Legal Hot Topics in Oncology Pharmacy

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Frier Levitt

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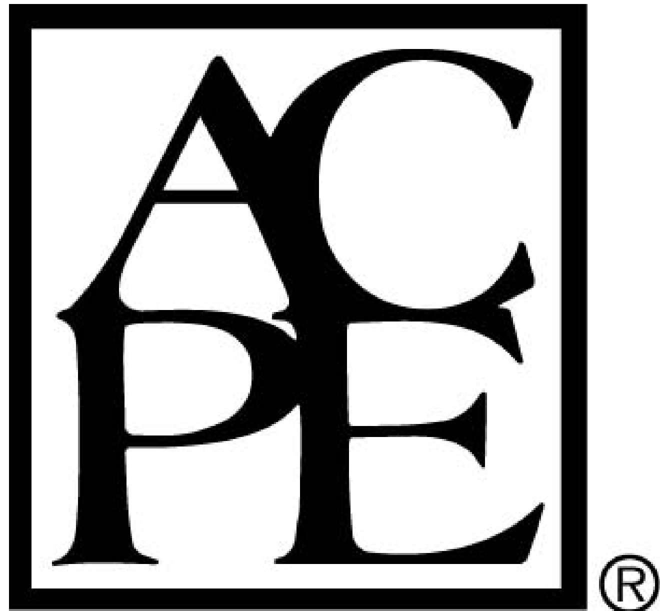

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About the Presenter

Jonathan Levitt, Esq. co-founded the national boutique healthcare law firm of Frier Levitt in 2000. Beginning with a 2003 national class action of pharmacies against a publicly traded Pharmacy Benefit Manager (PBM), Jonathan began his journey to understand all aspects of the drug supply chain.

Jonathan was invited to testify before the U.S. Senate Committee on Finance during its hearing titled “Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers,” which took place on March 30, 2023. As a leading voice in the healthcare industry, Jonathan shared his valuable insights into the role of PBMs in the prescription drug supply chain. During his testimony, he addressed many challenges faced by patients in accessing affordable medications, including concerns about the PBM rebate system, the need for greater transparency in PBM practices, and repercussions on patients, taxpayers, and independent pharmacies. The PBM hearing can be viewed on finance.senate.gov/hearings.

Jonathan is a trial attorney representing stakeholders in the drug supply chain, such as pharmacies, physician-dispensers, national provider associations, drug manufacturers, drug wholesalers, and plan sponsors. Jonathan prosecutes claims brought by these stakeholders against PBMs, often uncovering secretive PBM tactics used to hide funds through litigation. Additionally, he assists Self-Funded Plans with their pharmacy benefit design. Jonathan has tried numerous litigations or arbitrations involving Medicare Part D “Direct and Indirect Remuneration” (DIR) Fees. In addition, he represents state Medicaid systems and Fortune 100 companies auditing PBMs.

Jonathan is dedicated to pro-bono and public service assignments, reflecting his commitment to serving the community.

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Faculty/Reviewer/Planner	Reported Relevant Financial Relationships
Jonathan E. Levitt, Esq. *Faculty*	Disclosed no relevant financial relationships with ineligible companies.

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This presentation is intended solely to provide general legal and business information. It is not intended to encourage or facilitate any agreement or coordinated conduct among competing pharmacies. Participants should not discuss or share competitively sensitive information, including specific reimbursement rates, acquisition costs, pricing strategies, or plans regarding participation in PBM networks. Each pharmacy must make independent business decisions regarding contracting, pricing, and participation in PBM networks. If discussion moves into areas that could raise antitrust concerns, the conversation will be redirected.

About Frier & Levitt

Frier Levitt, established in 2000, is a national boutique law firm focused exclusively on Healthcare and Life Sciences. The firm draws on its experience representing stakeholders across the entire healthcare spectrum. Frier Levitt Life Sciences attorneys represent pharmacies of all kinds and assist with regulatory, transactional and litigation matters. Our Healthcare clients include large physician group practices, hospitals, hospital medical staffs, ambulatory surgery centers, laboratory companies, as well as the complete panoply of ancillary service providers.

We collaborate with our clinician attorneys, including multiple pharmacists and a podiatrist. Frier Levitt attorneys are licensed in many states and admitted in multiple federal courts throughout the country. We have offices in Pine Brook, NJ and New York, NY.

