

American
Pharmacies ®



LEGAL UPDATE

Miguel Rodriguez

General Counsel

ACPE # 0130-9999-24-343-H03-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.



Contact Me

Miguel S. Rodriguez
EVP and General Counsel
American Pharmacies
mrodriguez@aprx.org



Enforcement of State PBM Reform Laws

Pharmacy Claim Payors:

- Commercial Insured Claims
- **Commercial ERISA (employer sponsored)**
- **Medicare Part D**
- Medicaid
- Others (teachers, government employees, military)

High Court ERISA Ruling: Rutledge v. PCMA

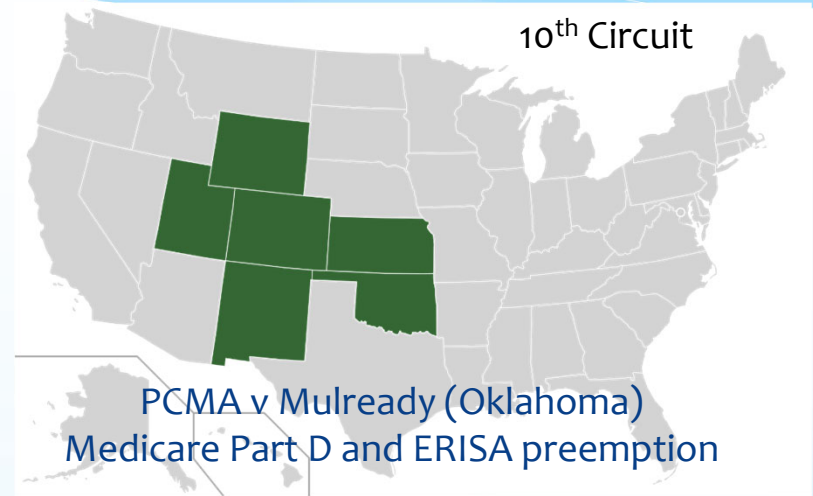
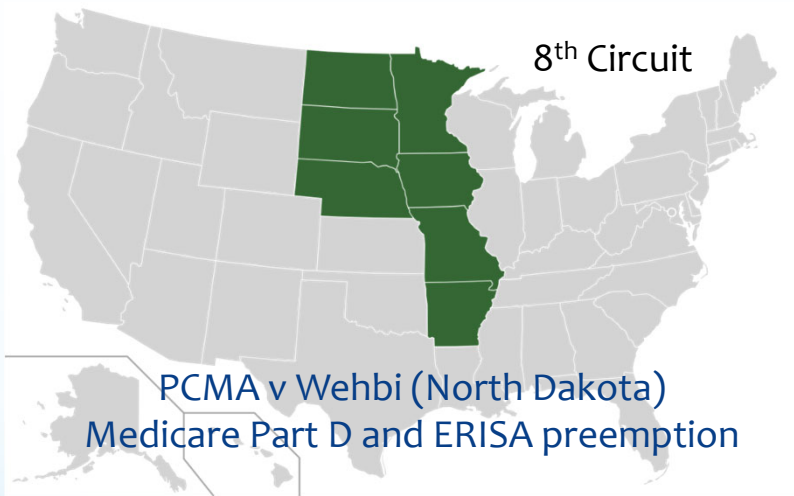
- State PBM regulations could be applied to PBMs administering ERISA plans.
- Rutledge: ERISA preempts “laws that require providers to **structure benefit plans in particular ways**, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining **beneficiary status**.”
- Rutledge: ERISA preempts a state law “if acute, albeit indirect, economic effects of the state law **force an ERISA plan to adopt a certain scheme of substantive coverage**.”



High Court ERISA Ruling: Rutledge v. PCMA

- Rutledge: “Crucially, not every state law that affects an ERISA plan or causes some disuniformity in plan administration has an impermissible connection with an ERISA plan. That is especially so if a law **merely affects costs.**”
- Rutledge: “In short, ERISA does not pre-empt state rate regulations **that merely increase costs or alter incentives for ERISA plans** without forcing plans to adopt any particular scheme of substantive coverage.”

A Circuit Split



PCMA v Wehbi (8 th Circuit)	PCMA v Mulready (10 th Circuit)
Followed Rutledge on pharmacy network regulation	Disagreed with <i>Wehbi</i> on ERISA preemption of pharmacy network regulation
Established Med D Preemption Standard	Disagreed with <i>Wehbi</i> on Med D Preemption Standard

Mulready Opinion Creates Confusion

- Examples of laws that are not preempted
 - MAC appeals (*Rutledge*)
 - Refuse to fill below cost scripts (*Rutledge*)
 - No onerous accreditation requirements (*Wehbi*)

- Examples of laws that Tenth Circuit found to be preempted
 - Any willing provider (*Mulready*)
 - Steering through differences in patient copay (*Mulready*)

No. 23-1213

In the Supreme Court of the United States

GLEN MULREADY, IN HIS OFFICIAL CAPACITY AS
INSURANCE COMMISSIONER OF OKLAHOMA, ET AL.,
PETITIONERS

v.

GLI

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

A
N
AMEI

BRIEF FOR AMERICAN PHARMACIES, INC.,
THE AMERICAN PHARMACISTS ASSOCIATION,
THE NATIONAL ASSOCIATION OF CHAIN DRUG
STORES, INC., THE NATIONAL COMMUNITY PHAR-
MACISTS ASSOCIATION, AND THE OKLAHOMA
PHARMACISTS ASSOCIATION AS AMICI CURIAE
SUPPORTING PETITIONERS

DANIEL L. GEYSER
Counsel of Record
HAYNES AND BOONE, LLP
2801 N. Harwood Street, Ste. 2300
Dallas, TX 75201
(303) 382-6219
daniel.geyser@haynesboone.com

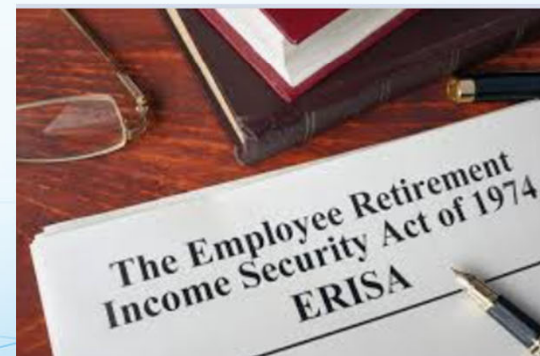
Friend of the Court Briefs

- *PCMA v. Wehbi*
- 8th Circuit Court of Appeals
- North Dakota PBM Reform Not Preempted by ERISA or Medicare Part D

