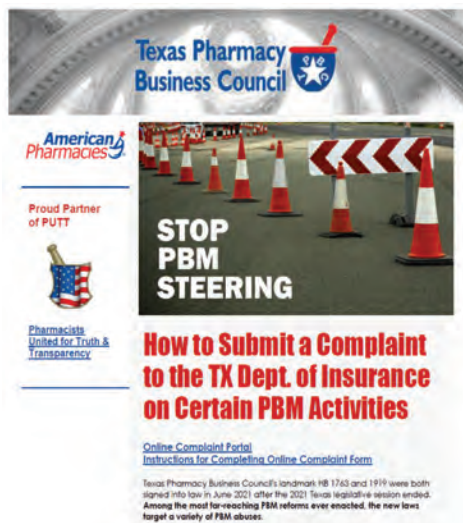
¹ Vertical relationships among insurers, PBMs, CPAs, pharmacies and other providers. <https://www.fda.gov/oc/2021/06/01/vertical-relationships-among-insurers-pbms-cpas-pharmacies-and-other-providers>

Complaints



- PBM law enforcement is a complaint driven process.
- Patients or pharmacies must submit a complaint so that state regulators can investigate and stop the harmful practices.

Complaints: Texas



- American Pharmacies provided instructions on submitting Texas complaints
- Dozens of complaints have been submitted to TDI and have provided useful information

Complaints: Texas

TDI | Texas Department of Insurance

PO Box 12010 | Austin, TX 78711 | 800-375-4877 | tdi.texas.gov

March 30, 2023

Vance Oglesbee RPh
Hometown Pharmacy LLC
201 E Commerce St.
Fairfield, Texas 75840

What we found

Caremark, as the pharmacy benefit manager, was requiring members of a self-funded health benefit plan subject to the Employee Retirement Income Security Act (ERISA) to refill their prescriptions in 90-day supplies at affiliated CVS pharmacies. Otherwise, the refill would not be covered under the plan. We confirm that this is a violation of Texas Insurance Code Sections 1369.554 and 1369.555. Caremark has not agreed to come into compliance with these provisions.

Caremark, as the pharmacy benefit manager, was requiring members of a self-funded health benefit plan subject to the Employee Retirement Income Security Act (ERISA) to refill their prescriptions in 90-day supplies at affiliated CVS pharmacies. Otherwise, the refill would not be covered under the plan. We confirm that this is a violation of Texas Insurance Code Sections 1369.554 and 1369.555. Caremark has not agreed to come into compliance with these provisions. It is asserting that the provisions do not apply to self-funded ERISA plans. Please review the company's response for details.

The next steps

Because Caremark has not agreed to bring the self-funded ERISA plan into compliance with Insurance Code Sections 1369.554 and 1369.555, the department may take further necessary action with regard to this complaint. In the meantime, please contact your patient's plan administrator about filing a complaint or appeal. You may also contact the U.S. Department of Labor at 972-850-4500.

Complaints: Tennessee

- Tennessee Pharmacists Ass'n Exec. Director **Anthony Pudlo** working closely with TDCI to obtain information on status of complaints.
- Myers & Stauffer is currently working through all previously pending External Appeals submitted to the state. These are those claims for medication reimbursement in which a pharmacy submitted their rate review directly to the PBM and the PBM denied the request for at cost reimbursement.
- TDCI hired an Investigator Darth Davenport to serve as the primary triage for all complaints filed with the division. He started work this week.
- TDCI confirms cases of some PBMs reversing their stance and complying with complaints related to the enhanced dispensing fees.
- TDCI only needs one complaint per PBM for issues of inadequate dispensing fee.
- TDCI has open cases under investigation for patient steerage. TDCI is actively collecting information from patients to have all proper information to showcase the PBM preventing a patient's right to choose their pharmacy. This has added a bit of time to addressing these steerage complaints.

- Court Interpretation
- Rulemaking
- Complaints
- Enforcement

Enforcement: Minnesota

April 26, 2022: Minnesota Dept. of Commerce Begins Enforcement Action Against CVS Caremark

RECEIVED
By: OAH on 4/26/2022 9:52 AM

OAH Docket No. 82-1902-58398

Agency Nos. 61965
61689
61694

Pharmacist DK (File 61965)

5. Caremark rejected a claim to fill a prescription for Minnesota consumer AM at a local independent pharmacy owned by Minnesota pharmacist DK. Caremark's rejection message stated that the prescription could only be filled at a CVS pharmacy and required the consumer to call the CVS customer care number.