Educational Objectives

After completion of this activity, participants will be able to:

- Describe the key provisions of the Consolidated Appropriations Act of 2026, the Department of Labor proposed rule, and the Federal Trade Commission (FTC) settlement with Express Scripts, and how each impacts pharmacy benefit manager (PBM) contracting with oncology practices.
- Evaluate cost-plus contracting models currently being implemented by major PBMs, including their definitions of "cost," reimbursement structures, and potential weaknesses for specialty oncology practices.
- Apply federal and state legal strategies, including Centers for Medicare & Medicaid Services (CMS) complaints, FTC monitor filings, maximum allowable cost appeals to challenge below-cost PBM reimbursement in an oncology setting.
- Develop a practice-specific action plan for responding to PBM contract changes, tracking acquisition and dispensing cost data, and engaging in the CMS rulemaking process over the next three years.

New Developments in Federal PBM Enforcement & Regulation

Background on DOL, CAA and FTC Settlement With ESI

Federal PBM Changes and FTC Enforcement: What Community Oncology Practices Need to Know

Policy Action	When	What It Does
Consolidated Appropriations Act	• Passed Feb. 3, 2026 • CMS RFI completed by Apr. 1, 2027; standards established by Apr. 3, 2028 • **Effective for plans starting Jan. 1, 2029**	• Requires PBM contracts in Medicare Part D to be "**reasonable and relevant**" including with respect to reimbursement rates • Creates a **CMS complaint process** if PBM contract terms are unfair
Department of Labor Proposed Rule	• Jan. 30, 2026 • **Comment period ended on Apr. 15, 2026**	• **Requires PBMs** working with employer health plans to **disclose pricing, rebates, and fees**. • Creates fiduciary obligation for plans to make sure PBM compensation is reasonable
FTC Settlement with Express Scripts	• Feb. 4, 2026 • Must implement as soon as feasible, no later than Jan. 1, 2028	• **Requires ESI to move toward cost-plus drug** reimbursement and **admit any willing pharmacy** • Establishes a **"monitor" to receive complaints** from pharmacies

Inside the CAA: What Oncology Pharmacies Need to Know

Consolidated Appropriations Act (CAA)

1. Adds **"reasonable and relevant contract terms and conditions" to Part D** statute and delegates authority to HHS (CMS) to establish standards for what comprises "reasonable and relevant" by April 2028.
   - CMS must issue a request for information (RFI) by **April 1, 2027,** to gather information on a host of topics like contract trends and contracting practices, the use of quality metrics, and importantly, whether pharmacy reimbursement and dispensing fees sufficiently cover the ingredient and operational costs of such pharmacies.
   - Practice participation in responding to this RFI is **extremely important**. This is likely to govern PBM contracting practices in Part D for the foreseeable future.

2. Creates **new enforcement paradigm** through which practices can submit complaints directly to CMS over PBM violations of "reasonable and relevant" standards.
   - Empowers CMS to impose civil monetary penalties (CMPs) on plans (which PBMs must pay if they manage the plan's pharmacy benefit), as well as injunctive relief.

3. Includes **anti-retaliation and anti-coercion clauses**, as well as a clause preventing contractual terms prohibiting providers from sharing information with CMS

4. Includes a **rule that the law not be construed to limit a pharmacy from pursuing other legal actions or remedies** under state or federal law with respect to a potential violation of these requirements.
   - In other words, a PBM cannot get a lawsuit/arbitration dismissed against it just because CMS is enforcing this law.

Weaknesses in CAA

- “Reasonable and Relevant” standards **not effective until Plan Year 2029**.
- CMPs are **weak deterrent**
  - CMPs are measured in thousands of dollars for companies with hundreds of billions in revenue.
  - There are **some teeth to the intermediate sanctions**, which include suspension of enrollment of beneficiaries, suspension of marketing activities, and suspension of payments to the organization for patients enrolled after notice of deficiency.
- Any **“reasonable and relevant” standard that touches on reimbursement will likely be challenged in court** under the Administrative Procedure Act as violating the Noninterference Clause (NIC).
  - The Act **should have expressly limited the NIC’s effect**; however, the fact that the statute itself requires HHS to gather information on whether reimbursement is sufficient to cover costs indicates **Congress likely intended “reasonable and relevant” to include reimbursement terms**, and this may withstand an APA challenge.
- “Reasonable and Relevant” standard will be subject to input from ALL stakeholders, including plans and PBMs.
  - **Practices need to be proactive in providing information to HHS in response to RFI.** Every practice should be providing information to HHS.