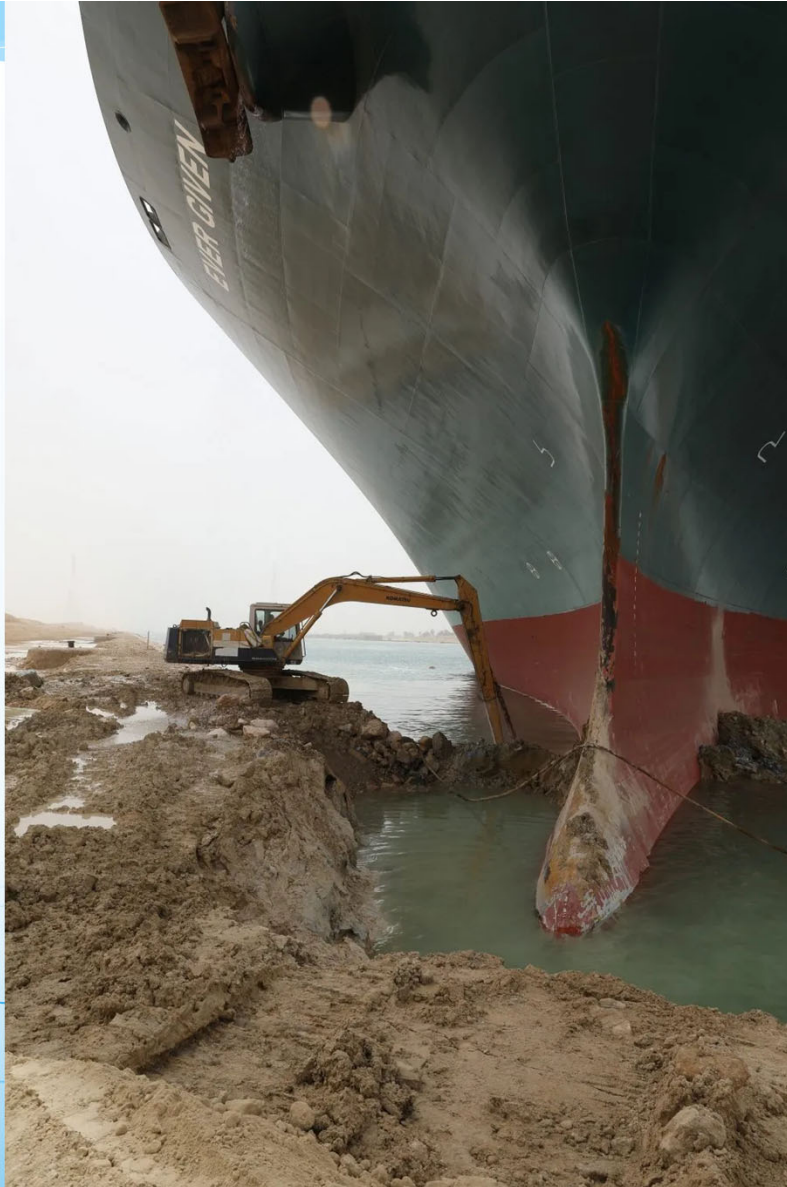
- *PCMA v. Mulready*
- 10th Circuit Court of Appeals
- Oklahoma PBM Reform Not Preempted by ERISA or Medicare Part D

- *PCMA v. Mulready*
- US Supreme Court
- Oklahoma PBM Reform Not Preempted by ERISA or Medicare Part D

Enforcement by State Regulators







States Are Grappling With Enforcement: Texas

RECEIVED
By Opinion Committee at 2:31 pm, May 13, 2024



RQ-0539-KP

1. Are HB 1763¹ and HB 1919² enforceable against an ERISA³ health benefit plan issuer and a pharmacy benefit manager administering the pharmacy benefits of such ERISA health benefit plan?
2. Are HB 1763 and HB 1919 enforceable against a health benefit plan issuer and a pharmacy benefit manager administering the pharmacy benefits of such health benefit plan where the health benefit plan is domiciled in a United States jurisdiction outside of Texas and the health benefit plan provides coverage to Texas residents and uses a pharmacy benefit manager that directly contracts with a network of providers including Texas pharmacy providers?

imposed on a "health benefit plan." See, e.g., TEX. INS. CODE §§1369.553-55 and 1369.603-609.

¹ Acts 2021, 87th Leg., R.S., ch. 142, §1 (H.B. 1763) (codified at TEX. INS. CODE §§1369.601-610) (hereafter "HB 1763").

² Acts 2021, 87th Leg., R.S., ch. 1012, §1 (H.B. 1919) (codified at TEX. INS. CODE §§1369.551-555) (hereafter "HB 1919").

³ Employee Retirement Income Security Act of 1974, 29 U.S.C. §1001 *et seq.* (hereafter "ERISA").

States Are Grappling With Enforcement: Michigan

From: Miguel Rodriguez, General Counsel
To: Michigan Department of Insurance and Financial Services
Date: May 21, 2024
Re: Interpretation of Select Provisions of the Pharmacy Benefit Manager Licensure and Regulation Act

A. The Act Permits Application to Claims Related to ERISA Plans and Medicare Part D Plans

The Pharmacy Benefit Manager Licensure and Regulation Act (the “Act”) contains a provision

² MCL 209.81(4) (defining claim to mean a request for payment for administering, mixing, or renewing a drug or for providing a pharmacy service or a medical supply or device to an enrollee”).

