Legal Considerations for Health System Pharmacies: White bagging, 340B and More

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Meet The Presenter

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Speaker Disclosures

I have no relevant financial conflicts of interest in relation to this activity to disclose.

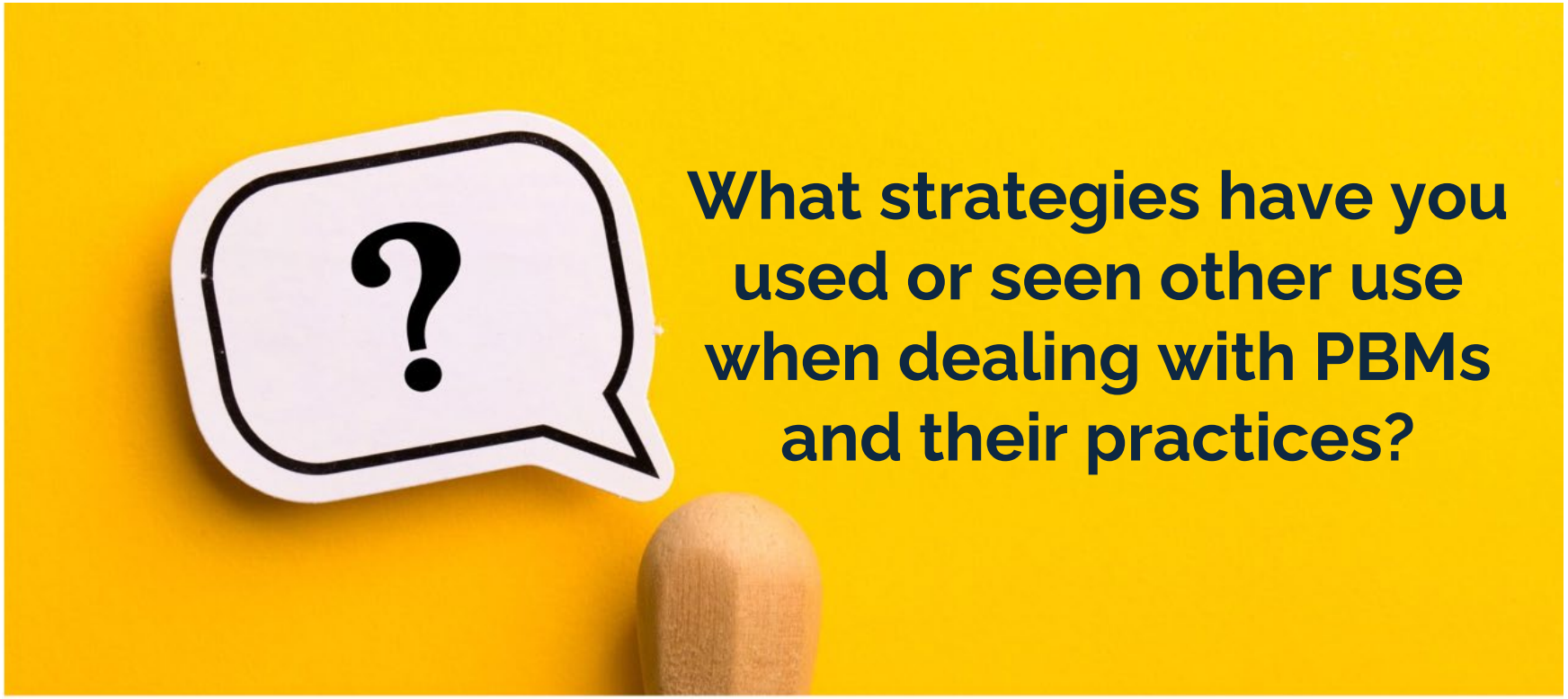
42 U.S. Code § 1395nn

Learning Objectives

- Describe state laws and current litigation efforts relating to contract pharmacy restrictions.
- Discuss potential barriers to utilizing such models and/or why such models may be permissible.
- Describe current rebate model policies and litigation efforts.