FTC Settlement with Express Scripts, Inc. (ESI)

- **Background**
  - In 2024, FTC sued Caremark, Optum, and ESI, alleging they engaged in anticompetitive and unfair rebating practices that artificially inflated insulin list prices.
  - FTC sought to end these rebating practices and drive down insulin prices.
  - In February 2026, the FTC entered into a settlement with ESI and its affiliates. **The settlement expands beyond just insulin and touches on many significant aspects of the contractual relationship** between PBMs and Plans and, importantly, PBMs and providers.
- **Terms of Settlement** (as related to providers)
  - Must be enacted **as soon as "commercially feasible but no later than 1/1/2028**
  - ESI **must compensate every "Retail Community Pharmacy" at cost plus dispensing** fee.
    - "Retail Community Pharmacy" means a **retail pharmacy business that includes three or fewer retail stores** and which is **not affiliated with Respondent**.
  - ESI must make **additional payments for all Non-Dispensing Services** performed by Retail Community Pharmacies.
  - ESI **may not exclude Retail Community Pharmacies willing to agree** to standard terms and conditions.
  - ESI must make **enumerated efforts to promote its standard terms and conditions** to providers.
  - ESI must **select a neutral "Monitor" who will report on compliance and to whom complaints can be sent** by non-parties.

Weaknesses and Action Points for ESI Settlement

- Definition of **Retail Community Pharmacies may** be interpreted by ESI to **exclude Community Oncology Practices**.
  - **Action Point**: When ESI makes its contract offerings, practices should engage in immediate outreach to contracting agents to **determine if they are being offered the "standard" terms and conditions**.
    - ESI likely won't offer these terms for 2027, arguing it is not "commercially feasible" to do so, but practices should still reach out upon receipt of the next contract offering (which is likely imminent, according to client sources), and ask ESI to clarify if the terms comply with the settlement. **Regardless of the answer, practices can use this process to determine whether ESI considers them to be "Retail Community Pharmacies."**

- "Cost-plus" may not be the optimum reimbursement model for practices.
  - **Action Point**: Hard negotiating stance on dispensing fees and, especially, "non-dispensing services."

- No standard set for dispensing fees or fees for "non-dispensing services."
  - **Action Point**: Practices will need to **be aggressive with contract negotiations and pushing their rights** under this settlement agreement, including filing complaints with the Monitor.

What This Means for Your Practice

1. PBM contracts may start changing

- PBMs are already sending contracts using cost-plus reimbursement models
- For specialty oncology, cost-plus “+ small fee” usually underpays because it ignores the heavy non-dispensing work, and flat rate dispensing fees may not cover operational costs
- Push for cost-plus + a fair markup + a real dispensing fee + separate payment for non-dispensing services

2. New opportunities for enforcement

- Practices can submit complaints directly to CMS over PBM violations of “reasonable and relevant” standards
- Practices can submit complaints to FTC monitor when paid below costs or prohibited from joining networks
- Private lawsuits/arbitrations, as well as state level tools, remain available

3. Data about pharmacy costs will matter more

- PBMs and regulators may request actual acquisition and dispensing cost data
- Practices that understand their real costs will be better positioned in negotiations
- Track drug acquisition costs and the time/cost of non-dispensing work so you can justify fees now and influence CMS’s rule

4. Changes will happen gradually

- Most federal reforms do not fully take effect until 2028–2029
- The first real impact will likely appear through new PBM contracts

Develop a Plan of Action

Now (next 0 – 3 months)

- When ESI or any PBM sends a contract, **don't auto-sign**. Ask about all contracts that are available. **Inquire** about plan sponsors covered by the rates. **Request** cost + ***markup*** + dispensing fee + non-dispensing service fees. **Consider** year-over-year inflation.
- Start tracking your drug acquisition costs, time/cost for non-dispensing tasks (PAs, counseling, procurement, coordination), audit burden. You'll use this both in negotiations and in comments to CMS.