³ Compare with MCL 550.833(5) (“This section does not apply to a contract between a pharmacy benefit manager and the department of health and human services under Medicaid.”). Other states have crafted broad limitations of certain PBM regulations related to ERISA or federal programs. See, e.g., TEX. INS. CODE §1369.252 (Texas law regulating PBM audit practices “does not apply to an issuer or provider of health benefits under or a pharmacy

States Are Grappling With Enforcement: Tennessee



February 1, 2024

Commissioner Carter Lawrence
Tennessee Department of Commerce & Insurance
500 James Robertson Pkwy
Nashville, TN 37243



STATE OF TENNESSEE
DEPARTMENT OF COMMERCE AND INSURANCE
500 JAMES ROBERTSON PARKWAY
NASHVILLE, TENNESSEE 37243-5065
615-741-6007

BILL LEE
GOVERNOR

CARTER LAWRENCE
COMMISSIONER

- **Question 1: Does the TDCI intend to enforce all or part of the Tennessee Laws & Regulations against self-insured ERISA plans and their sponsors (e.g., employers and unions)?**

Our questions, which are stated below, are made in reference to laws passed in 2021 and 2022 affecting health plans and pharmacy benefit companies under Pub. Ch. 569 (HB 1398), Pub. Ch. 1070 (HB 2661), and Pub. Ch. 998 (HB 2660) (codified at Tenn. Code Ann. §§ 56-7-3101 - 56-7-3123; 56-7-3201 - 56-7-3210), and their 2023 implementing regulations codified at Tenn. Comp. R. & Regs. 0780-01-95, as well as certain TDCI proposed rules issued in October 2023 (to be codified at 0780-0195-.13 - .18 (new language) and 0780-01-95-.02, .04, .05, and .07 (amendments) ("Proposed Rule") (together, "Tennessee Laws & Regulations").

Questions:

We respectfully request that the TDCI formally express its position with regard to the following questions either in the form of an Interpretive Opinion, Bulletin, or in some other manner.

- **Question 1:** Does the TDCI intend to enforce all or part of the Tennessee Laws & Regulations against self-insured ERISA plans and their sponsors (e.g., employers and unions)?
- **Question 2:** If the TDCI answers Question 1 in the affirmative (i.e., confirming its intent to enforce all or part of the Tennessee Laws & Regulations against self-insured ERISA plans), what authority would the TDCI have to enforce the Tennessee Laws & Regulations—in particular, provisions of those Laws & Regulations that regulate provider network design—against self-insured ERISA plans in light of the decision of the U.S. Court of Appeals for the Sixth Circuit in *Ky. Ass'n of Health Plans, Inc. v. Nichols*, 227 F.3d 352, 362 (6th Cir. 2000)?
- **Question 3:** If the TDCI answers Question 1 in the affirmative (i.e., confirming its intent to enforce all or part of the Tennessee Laws & Regulations against self-insured ERISA plans), what constitutional basis and authority would the TDCI have to enforce the

Page 1

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmnet.org

Re: Response to February 1, 2024, Letter re: Request for TDCI Guidance

Dear Mr. Fjelstad:

This letter is in response to Pharmaceutical Care Management Association's ("PCMA") February 1, 2024, letter requesting clarification on the Tennessee Department of Commerce and Insurance's ("Department") enforcement intentions as to the regulation of self-insured health plans governed by the federal Employee Retirement Income Security Act of 1974 ("ERISA") and their sponsors.

As previously stated in Bulletin 21-01 issued on July 8, 2021, the definition of "covered entity" in the Tennessee Laws & Regulations¹ in effect at that time included self-funded entities, which includes ERISA plans. After that bulletin was issued, the General Assembly further clarified this applicability in 2022 by enacting Sections 7 and 8 of Pub. Ch. 1070, which were later codified at Tenn. Code Ann. § 56-7-3122 and -3209, respectively. Those sections state unequivocally that "[n]otwithstanding another law, [Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32] appl[y] to plans governed by the Employee Retirement Income Security Act of 1974 (ERISA) (29 U.S.C. § 1001 et seq.)." Finally, the Department reiterated this position on March 29, 2023, when it filed a Rulemaking Hearing Rule Filing Form for Tenn. Comp. R. & Regs. Chapter 0780-01-95 containing responses to comments submitted during the Department's February 3, 2023, public hearing. Therefore, the Department intends to enforce Tennessee state law, including the requirements of the Tennessee Laws & Regulations, that are applicable to pharmacy benefits managers (as defined by Tenn. Code Ann. § 56-7-3102(5)) administering the medication and/or

¹ As defined in PCMA's February 1, 2024, letter.



States Are Grappling With Enforcement: Oklahoma



Search

About Need Help? What We Do Forms News Resources Opinions Careers

OAG > About > Divisions > Pharmacy Benefit Managers Compliance and Enforcement

Pharmacy Benefit Managers Compliance and Enforcement

Overview

The Pharmacy Benefit Managers Compliance and Enforcement Unit is committed to ensuring a safe and fair marketplace for pharmaceuticals in Oklahoma.

Patient's Right to Pharmacy Choice Act

The Patient's Right to Pharmacy Choice Act created prohibitions on restrictions of an Oklahoman's right to choose a pharmacy provider.

The Act also prohibits PBMs from:

- Charging certain fees;
- Reimbursing a pharmacy an amount less than the amount that the PBM reimburses a pharmacy owned by the PBM for providing the same covered services;
- Failing to make any payment due to a pharmacy for covered services properly rendered in the event a PBM terminates a provider from a pharmacy benefits manager network; and/or
- Utilizing "spread pricing" in reimbursements to pharmacists or pharmacies.

Read information about the [Oklahoma Patient's Right to Pharmacy Choice Act, 36 O.S. §§ 6958 - 6969](#).

Patients & Consumers

- [Patient's Right to Pharmacy Choice Act](#)
- [Pharmacy Audit Integrity Act](#)
- [Pharmacy Benefit Plans](#)

Complaint Forms

- [Patient & Consumers](#)
- [Pharmacist & Pharmacy](#)
- [PSAO](#)

Pharmacy Benefits Managers

- [Attestation Pharmacy Benefit Manager Reporting](#)
- [Network Access Adequacy Standards Template](#)
- [PBM Reporting FAQs.pdf](#)
- [Section 6962 Quarterly Report Template](#)

- Oklahoma Attorney General tasked with PBM enforcement
- AG's office hired a dozen new employees in a new PBM Compliance and Enforcement Division



States Are Grappling With Enforcement: Oklahoma



- Deputy Attorney General Michael Leake heads the new division
- Leake: “Any business owner knows that if you’re losing money with the product that’s going out the door, you can’t sustain that model. That should be a concern to all Oklahomans.”
- May 2024: Lawsuit against Big 3 PBMs regarding insulin pricing

Federal Trade Commission

Federal Trade Commission

- 2022: 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
- March 30, 2023: American Pharmacies interviewed by FTC investigators for study
- May 2023: Expanded study to GPOs owned by the PBMs