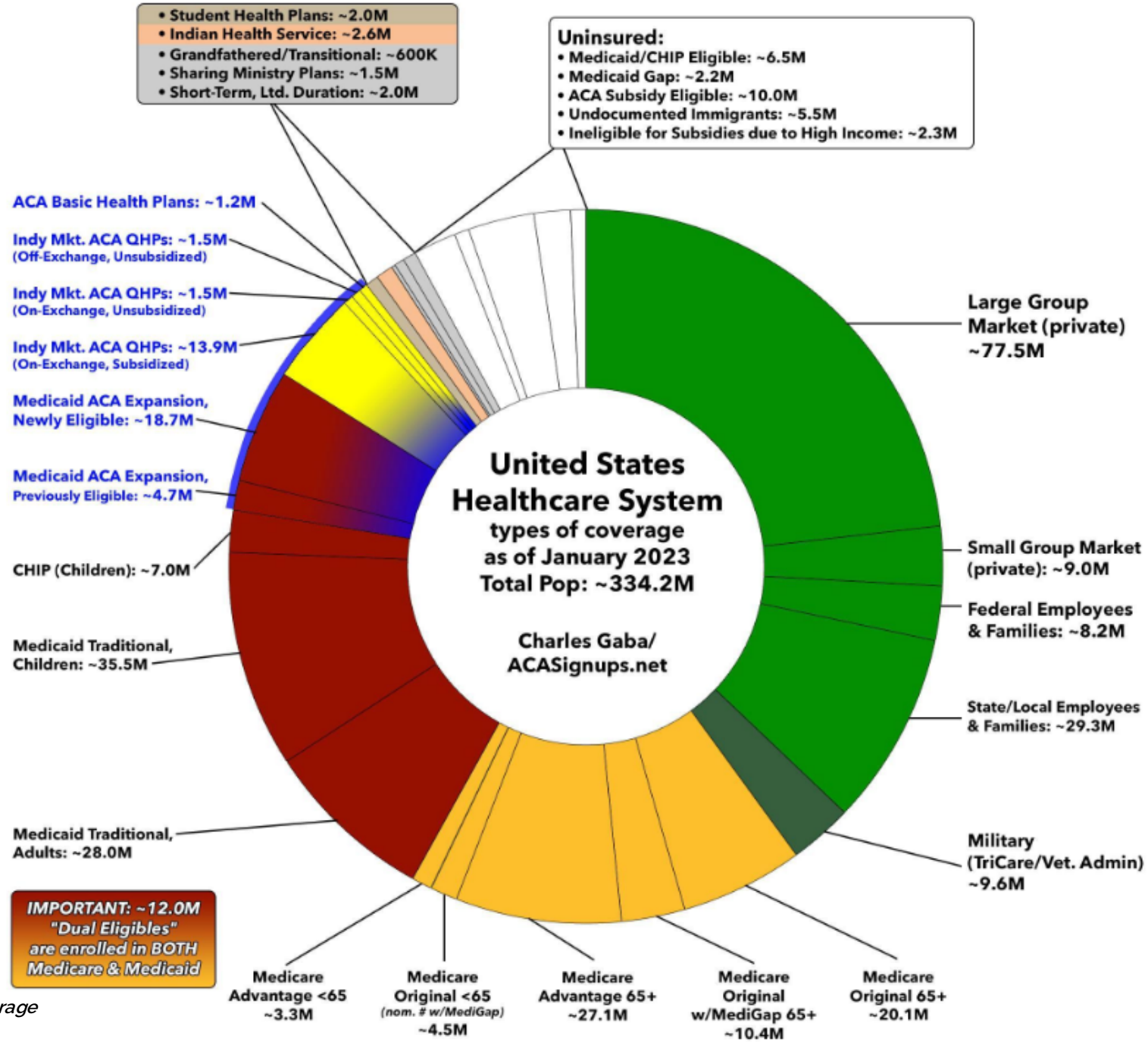
42 U.S. Code § 1395nn

Stop and Think



PBM Contracting & Reimbursement Pressures

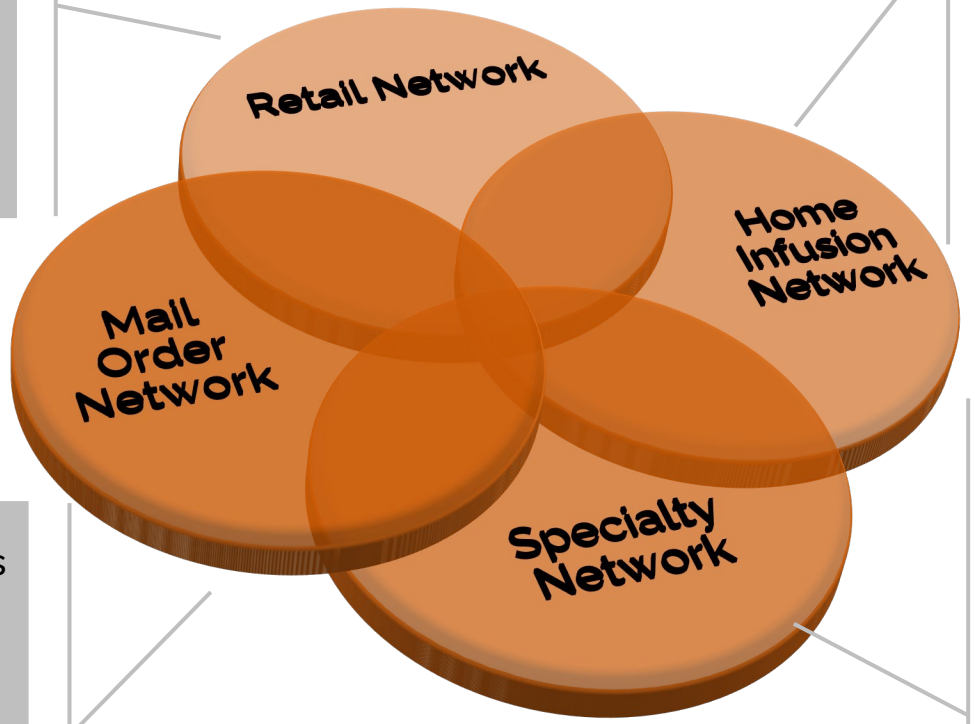
42 U.S. Code § 1395nn



Source Credit:
https://acasignups.net/estimates/coverage

Typical PBM Networks

- Most open of all networks
- Generally highest reimbursement rates
- Limitations on % of mailing and specialty medications

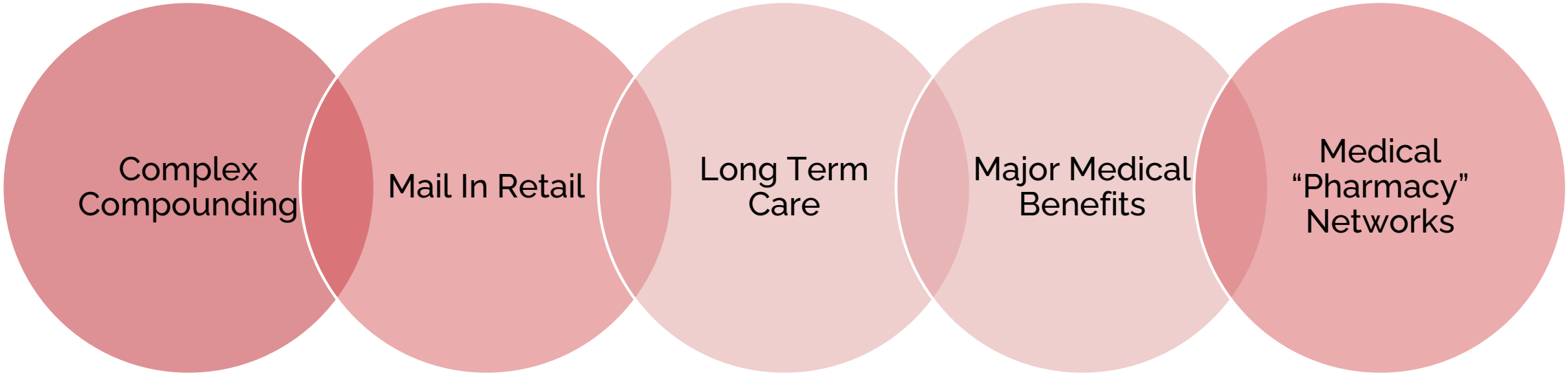


- Generally an “open” network subject to compliance with Medicare Part D requirements
- Provides some ability to perform “delivery”
- Often limited to Medicare Part D
- Provides specific rules for billing home infusion medications

- Restricted or “closed” networks
- Heightened conditions for entry (i.e., accreditation)
- Allows for mailing
- Very low reimbursement

- Restricted or “closed” networks
- Heightened conditions for entry (i.e., accreditation)
- Often allows for mailing
- Generally lower reimbursement

Other PBM and Payor Networks



Types of Specialty Pharmacy Networks

- "Closed" or "Exclusive" Specialty Pharmacy Networks
  - Often found in self-funded commercial plans
- "Open" Specialty Pharmacy Networks, but with heightened admission criteria
  - Often found in states with "any willing provider" laws and certain Medicaid managed care plans
- Open Specialty Pharmacy Networks
  - Often associated with Medicare Part D plans

Specialty Pharmacy Credentialing Requirements

- Accreditation in Specialty Pharmacy from at least one of the following:
  - Accreditation Commission of Healthcare, Inc. (ACHC)
  - URAC
  - The Joint Commission Accreditation
- Higher insurance coverage
- Detailed Policies & Procedures
- Shipping tracking and controls
- Mechanical systems and tools