6–9 months out (when CMS Request for Information is available, due by 4/1/2027 but could be earlier)

- **Submit comments** with your numbers and stories, sharing whether your current payments cover ingredient and operating costs, the non-dispensing work do you do, how you reinvest your profit into the practice, and how audits and network limits affect care and cost. **Coordinate with COA** to leverage positioning.

Mid-2027 to 2028 (as plans build 2028–2029 documents and CMS finalizes standards by 4/3/2028)

- As 2028 plan documents and contract templates circulate, push for terms aligned with emerging CMS **"reasonable and relevant" standards**.
- Once CMS finalizes the standards, be ready to **use the new CMS complaint process** for Part D issues and **update your contract** policies to align.
- File complaints with FTC "monitor" as applicable.

2029 and after (Part D standards in force 1/1/2029)

- Expect Part D contracts to reflect the new "reasonable and relevant" guardrails. **Document everything** in case to defend your fees and to support any future CMS complaints.

Cost Plus Contracting: Recent Trends

Cost Plus Contracting

What Is It?

- Traditional PBM tied reimbursement to negotiated discounts off of benchmark prices with little bearing to actual acquisition costs (AWP minus contracted discount, MAC price, etc.)
- Cost + Dispensing Fee (+ Markup)
- How is “cost” defined?
  - Actual reported acquisition cost
  - National Averaged Drug Acquisition Cost (NADAC)
  - Predicative Acquisition Cost (PAC)
  - Wholesale Acquisition Cost (WAC)
- Lesser of logic still applies

Cost Plus Contracting

Historical Examples

Cost Plus Contracting

Recent Trends

CVS Caremark → CostVantage	OptumRx → Cost Clarity	Express Scripts → Evernorth Pharmacy Network
▪ CVS started compensating their own retail pharmacies using an internally computed acquisition cost index + a percentage mark up + a patient management fee ▪ CVS does not disclose the exact acquisition cost calculation and may rely on internal cost indices or cost "buckets" ▪ CVS has expressed plans to expand the cost-plus model to non-CVS pharmacies in the future	▪ OptumRx pays the pharmacy based on a pricing logic that approaches acquisition costs (i.e., NADAC or WAC) + a defined markup + a dispensing fee ▪ Full implementation by 2028	▪ ESI will reimburse pharmacies acquisition cost + dispensing fee + enhanced dispensing fee ▪ Invites pharmacies to share actual acquisition costs on quarterly basis (otherwise, NADAC, WAC or PAC will be used) ▪ Implements a sponsor-funded Network Performance Program when selected by each sponsor ▪ Cigna to adopt this model for all fully insured lives beginning in 2027, with it becoming the standard model available for all clients beginning in 2028

Cost Plus Contracting

Best Practices

- **Avoid broad definitions** open to manipulation (e.g., "estimated acquisition cost," "network average acquisition cost," "PBM-determined acquisition cost," etc.)
- Seek to **tie dispensing fees to rising CPI**
- Evaluate **pharmacy types and enhanced dispensing** fees
- Calculate impact of **Extended Days' Supply dispensing fees vs. 30-day fill** dispensing fees
- Quantify and seek reimbursement for **non-dispensing pharmacy services** (including **vaccine** administration, **consultation** and **prescribing** services, and **diagnostic** testing services)
- Include protections for **drug availability issues**
- **Model financial impact** before signing
- Seek information on **Plan Sponsor adoption of specific networks**

Cost Plus Contracting

Legal Considerations

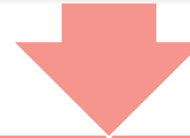
- State minimum reimbursement laws
- State MAC appeal laws and “cost” as a proxy to cap reimbursement
- State fair pharmacy audit laws and expanded audit activity to focus on acquisition prices
- Consideration of confidentiality terms in agreements with suppliers (including wholesalers and manufacturers)
- Medicare Any Willing Provider Law

Cost Plus Contracting

Federal Any Willing Provider Law

Federal Statute

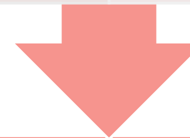
A Medicare Part D “prescription drug plan shall permit the participation of any pharmacy that meets the *terms and conditions* under the plan.” 42 U.S.C. §1395w-104(b)(1)(A)



Federal Regulations

A Part D plan must agree to have “a standard contract with *reasonable and relevant terms and conditions of participation* whereby any willing pharmacy may access the standard contract as a network pharmacy.”