Enforcement ▾ Policy ▾ Advice and Guidance ▾ News and Events ▾ About the FTC ▾

[Home](#) / [News and Events](#) / [News](#) / [Press Releases](#)

For Release

FTC Launches Inquiry Into Prescription Drug Middlemen Industry

Agency to Scrutinize the Impact of Vertically Integrated Pharmacy Benefit Managers on the Access and Affordability of Medicine

June 7, 2022



Federal Trade Commission



Office of the Chair

UNITED STATES OF AMERICA
Federal Trade Commission
WASHINGTON, D. C. 20580

February 13, 2024

The Honorable Charles E. Grassley
United States Senate

Although our compulsory orders were issued in June 2022, and May and June 2023, to date no company has turned over sufficient documents and data to be in full compliance with those orders. FTC staff continues to push the PBM/GPOs to finalize their production of documents and data required by the Orders as quickly as possible. The respondents have proceeded with varying levels of speed in their productions and compliance with the Orders. We expect to have all the materials very soon. If, however, some of the companies fail to fully comply with the orders or engage in any actionable delaying tactics, the FTC can take them to court to compel compliance.

As you know, in June 2022, the FTC issued Orders to PBMs pursuant to its 6(b) authority to study a range of PBM business practices that may affect drug affordability and access.¹ The Order requires the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc.—to provide data and documents regarding certain business practices. This inquiry

¹ Ashley Kürzinger, et al. PUBLIC OPINION ON PRESCRIPTION DRUGS AND THEIR PRICES (2023), <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>; see also, Laryssa Mykyta & Robin A. Cohen, *Characteristics of Adults Aged 18–64 Who Did Not Take Medication as Prescribed to Reduce Costs: United States, 2021*, NAT'L CTR. FOR HEALTH STATISTICS (2023) at 5, doi:10.15620/cdc:127680 (research from the CDC found that 9.2 million adults in the U.S. are not taking their prescription drugs as prescribed, due to the high cost of medications).

² Press Release, Fed. Trade Comm'n, FTC Launches Inquiry Into Prescription Drug Middlemen Industry (June 7, 2022), <https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-launches-inquiry-prescription-drug-middlemen-industry>.



GoodRx Most Favored Nation Reimbursement

GoodRx-Caremark Cost Saver Program



Prescription sent to pharmacy



Pharmacist submits claim using member's CVS Caremark ID

Drug price comparison occurs



Invisible to members



Claim returns with 'patient owes' amount of **\$16**



Member pays **\$16** that payment is applied to the deductible and no paper claims are necessary

GoodRx-Caremark Cost Saver Program

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE: REALPAGE, RENTAL
SOFTWARE ANTITRUST LITIGATION
(NO. II)

Case No. 3:23-MD-3071

This Document Relates to:
ALL CASES

Chief Judge Waverly D. Crenshaw, Jr.

MEMORANDUM OF LAW IN SUPPORT OF THE
STATEMENT OF INTEREST OF THE UNITED STATES

JONATHAN S. KANTER
Assistant Attorney General

HENRY C. LEVENTIS
United States Attorney

DOHA G. MEKKI
Principal Deputy Assistant Attorney General

MICHAEL C. TACKEFF, B.P.R. #036953
Assistant United States Attorney

MAGGIE GOODLANDER
Deputy Assistant Attorney General

Middle District of Tennessee
719 Church Street, Suite 3300

ANDREW J. FORMAN
Deputy Assistant Attorney General

Nashville, TN 37203
Telephone: (615) 736-5151
Email: michael.tackeff@usdoj.gov

DAVID B. LAWRENCE
Policy Director

JACOBUS VAN DER VEN
Counsel to the Assistant Attorney General

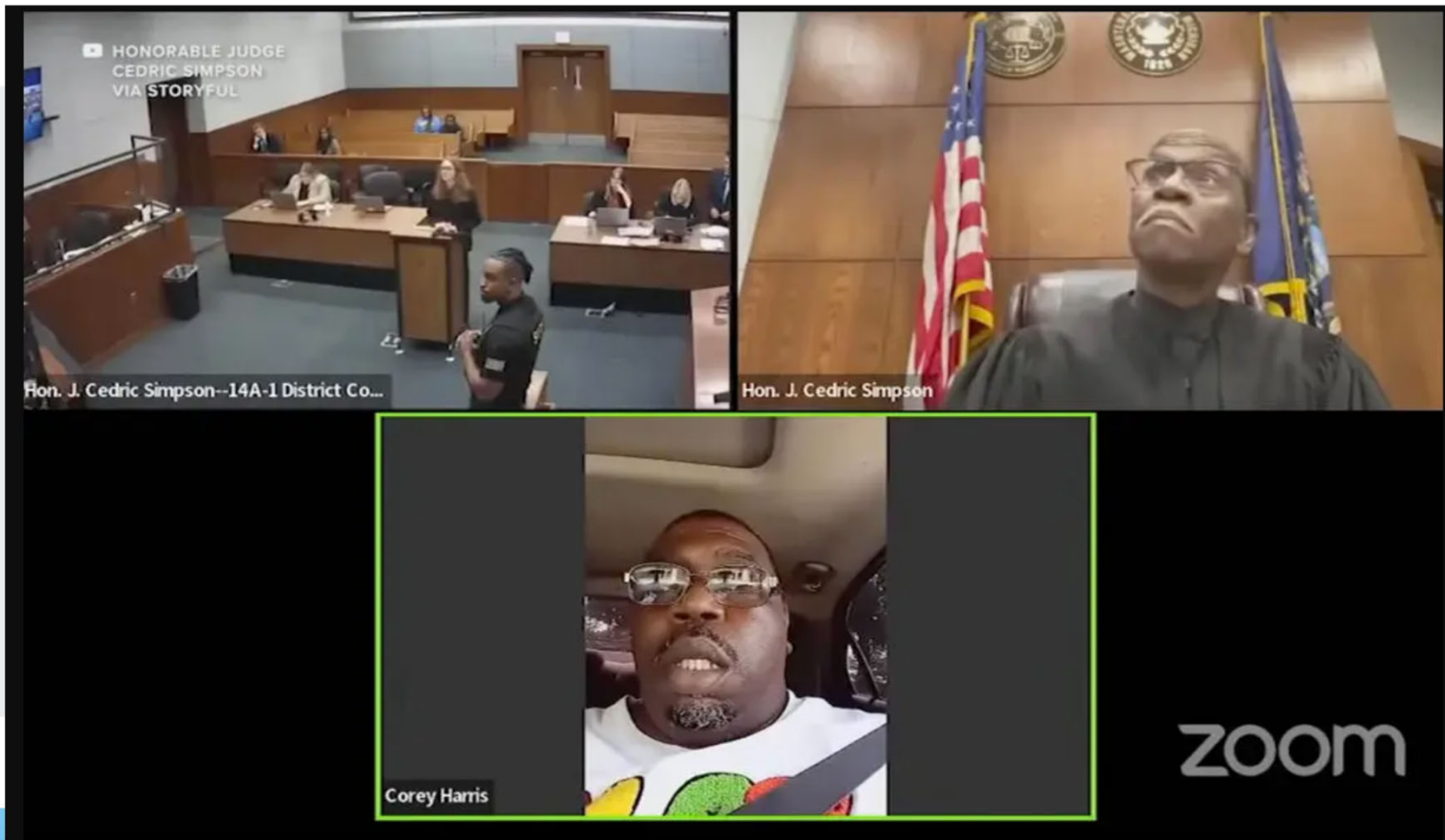
DANIEL E. HAAR
NICKOLAI G. LEVIN
STRATTON C. STRAND
YIXI (CECILIA) CHENG
Attorneys