Specialty Pharmacy Credentialing Requirements (cont'd)

- Proof of access to limited distribution drugs
- Detailed reporting requirements and capabilities
- FDA recall procedures
- Patient utilization tracking and monitoring of in-home inventories
- Licensure in specific states
- Nursing services
- Call answering speed

PBM Treatment of Prescription Mailing

- Several PBMs explicitly prohibit mailing under their Provider Manuals; others suggest that pharmacies are liable to receive separate contracts if they mail more than a certain percentage of claims
- Several PBMs nominally offer participation in “mail order networks,” but set the terms and conditions exceedingly high
- Many PBMs relaxed mailing prohibitions and restrictions during the COVID-19 Public Health Emergency (PHE)
- Since the lifting of the PHE, several PBMs have endeavored to reassert enforcement of the mailing restrictions
  - Cease and desist letters
  - Network terminations
  - Audit recoupments

Below Water Reimbursement Rates

- In a post-Direct and Indirect Remuneration (DIR) fee world, net rates are below water in many instances in starting in January 2024
  - Some health systems have reported decreases by 15%
- Express Scripts Reimbursement Rates
  - Year-over-year rate degradation
  - "Up to an average, aggregate network discount of AWP minus …"
  - WellCare/Centene/Fidelis migrated from CVS Caremark to Express Scripts
    - WellCare made up a large percentage of providers' DIR Fees in under CVS Caremark

Source: https://www.sec.gov/Archives/edgar/data/1402479/000162828020013237/exhibit1023-sx4xpharma.htm
https://www.wellcare.com/en/providers/medicare-bulletins/express-scripts-transition

Below Water Reimbursement Rate

- Publicly available contracts have been seen with rates of AWP-26.3%
- Contract allows for a reimbursement of "up to an average" discount off of AWP
- This average includes not only the reimbursement to a single provider, but for a network of providers over an entire year, allowing for payments to one provider to be better than another, even with the same contract

	BRANDS Up to an Average Discount for Single-Source & Multi-Source[4.1] Brands not paid on ESI MAC + Not less than an Average Dispense Fee:	GENERICS - A Up to an Average Discount for Generic Drugs not paid on ESI MAC + Not less than an Average Dispense Fee:	GENERICS - B Generic Drugs and Multi-Source[4.1] Brands paid on ESI MAC + Not less than an Average Dispense Fee:
30 Day Network Participation			
Year 1	AWP - 26.30% + $0.00	AWP - 57.00% + $0.00	ESI MAC + $0.00
90 Day/EDS Benefit Participation			
Year 1	AWP - 31.30% + $0.00	AWP - 57.00% + $0.00	ESI MAC + $0.00

How Do Low Reimbursement Rates Impact Your Business When Coupled with Your COGS?

Reimbursement	WAC Equivalent	Margin if COGS is WAC	Margin if COGS is WAC -1%	Margin if COGS is WAC -2%
AWP - 16.66%	WAC + 0.00%	**Break Even**	1.00% Margin Before Op. Exp.	2.00% Margin Before Op. Exp.
AWP - 17.00%	WAC - 0.40%	0.40% below Acq. Cost	1.40% Margin Before Op. Exp.	1.60% Margin Before Op. Exp.
AWP - 17.50%	WAC - 1.00%	1.00% below Acq. Cost	**Break Even**	1.00% Margin Before Op. Exp.
AWP - 18.00%	WAC - 1.60%	1.60% below Acq. Cost	0.60% below Acq. Cost	0.40% Margin Before Op. Exp.
AWP - 18.33%	WAC - 2.00%	2.00% below Acq. Cost	1.00% below Acq. Cost	**Break Even**
AWP - 18.50%	WAC - 2.20%	2.20% below Acq. Cost	1.20% below Acq. Cost	0.20% below Acq. Cost
AWP - 22.50%	WAC - 7.00%	7.00% below Acq. Cost	6.00% below Acq. Cost	5.00% below Acq. Cost
AWP - 25.50%	WAC - 10.60%	10.60% below Acq. Cost	9.60% below Acq. Cost	8.60% below Acq. Cost
AWP - 26.30%	WAC - 11.56%	11.56% below Acq. Cost	10.56% below Acq. Cost	9.56% below Acq. Cost

Publicly Available: https://www.thebignewsletter.com/p/the-red-wedding-for-rural-pharmacie

Strategies to Combat Below Water Reimbursement Rates

- 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

Source: https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/memopdbmanualchapter5_093011.pdf

Strategies to Combat Below Water Reimbursement Rates (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.