CMS requires that: “*[e]ach and every contract must specify that first tier, downstream, and related entities must comply with all applicable Federal laws, regulations, and CMS instructions*.” 42 C.F.R. § 423.505(i)(3)(iv)



Federal Guidance

CMS states that the AWPL requires “Part D sponsors must offer *reasonable and relevant reimbursement* terms for all Part D drugs”

“Offering pharmacies unreasonably low reimbursement rates for certain ‘specialty’ drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer *reasonable and relevant reimbursement terms for all Part D drugs* as required by [law]”.

Cost Plus Contracting

State Any Willing Provider Laws

- 30+ States have some form of Any Willing Provider Law
  - Some states allow suits directly against PBMs
- **Arkansas**
  - Ark. Code Ann. § 23-99-207
- **North Carolina**
  - N.C. Gen. stat. § 58-51-37

Cost Plus Contracting

State Any Willing Provider Laws (Cont'd)

- **Arkansas — Ark. Code Ann. § 23-99-207 (Any Willing Provider)**
  - **Who can sue:** Any provider (including pharmacies) adversely affected by a violation.
  - **Who can be sued:** Health care insurers administering/controlling the network.
    - Generally cannot apply to ERISA plans
  - **Covered violations:** Denial or discrimination in network participation contrary to AWP protections.
  - **Remedies:** Injunctive relief; prevailing party may recover reasonable attorneys' fees and costs.

- **North Carolina — N.C. Gen. Stat. § 58-51-37 (Any Willing Provider)**
  - **Who can sue:** Any person or pharmacy aggrieved by a violation.
  - **Who can be sued:** Health benefit plan/insurer entities restricting lawful pharmacy choice.
  - **Covered violations:** Interference with a beneficiary's right to use any willing participating pharmacy; discriminatory network terms.
  - **Remedies:** Damages and injunctive relief.
    - One of the broadest AWP enforcement tools because it **expressly authorizes damages**

Cost Plus Contracting

Considerations and Potential Pitfalls

- 340B Program
- Specialty, Home Infusion and LTC Pharmacies
- Cash Discount Programs
- Enhanced Services Agreements and Bona Fide Service Fees
- Calculation of Performance Metrics/Payments
- Annual Aggregate Average Reimbursement Rates for each Book of Business
- Plan Sponsor Adoption

Cost Plus Contracting

Strategies for Pharmacies

- Participate in RFI process with CMS on “reasonable and relevant” standards
- Utilize MAC appeal rules
- Leverage state PBM regulatory complaint processes
- Communicate with elected representatives
- Submit complaint to independent compliance monitors appointed under FTC settlements
- Submit complaint to CMS for failure to offer “reasonable and relevant” terms and conditions as set forth under the Consolidated Appropriations Act
- Escalate contract disputes through arbitration or litigation

Underwater Reimbursement: COA Practice's Biggest Issue

Biggest Issue: Underwater Reimbursement

- COA practices are reporting underwater reimbursement as the biggest issue facing them in 2026
- We are seeing below water reimbursement on both medical benefit plans and pharmacy benefit plans
  - Multiple practices have reported below cost reimbursement from Aetna on specific drugs, such as Neulasta
- We are seeing below water reimbursement across all plan types, including Medicare Advantage, Managed Medicaid and Commercial

Strategies to Challenge Below Water Reimbursement

Data

- Build **claim-level cost vs. paid analysis**; track data by drug and PBM; document efforts to negotiate reimbursement.

Laws

- State and Federal laws afford protection requiring **reasonable or above-cost reimbursement** or **prohibit certain fees or discriminatory reimbursement**.

Litigation

- **Leverage dispute provisions and litigation** to gain negotiating leverage or litigate violations of contract and law.

Government Action

- **File complaints** with state and federal enforcement **agencies to ensure PBM compliance** with state laws.