U.S. Department of Justice
Antitrust Division
950 Pennsylvania Ave NW, #3224
Washington, DC 20530
Telephone: 202-705-8342
Email: yixi.cheng@usdoj.gov

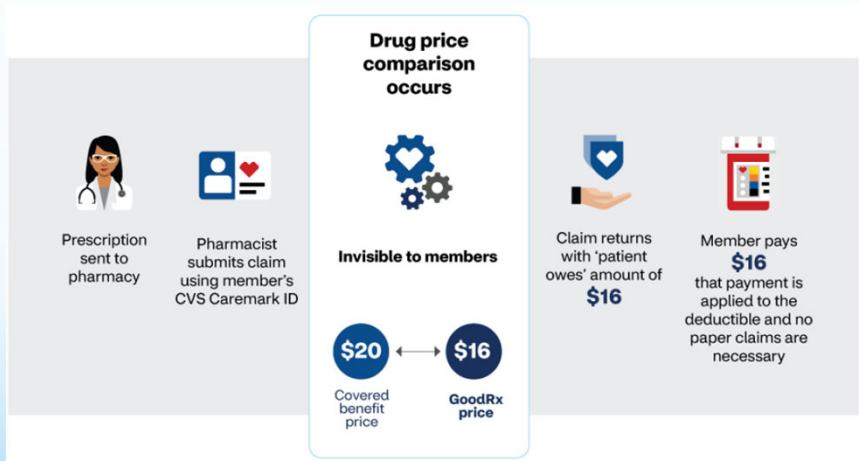
Counsel for the United States of America

- March 2024: Joint Statement of the FTC and DOJ on Algorithmic Price Fixing
- Algorithmic Price Fixing is a **per se** violation of the Sherman Act
- Hotels using an algorithm to “suggest” prices for their rooms is a violation of the Sherman Act even if the competing hotels never specifically communicated about it or set up a contract around it.
- Also potential violation of state transaction fee bans, clawback bans and prompt pay laws.

GoodRx-Caremark Cost Saver Program



GoodRx-Caremark Cost Saver Program



- Commercial, Medicare and Medicaid
- Due from Insurance is a negative amount
- NCPDP Network Reimbursement ID Field (545-2F) shows #####GDRX
- NCPDP Additional Message Information Field (526-FQ) shows CLAIM PAID NON-CMK DISCOUNT CONTRACT



TRUST LLC claims against PBMs

Osterhaus Pharmacy v. CVS Health Class Action

Case 2:23-cv-01500 Document 1 Filed 09/26/23 Page 1 of 29

Summary of claims:

- Suit filed September 26, 2023
- Class action on behalf of all pharmacies in the country.
- It seeks damages based on DIR fees paid to CVS after September 2019.
- It's primary cause of action is an antitrust action claiming that CVS withheld access to its Medicare Part D beneficiaries unless the pharmacy agreed to contract terms including a DIR fee and that the DIR fees are arbitrary and unconscionable.
- Pending before the court are questions of whether the case should be moved to either arbitration or to another court.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

OSTERHAUS PHARMACY, INC. on behalf
of itself and all others similarly situated,
Plaintiff,
v.
CVS HEALTH CORPORATION, CVS
PHARMACY, INC., CAREMARK Rx,
L.L.C. (f/k/a/ CAREMARK Rx, INC.),
CAREMARK, L.L.C., CAREMARKPCS,
L.L.C., CAREMARK PCS HEALTH L.L.C.,
CAREMARK IPA, L.L.C., CAREMARK
PART D SERVICES, LLC, AETNA INC.,
AETNA HEALTH HOLDINGS, LLC, AND
AETNA HEALTH MANAGEMENT, LLC,
Defendants.

NO.
CLASS ACTION COMPLAINT
JURY TRIAL DEMANDED
CLASS ACTION

Plaintiff Osterhaus Pharmacy, Inc. ("Osterhaus" or "Osterhaus Pharmacy" or "Plaintiff") brings this action on behalf of itself and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure against defendants Caremark Rx, L.L.C. (f/k/a Caremark Rx, Inc.), Caremark, L.L.C., CaremarkPCS, L.L.C., Caremark PCS Health L.L.C., Caremark IPA, L.L.C., Caremark Part D Services, LLC, Aetna Health Management, LLC, CVS Health Corporation, CVS Pharmacy, Inc., Aetna Inc., and Aetna Health Holdings, LLC (collectively, "CVS Caremark"). Plaintiff seeks damages for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and breach of the covenant of good faith and fair dealing. Plaintiff also seeks equitable and declaratory relief on the basis of claims for unjust enrichment, unconscionability, and quantum meruit.

TERRELL MARSHALL LAW GROUP PLLC
510 North 24th Street, Suite 300
Seattle, Washington 98103-3800
TEL: 206.835.6003 • FAX: 206.219.5400
www.terrellmarshall.com

CLASS ACTION COMPLAINT - 1
CASE NO.