The purpose of the prehearing conference includes: confirming the hearing date and location, setting scheduling deadlines in advance of the hearing for conducting discovery and exchanging exhibit and witness lists, simplifying the issues to be determined, considering whether an interpreter or other accommodation is needed, and, if possible, reaching a settlement without the necessity for further hearing. See Minn. R. 1400.0300 (2021).

Enforcement: Minnesota

April 28, 2023: Caremark agrees to settle complaint in a Consent Decree



- B. Caremark shall **PAY** a civil penalty in the amount of **\$500,000** to the State of Minnesota.
- C. Caremark shall **CEASE AND DESIST** from further violations of Minnesota Statute Chapter 62W (2022).
- D. In accordance with Minnesota law and with this order, Caremark shall open its Maintenance Choice program, or any successor or similar program, to any pharmacy that wishes to enroll and accepts the network's standard terms, conditions and pricing. This modification will apply to all plans enrolled in the program, regardless of the nature of the plan, including but not limited to any ERISA plans that are enrolled in it.

Enforcement: Oklahoma



- January 19, 2023: Oklahoma Insurance Commissioner Mulready Announces Consent Decree with CVS Caremark
- March 31, 2023: Oklahoma Insurance Commissioner Mulready Announces CVS Caremark is violating the Consent Decree

Enforcement: Oklahoma

Insurance Commissioner Glen Mulready



Federal Trade Commission

Federal Trade Commission



- Section 6(b) Study of Six Largest PBMs' practices:
 - Fees and clawbacks of unaffiliated pharmacies
 - Unfair audit practices
 - Pharmacy reimbursement
 - Prior authorizations and administrative restrictions
 - Specialty drug lists and policies
 - Connection between manufacturer rebates and formulary design and drug costs
- PBMs had 90 days to respond to the FTC; however, PBMs have been slow to turn over documents
- March 30, 2023: American Pharmacies interviewed by FTC investigators for study



CMS's New
"Negotiated Price" Rule
Goes Into Effect
January 1, 2024



CMS's New "Negotiated Price" Rule

- What the New Rule Does:
 - Requires Part D plans to report to the pharmacy the lowest possible reimbursement to the pharmacy
 - Requires the Part D plan to provide the patient a copayment based on the lowest possible reimbursement to the pharmacy (including when the patient is in the "donut-hole")
 - This will provide the pharmacy with some transparency; the pharmacy will know what the worst-possible reimbursement will be
 - Pharmacy cash flow will be reduced since the patient copayment will be based on the lowest possible reimbursement



CMS's New "Negotiated Price" Rule

- What the New Rule Does Not Do:
 - It does not prohibit post point of sale DIR fee arrangements

CMS: The proposed rule noted that the regulatory change we proposed would change the reporting requirements for Part D sponsors, but it does not affect what sponsors may arrange in their contracts with network pharmacies regarding payment adjustments after the point of sale.

- It does not eliminate the incentives for Part D plans to continue to charge fees to pharmacies based on "performance" metrics.
- **New June 2, 2023 CMS Guidance** answered a question about a Part D plan that would require pharmacies to contribute to a bonus pool based on the volume of claims the pharmacy has. CMS said that the contributions to the bonus pool had to be factored into the lowest possible reimbursement calculation.



Other PBM Litigation



MAC Price Litigation Against OptumRx



- Mark Cuker's and Jacobs Law Group's MAC lawsuits against OptumRx representing dozens of pharmacies across multiple states
- March 15, 2023: Wins Ruling in California Court of Appeals that claims against OptumRx do not have to be arbitrated because Optum arbitration clause:
 - Requires pharmacies to arbitrate their claims but allows OptumRx to immediately collect any monies it claims;
 - Costs of arbitration are prohibitive, especially when amount in dispute is small; and
 - Very limited amount of discovery prevents full airing of claims.
- But...April 14, 2023: On exact same set of facts, Illinois Court of Appeals ruled the opposite; that the claims had to be arbitrated. Cuker is appealing to the Illinois Sup. Ct.
- American Pharmacies is working on an amicus brief with the Illinois Pharmacy Association and the California Pharmacy Association to file



AIDS Healthcare Foundation v Caremark

5. While the contracts were contracts of adhesion, the Award is based on the substantive unconscionability of the variable rate DIR provisions and their operation.
6. The variable rate DIR's as set forth and applied in the years at issue are enjoined going forward. Nothing prevents CVS from moving forward with a fair and nondiscriminatory variable DIR methodology based on sound principles.
7. AHF has sustained \$22,696,289.44 in damages and is entitled to recover that amount.