PBM Manual Updates

OptumRx

- OptumRx recently updated its Provider Manual to redefine the concept of "retail pharmacy," and provide limitations on the ability of providers to focus on one particular therapeutic class
  - "Network Pharmacy Providers without specific arrangements previously approved by Administrator shall not have over 25% of their total claim submissions and/or amount paid related to Optum Rx members attributed to a single therapeutic class."

- Given that COA practices necessarily involve dispensing large quantities of oncology related medications, this is **likely to have a significant impact on their participation in OptumRx networks**

- We have sought additional clarification from OptumRx on behalf of COA

PBM Manual Updates

CVS Caremark

- Added language explicitly allowing:
  - **Extensions** to be granted in audits
  - Providers to **share information with patients** about the cost and reimbursement amounts of products
  - Providers to **communicate with elected officials or government agencies**
    - Includes sharing information about the network itself
- Adds language that providers will be paid the **Medicare Drug Price Negotiation Maximum Fair Price plus the applicable Dispensing Fee** less the applicable Patient Pay Amount, if applicable to an MFP-eligible individual
- Added language around prescription payment plans for **"smoothing" of Medicare Part D copays**
- Adds language indicating that a **"Dispensing Practitioner" can be considered a "retail pharmacy"** under the contract and the law

Under Water Reimbursement

Strategies for Pharmacies

- Keep track of any prescriptions you are sending out to other providers to fill

- Consider state law claims, especially for commercial reimbursements, as some states prohibit below acquisition cost reimbursement or provide unique reimbursement appeal processes

- Federal law prohibits unreasonable low reimbursement rates for all Medicare Part D drugs
  - CMS guidance provides, "[o]ffering pharmacies unreasonably low reimbursement rates for certain 'specialty' drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by [the Medicare AWPL]." Medicare Prescription Drug Benefit Manual, Chapter 5, Section 50.3.

- Utilize the dispute process in each PBM payor contracts to initiate disputes and explore initiating arbitration/litigation

Under Water Reimbursement

Strategies for Pharmacies (cont'd)

- Providers should also file a complaint with CMS directly requesting that it investigate PBM practices, enforce existing AWPL
  - CMS's December 14, 2023 letter to PBMs and plan sponsors was not sufficient to effectuate change
  - CMS should also enforce the "flow down" provisions which require each PBM to include in their contract with providers a contractual obligation to comply with applicable law

- Providers should pursue an APA claim against CMS if they fail to act after receipt of one or more complaint letters

- Providers should take further efforts to inform legislature and the FTC about PBM wrongful conduct.

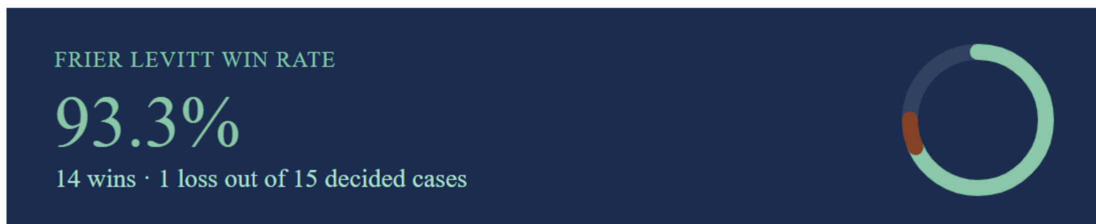
Update: DIR Fee Cases

DIR fee litigation — case status overview

Frier Levitt · 22-case portfolio

AGGREGATE CLIENT RECOVERIES — 14 CASES

WIN RATE — 15 DECIDED CASES



- Memorable Quotes:
  - “Caremark’s PNP was an apple rotten to the core”
  - “At first blush it is astonishing that Caremark got away with that for eight years.”

Fighting Back: A Sampling of Potential State Claims Against PBMs

Texas Claims Against PBMs

Texas Insurance Code: Chapter 1369 and the Deceptive Trade Practices Act

- Oncology practices in Texas can file claims against PBMs for breach of contract based on violations of the Texas PBM Regulations
  - Texas Insurance Code prohibits PBMs from waiving, voiding, or nullifying certain audit provisions by contract (Example: Sec. 1369.268)
    - Audit conduct violations , limitations on recoupment and interest, and MAC list violations (Sec. 1369.251-270)
    - Discriminatory accreditation requirements and contract transparency (Sec. 1369.601-610)
    - Unlawful Retaliation (Section 1369.609)
  - Prompt Payment Violations
    - Recovery includes penalties for claims not paid in full within 18 days