Osterhaus Pharmacy v. ESI Class Action

Case 2:24-cv-00039 Document 1 Filed 01/09/24 Page 1 of 22

1
2
3
4
5
6 UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

7 OSTERHAUS PHARMACY, INC.
8 CAMMACK'S PHARMACIES INC., DBA
9 JIM'S PHARMACY AND HOME HEALTH,
10 HARBOR DRUG CO., INC. and VALU
11 DRUGS INC., on behalf of themselves and all
others similarly situated,
12 Plaintiff,
13 v.
14 EXPRESS SCRIPTS, INC. and
EVERNORTH HEALTH, INC., formerly
known as Express Scripts Holding Company,
15 Defendants.

16
17 Plaintiffs Osterhaus Pharmacy, Inc. ("Osterhaus" or "Osterhaus Pharmacy"), Cammack's
18 Pharmacies Inc., d/b/a Jim's Pharmacy and Home Health, ("Jim's" or "Jim's Pharmacy"),
19 Harbor Drug Co., Inc., and Valu Drugs Inc. (collectively "Plaintiffs") bring this action on behalf
20 of themselves and all others similarly situated, pursuant to Federal Rule of Civil Procedure 23,
21 against defendants Express Scripts, Inc. and Evernorth Health, Inc. (collectively "Express
22 Scripts"). Express Scripts has entered into a series of price-fixing agreements (the
23 "Agreements") with each of its co-conspirators, Prime Therapeutics LLC ("Prime"), Benecard
24 Services, LLC ("Benecard"), and Magellan Rx Management, LLC ("Magellan") (Express
25 Scripts' "Co-Conspirators," and, including Express Scripts, the "Conspirators").
26 Plaintiffs seek treble damages, costs, attorneys' fees, and other monetary relief for
27 Defendants' violations of Section 1 of the Sherman Act, 15 U.S.C. § 1.

TERRELL-MARSHALL LAW GROUP PLLC
191 North 34th Street, Suite 300
Seattle, Washington 98102-4809
TEL: 206.810.6600 • FAX: 206.319.5450
www.terrellmarshall.com

CLASS ACTION COMPLAINT - 1
CASE NO.

Summary of claims:

- Suit filed January 9, 2024
- Class action on behalf of all pharmacies in the country.
- It seeks damages based on DIR fees paid to ESI after April 2020.
- It's primary cause of action is an antitrust action claiming that ESI conspired with Prime Therapeutics and another PBM to fix prices.
- The court is considering a motion to dismiss the claims and to move venue to St. Louis.



Osterhaus Pharmacy v. OptumRx Class Action

Summary of claims:

- Suit filed December 18, 2023
- Class action on behalf of all pharmacies in the country.
- It seeks damages based on DIR fees paid to OptumRx after September 2019.
- It's primary cause of action is an antitrust action claiming that OptumRx withheld access to its Medicare Part D beneficiaries unless the pharmacy agreed to contract terms including a DIR fee and that the DIR fees are arbitrary and unconscionable.
- The parties appear to be negotiating a way to have all claims heard in arbitration if appropriate safeguards ensure a more fair arbitration proceeding.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

OSTERHAUS PHARMACY, INC., on behalf of itself and all others similarly situated, <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> UNITEDHEALTH GROUP INCORPORATED; OPTUM, INC.; OPTUMRX, INC.; OPTUMRX HOLDINGS, LLC, <p style="text-align: center;">Defendants.</p>	NO. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED
--	--

Plaintiff Osterhaus Pharmacy, Inc. ("Osterhaus" or "Osterhaus Pharmacy" or "Plaintiff") brings this action on behalf of itself and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure against defendants UnitedHealth Group, Inc.; Optum, Inc.; OptumRx, Inc.; and OptumRx Holdings, LLC (collectively, "OptumRx"). Plaintiff seeks damages for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, breach of contract, and breach of the covenant of good faith and fair dealing.

Plaintiff also seeks equitable and declaratory relief on the basis of claims for unjust enrichment, unconscionability, and quantum meruit.

I. NATURE OF THE ACTION

Plaintiff is a pharmacy that is bringing six claims on behalf of itself and a proposed class.

TERRELL MARSHALL LAW GROUP PLLC
 316 North 34th Street, Suite 300
 Seattle, Washington 98103-8869
 TEL: 206.516.8600 • FAX: 206.516.5450
 www.terrellmarshall.com

CLASS ACTION COMPLAINT - 1



Pharmacy Assigns Claims Against PBMs to TRUST LLC

ASSIGNMENT AND TRANSFER AGREEMENT AND POWER OF ATTORNEY

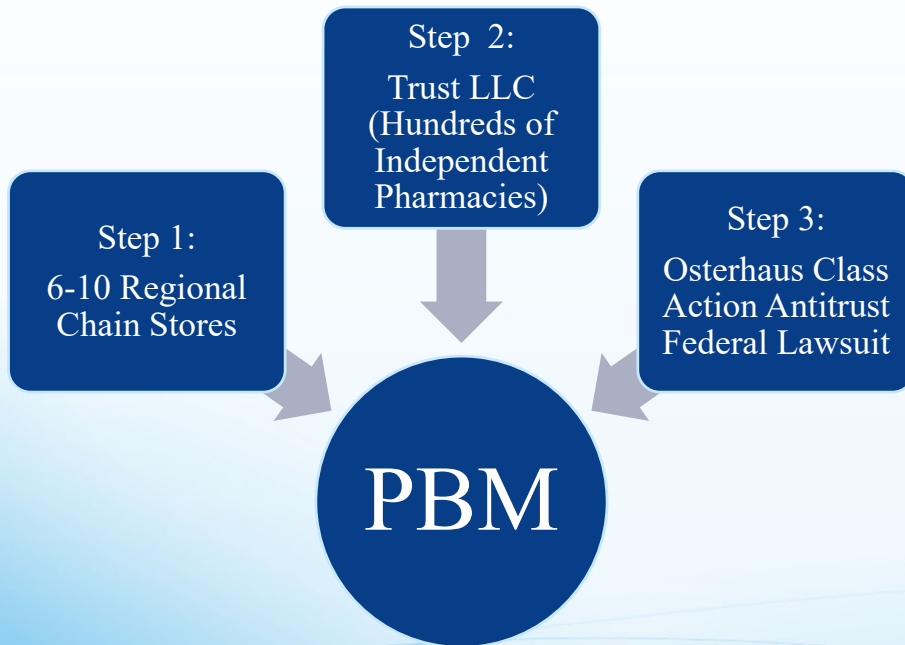
This Assignment and Transfer Agreement and Power of Attorney (the "Agreement") is made between _____ (hereinafter referred to as the "Company," or "You"), and Protecting Access to Retail Pharmacy (PARPh) d/b/a Team for Recouping Unfair Sham Terms ("TRUST LLC").