CONCLUSION

Based on the foregoing, the Arbitrator holds that the variable DIR provisions are substantively unconscionable and unenforceable. AHF is entitled to damages in the amount of \$22,696,289.44 and arbitration expenses of \$365,799.44.

expressly granted herein are hereby denied.

Dated: November 12, 2021


William "Pat" Taylor, Arbitrator

AIDS Healthcare Foundation v Express Scripts

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MISSOURI EASTERN DIVISION

AIDS HEALTHCARE FOUNDATION, }

Plaintiff, }

vs. }

EXPRESS SCRIPTS, INC. }

Defendant. }

Case No. 4:22-cv-00743-AGF

MEMORANDUM AND ORDER

This matter is before the Court on Defendant Express Scripts, Inc.'s ("Express

IT IS HEREBY ORDERED that Defendant Express Scripts, Inc.'s motion to dismiss is **GRANTED**. ECF No. 15.

considers "[d]ocuments necessarily embraced by the pleadings," meaning "documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the pleading." *See Atlanta v. City of Golden Valley*, 666 F.3d 1148, 1151 (8th Cir. 2012) (holding that such documents may be considered on a 12(b)(6) motion); *see also Podraza v. Whiting*, 790 F.3d 828, 833 (8th Cir. 2015) (holding the same as to "documents incorporated into the complaint by reference.")

Ohio Antitrust Suit Against ESI and Humana



DAVE YOST
OHIO ATTORNEY GENERAL

IN THE COURT OF COMMON PLEAS
DELAWARE COUNTY, OHIO

STATE OF OHIO, as of: DAVE YOST
ATTORNEY GENERAL OF OHIO,
30 East Broad St., 17th Floor
Columbus, Ohio 43215

Plaintiff:

CASE NO. _____
JUDGE: _____

COMPLAINT FOR DISGORGEMENT,
INJUNCTIVE RELIEF AND
DECLARATORY JUDGMENT

vs.

ASCENT HEALTH SERVICES LLC,
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

EXPRESS SCRIPTS, INC.,
One Express Way
St. Louis, MO 63121

Also name:
Express Scripts Inc.
c/o C.T. Corporation System
4400 Kansas Commerce Way
Suite 125
Columbus OH 43219

CEENA GROUP,
900 Campus Center Road
Bloomfield, CT 06002

Also name:
Cigna Group
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange St.
Wilmington, DE 19801

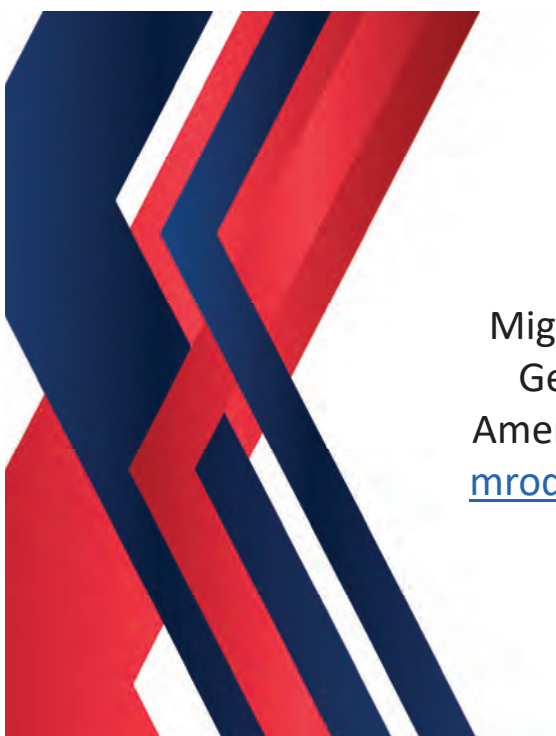
EVERNORTH HEALTH, INC.,
One Express Way
St. Louis, MO 63121

FILED BY: COURT CLERK - DELAWARE COUNTY, OH - COMMON PLEAS COURT
CV H 03 0179 - SCHUCK, JAMES P.
D: 03/27/2023 08:40 AM

- March 27, 2023: Ohio AG Dave Yost sues Express Scripts and Humana
- ESI and Human formed a group purchasing organization called Ascent. They use Ascent to collude on pricing and rebate negotiations with manufacturers.
- “Pharmacies, too – especially independent pharmacies – have been ‘strangled’ by nefarious PBM tactics.”
- Yost said: “PBMs are modern gangsters”

**American
Pharmacies**





Contact Me

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mrodriguez@aprx.org



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