- Texas Deceptive Trade Practices Act (DTPA)
  - Oncology practices harmed by deceptive conduct, such as misrepresentations about reimbursement methodology, formulary positioning, or audit procedures, can assert DTPA claims
  - Potential for treble damages for knowing or intentional violations

California Senate Bill 41

- **Became Effective January 1, 2026**: amended existing provisions of the Health and Safety Code and Insurance Code and creates an entirely new regulatory division (Division 6 of the Insurance Code) to house the comprehensive PBM licensing and oversight framework.
- **Network Access:** PBMs are prohibited from denying a nonaffiliated pharmacy the opportunity to participate in their network if the pharmacy is willing to accept the same terms and conditions established for affiliated pharmacies.
- **No More Patient Steering:** PBMs are prohibited from directing patients away from your practice to PBM-owned or affiliated pharmacies. Violations constitute unfair competition under California law.
- **Ban on Spread Pricing:** PBMs can no longer charge insurers more than they reimburse your dispensing pharmacy. Effective for new contracts Jan. 1, 2026; all contracts by Jan. 1, 2029.
- **100% Rebate Passthrough:** PBMs must pass 100% of manufacturer rebates and fees to the payer, to be used solely to reduce patient cost-sharing or premiums.
- **Enforcement**: Civil penalties of $1,000–$7,500 per violation, enforceable by the Attorney General. Injunctive relief and attorney's fees also available.

New Mexico Claims Against PBMs

New Mexico's Pharmacy Benefits Manager Regulation Act

- New Mexico Statute Section 59A-61-5(D) explicitly prohibits PBMs from waiving the requirements of the **PBM Regulation Act**
  - Pharmacies can invoke this provision to **void contract provisions and argue breach of contract** for PBMs that do not abide by the applicable laws.
  - **Protections that Cannot be Waived**:
    - Contract participation tying: PBMs cannot require participation in one contract as a condition of another
    - Reimbursement Floors: Reimbursement cannot be less than NADAC (or WAC if unavailable); dispensing fee floor of $10.49/drug
    - Prohibition against deceptive practices
      - Untrue, deceptive, or misleading advertising, solicitation, or representations
    - Prohibition against excessive accreditation requirements: PBMs cannot impose standards more stringent than state/federal licensure requirements
    - Anti-gag Clauses: Pharmacies may discuss pricing, offer affordable alternatives, and share information with regulators
    - Anti-Retaliation: PBMs cannot retaliate against pharmacies for invoking their rights under the Act

Montana's Private Right of Action

Montana Code § 33-22-177(6)

- "A pharmacy or a PSAO has a ***private right of action*** to enforce provisions of **33-22-175, through 177**
  - Private right of action is **available to both pharmacies and PSAOs**
  - Remedies are **not expressly limited to injunctive relief** and **include monetary damages**
- Three-tier protection:
  - **Fee prohibitions** (§ 175)
  - **Copayment limits** (§ 176)
  - **Comprehensive pharmacy rights** (§ 177)
- Key 2025 expansions included: uniform utilization review requirements, mail-order protections, reimbursement parity, and anti-steering provisions
- Section 33-22-177 currently operates in a temporary version through June 30, 2029
  - Practitioners should monitor for changes when the **permanent version takes effect July 1, 2029**

South Dakota’s Private Right of Action

South Dakota Codified Laws: Section 58-29E-10

- “A third-party payor, 340B entity, or a pharmacy may bring a civil action to enforce this chapter, including **injunctive relief**, and **seek civil damages for a violation of this chapter.”**
- **Many oncology practices participate in the federal 340B Drug Discount Program, which allows eligible covered entities to purchase outpatient drugs — including high-cost oncology therapeutics — at significantly reduced prices.**
- Sample Provisions covered by the Private Right of Action include:
  - PBM Licensure requirement
  - Good Faith Performance of duties by PBM
  - Disclosure of rebates and other revenues--Confidentiality
  - Annual audit of pharmacy benefit manager authorized
  - Prohibition on publication or disclosure of information
  - Prohibition against charging cost share that exceeds amount retained by pharmacy
  - Prohibition against retroactive reimbursement adjustment
    - Treble damages, fees, and costs awarded if discriminated against