“DIR Claims” means all Claims arising out of or related to the collection by PBMs of DIR fees which relate to the period since January 1, 2016.

“ESI/Prime Claims” means all Claims concerning antitrust, collusion, price fixing or unfair competition arising out of or related to any agreement between ESI and Prime that involves either of ESI or Prime utilizing the other’s commercial and government networks.

ii. Expenses means all expenses reasonably necessary to pursue 1001.2011 Claims, including without limitation (i) Contingent or hourly fees paid to lawyers; (ii) Fees paid to expert consultants retained by the lawyers; (iii) Out of pocket costs such as costs of filing of the complaint, arbitration administrative fees such as the initial filing and final fees, costs of the arbitrator, fees for any mediator, mediation administrative fees, cost of travel expenses, postage, telephone charges, facsimile charges, transcript costs, other docket and filing fees, process server

Apparent Litigation Strategy



Step 1: Several Regional Drug Chains Initiate Separate Arbitrations Against each PBM and Develop a Win/Loss Ratio

Step 2: Plaintiffs Attorneys Attempt to Settle Trust LLC Claims Using Win/Loss Ratio from Regional Drug Chain Arbitrations

Step 3: Utilize Class Action Lawsuit to Toll Statute of Limitations and Potentially Settle All Retail Pharmacy Claims, Even Those Not in Trust LLC

American Pharmacies-NCPA Webinar

January 31, 2024

You're invited to present at TRUST LLC Webinar with NCPA and American Pharmacies

Hi Miguel Rodriguez,

Thanks for being a speaker at our event! Use your unique join link below when it's time to enter. This link is private to you—please don't share or forward it. Your link can be used to join the event from a max of three devices.

TRUST LLC Webinar with NCPA and American Pharmacies

Wed, Jan 31, 2024 2:00 PM - 3:00 PM (UTC-05:00) Eastern Time (US &

Presenters:

Miguel Rodriguez

Matt Seiler, General Counsel of NCPA

John Roberti, Partner of COHEN & GRESSER LLP

Format: 20 minutes of presentation and 40 minutes of Q&A





DIR Redux

DIR Redux

- CMS rule change went into effect in 2024. CMS did not ban DIR fees, it only required a Part D plan to ensure that patients received the benefit of the DIR fee at the point of sale through a lower copay.
- CVS's 24D contract had proposed the creation of a bonus pool by collecting a per-claim fee from each participating store that might be used to pay back to pharmacies based on performance.

DIR Redux

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE

DATE: June 2, 2023
TO: All Part D Sponsors
FROM: Jennifer R. Shapiro, Director, Medicare Plan Payment Group
SUBJECT: Reminder of Regulatory Requirements for Pharmacy Price Concessions

In order to remind Part D plan sponsors of regulatory guidance regarding pharmacy price concessions that takes effect January 1, 2024, the Centers for Medicare & Medicaid Services (CMS) is re-stating for broader dissemination through this memorandum the answers provided to questions recently received on said guidance during the [CMS Office of the Actuary's Actuarial User Group Calls](#).

Question: We have a pharmacy payment arrangement whereby pharmacies, as a condition of participation in the plan's network, must contribute to a pool of money that would then be used to make post-point-of-sale payments to network pharmacies based on pharmacy performance. The pharmacy contribution is not based on the number of prescriptions filled at the pharmacy or otherwise assessed at the claim level. Instead, each pharmacy's contribution to the pool is based on the volume of Part D patients attributed and total payment made to that pharmacy per month. How should the pharmacy's contribution and any potential performance payment to the pharmacy be reported and accounted for in the bid pricing tool?

Answer: We wish to remind plans that the pharmacy price concessions provision finalized in the May 9, 2022 final rule (CMS-4192-F) takes effect January 1, 2024 and requires the application of all pharmacy price concessions at the point of sale.¹ If the payment to a Part D pharmacy may be reduced by up to a certain amount, the maximum possible reduction in payment must be treated as a pharmacy price concession and reflected in the negotiated price available at the point of sale and reported to CMS on a PDE record. This is the case regardless of whether the maximum possible reduction in payment is calculated on a per claim basis. As stated on pg. 27851 of the final rule, for pharmacy price concessions that are not assessed at the claim level, Part D sponsors would have to determine a methodology to attribute such concessions to the claim level to remain in compliance with the definition of negotiated price.

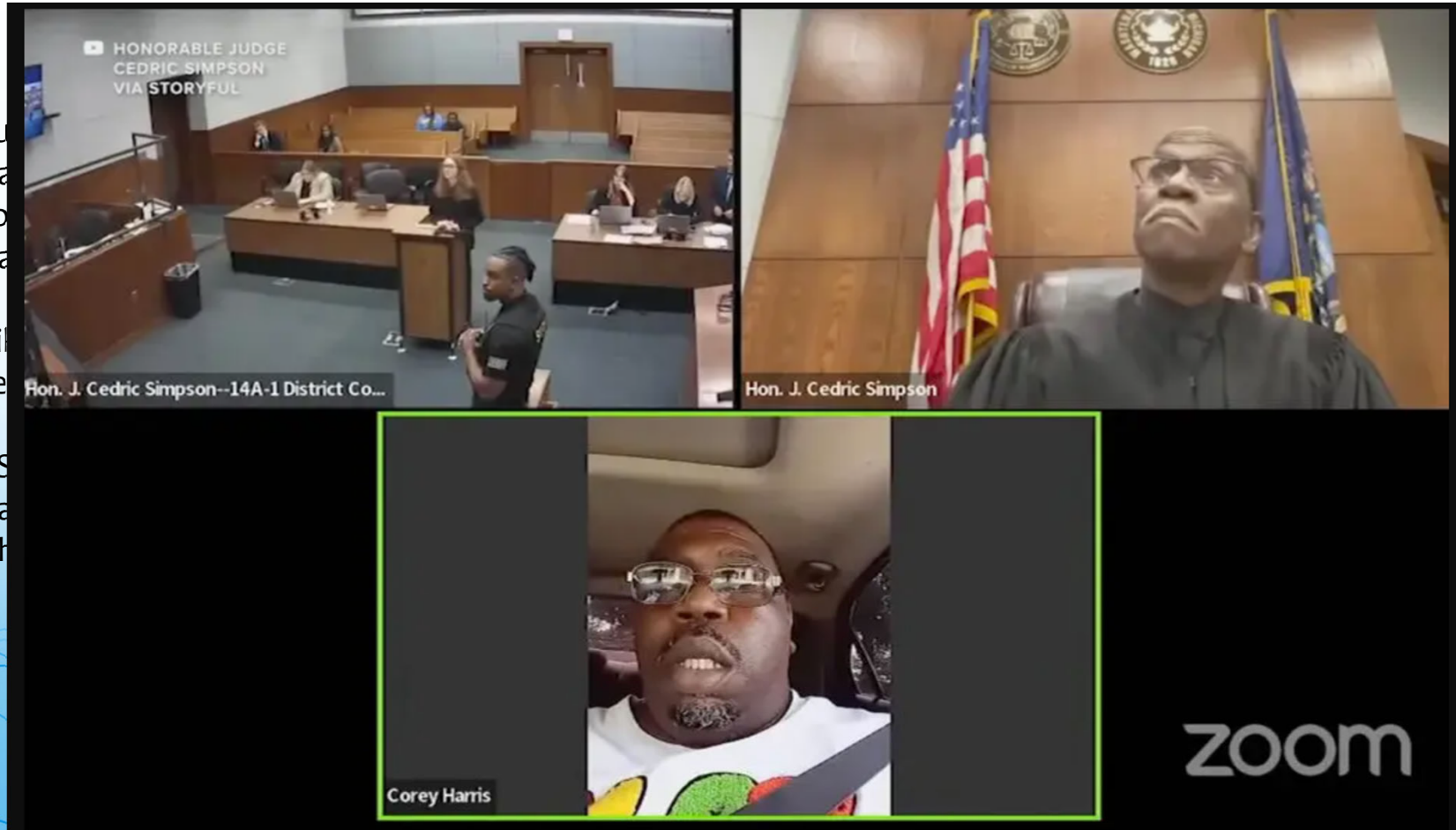
This guidance is applicable for the kinds of arrangements described in the question. We remind Part D sponsors that the pharmacy's contribution to the plan's pool, even when not assessed on a per claim basis, is considered a price concession that must be applied at the point of sale to

¹ See final rule titled "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" (CMS-4192-F) (87 FR 27704) at: <https://www.govinfo.gov/content/pkg/FR-2022-05-09/pdf/2022-09375.pdf>

- June 2023, CMS states that bonus pool payments are permitted but that a Part D sponsor must provide the patient a reduction in the copayment at the point of sale.
- Likely because of the difficulty of making this calculation, CVS did not implement the bonus pool mechanism.
- However, ESI did implement a bonus pool mechanism effective January 1, 2024 on certain Part D business.

DIR Redux

- Ju
- ba
- to
- pa
- Li
- re
- ES
- pa
- ph



Express
Communications



Cost Plus Reimbursement Trend

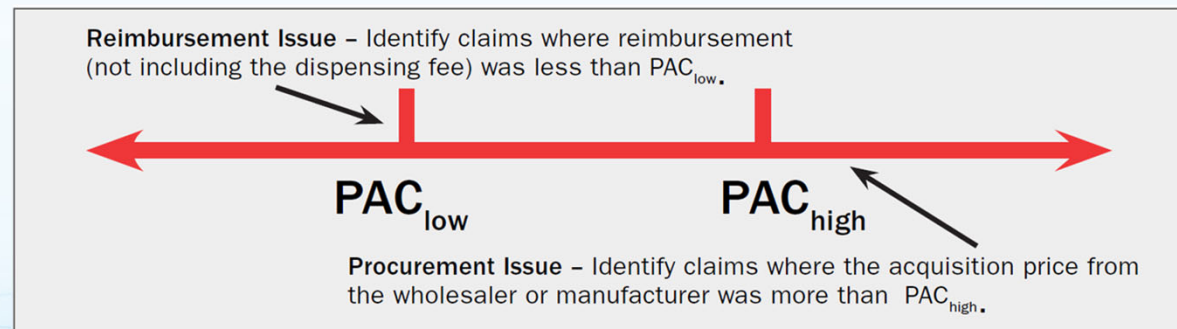
New Cost Plus Reimbursement Models

	Pharmacy Reimbursement		
	Ingredient Cost	Dispensing Fee	Profit
Traditional	Brand: AWP-24% Generic: MAC	\$0.10	-0-
Mark Cuban Cost Plus	Cuban's Acquisition Cost	\$8.00	-0-
Express Scripts Clear Network	Lesser of Predictive Acquisition Cost, NADAC, or WAC	\$5.00	"Margin Fee" 5% (up to 15%?)

Predictive Acquisition Cost



PAC's predictive analytics model helps pharmacies perform their loss file analysis to determine if a claim that was reimbursed at less than the acquisition cost is actually a reimbursement issue or a procurement issue by using the PAC_{low} and PAC_{high} range.



"Predictive Acquisition Cost" or "PAC" shall mean the estimated actual acquisition cost as defined by Glass Box Analytics and published by Elsevier.

New Cost Plus Reimbursement Models

	Pharmacy Reimbursement		
	Ingredient Cost	Dispensing Fee	Profit
Traditional	Brand: AWP-24% Generic: MAC	\$0.10	-0-
Mark Cuban Cost Plus	Cuban's Acquisition Cost	\$8.00	-0-
Express Scripts Clear Network	Lesser of Predictive Acquisition Cost, NADAC, or WAC	\$5.00	"Margin Fee" 5% (up to 15%?)
Capital Rx	NADAC	\$6.00- \$11.00	-0-
CVS <u>CostVantage</u> (2025)	Acquisition Cost (unspecified)	Yes, but unspecified	Yes, but unspecified



Contact Me

Miguel S. Rodriguez
EVP and General Counsel
American Pharmacies
mrodriguez@aprx.org





Thank You