White Bagging & Brown Bagging: State Laws & Legal Claims for Oncology Dispensing Practices

***White bagging :** specialty pharmacy ships medication to the provider's office*

***Brown bagging:** medication ships to the patient, who brings it to the provider's office.*

- **Texas**: Prohibits requiring cancer drugs be dispensed by plan-selected pharmacy; bars reclassification from medical to pharmacy benefit; bars coverage exclusions if drug not obtained from plan pharmacy; bars PBM steering/incentives to affiliated pharmacies.
- **Louisiana:** Near-complete prohibition on mandatory white/brown bagging; cannot deny/reduce payment because provider used non-network pharmacy; violations deemed unfair trade practices with private enforcement.
- **Rhode Island:** Outright ban on white bagging for infused drugs.
- **Florida:** Prohibits requiring patients to use affiliate pharmacy for physician-administered drugs.
- **Ohio:** Bans brown bagging for chemotherapy specifically (silent on white bagging) .

Question 1

A community oncology practice receives a new PBM contract for its Medicare Part D patients. The practice manager wants to understand what new federal protections are available if the contract terms appear unfair.

Which of the following correctly describes a protection created by the Consolidated Appropriations Act of 2026?

A. It immediately prohibits all PBM spread pricing in Medicare Part D effective upon enactment.

B. It creates a CMS complaint process for unfair contract terms.

C. It mandates that all PBMs adopt cost-plus reimbursement by January 1, 2027.

D. It grants pharmacies an automatic private right of action in federal court against any PBM.

Question 2

An oncology pharmacy is evaluating a new cost-plus contract offer from a PBM. The contract proposes acquisition cost plus a dispensing fee. Which of the following best describes a key weakness of the cost-plus reimbursement model for specialty oncology practices?

A. Cost-plus models always reimburse above acquisition cost, eliminating financial risk.
B. Cost-plus models tied to a small dispensing fee typically underpay specialty oncology practices because they ignore the heavy non-dispensing work these practices perform.
C. Cost-plus models are prohibited under Medicare Part D.
D. Cost-plus models eliminate the need for pharmacies to track acquisition cost data.

Question 3

A community oncology practice in Texas has been receiving below-cost reimbursement from a PBM on several specialty oncology drugs. The practice wants to take legal action. Which combination of federal and state strategies would be most appropriate for this practice to pursue?

A. File a complaint with the state board.

B. Submit a MAC appeal and wait for the 2029 standards to take effect before pursuing further action.

C. File suit directly in federal court under the Consolidated Appropriations Act.

D. Submit a complaint to CMS regarding violations of the Any Willing Provider Law, file a complaint with the FTC monitor, and pursue state claims under the Texas Insurance Code and the Deceptive Trade Practices Act.

Question 4

Your oncology practice has just received a new PBM contract offer. Based on the regulatory timeline outlined in this presentation, which of the following represents the most appropriate sequence of actions for your practice over the next three years?

A. When the CMS Request for Information becomes available (due by April 1, 2027), submit comments with cost data and practice experiences. As CMS finalizes standards by April 2028, push for contract terms aligned with emerging "reasonable and relevant" standards and prepare to use the CMS complaint process once Part D standards take effect January 1, 2029.

B. Wait for CMS to finalize "reasonable and relevant" standards before taking any action on new PBM contracts.

C. Immediately file suit against all PBMs currently reimbursing below cost and refuse to sign any new contracts.

D. Sign the new contract as offered and renegotiate only after the 2029 standards are published.

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- Go to: https://www.pharmacytimes.org/credit
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  - To continue, you will need to be logged into your *PT*CE account.
  - If you do not have a *PT*CE account, create one using the prompt on the page.
- Once logged in, answer the activity evaluation and click "Complete Survey."
- After completing the survey, click the blue arrow button to complete the activity and request credit.
- Your credit will be uploaded to CPE Monitor. You may view your credit within 48 hours at www.mycpemonitor.net

NOTE: Participation data will not be uploaded into CPE Monitor if you do not have your NABP (e-profile ID) number and date of birth entered in your profile. All participants must request credit by June 29, 2026.

Let's Continue the Conversation

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