Source: https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-manager

Prescription Discount Cards

- Effectively a means for pharmacies to accept a lower "cash price" without impacting Usual and Customary ("U&C")
  - U&C prices are typically set at full AWP, even though pharmacies often get reimbursed by payers much less
- Pharmacy submits a "third party" claim to BIN/PCN number associated with prescription discount card program, which "adjudicates" the claim for a discounted price

AWP:	$100.00
U&C:	$105.00
Acquisition Cost:	$20.00
Claims Submission Segment	
Patient Pay Amount:	$30.00
Insurance Pay Amount:	($5.00)
Approved Amount:	$25.00
Net Profit:	**$5.00**

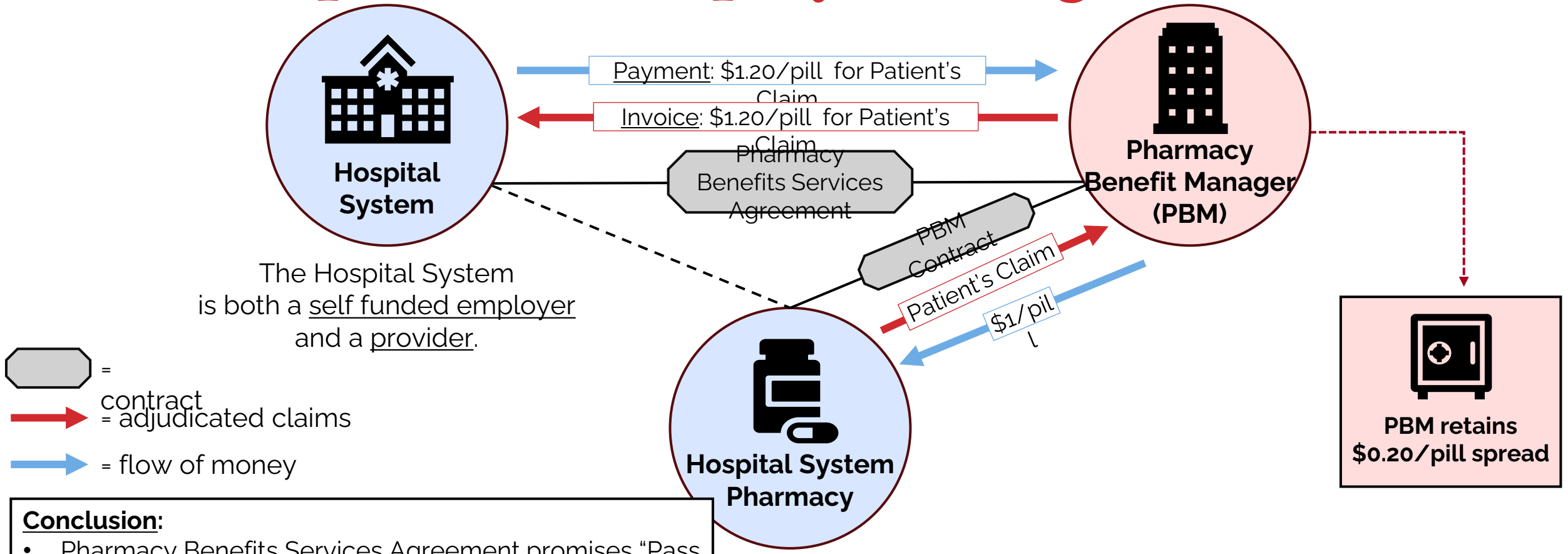
Prescription Discount Card makes $5.00 fee

Prescription Discount Cards typically process on existing PBM platforms, allowing PBM to deduct fees from remittances

Prescription Discount Cards and PBMs

- Several major PBMs and insurance plans have announced partnerships with prescription discount card companies
  - PBMs have suggested that prescription discount card companies have negotiated deeper discounts than they have
  - PBMs carve out certain generics from coverage altogether, in favor of highly rebated brand drugs
  - Rather than allow patients to receive claims denials for non-covered generic medications, the PBMs automatically convert the claims to a prescription discount card, resulting in a patient out-of-pocket that is typically less than what most copays are
- In these models, insurance companies pay nothing on the claims (in fact, there's "negative" reimbursement), but patients are deceived into thinking they have coverage

Plan Sponsor Alert: Spread on Employee Drug Claims



The Hospital System is both a <u>self funded employer</u> and a <u>provider</u>.

= contract

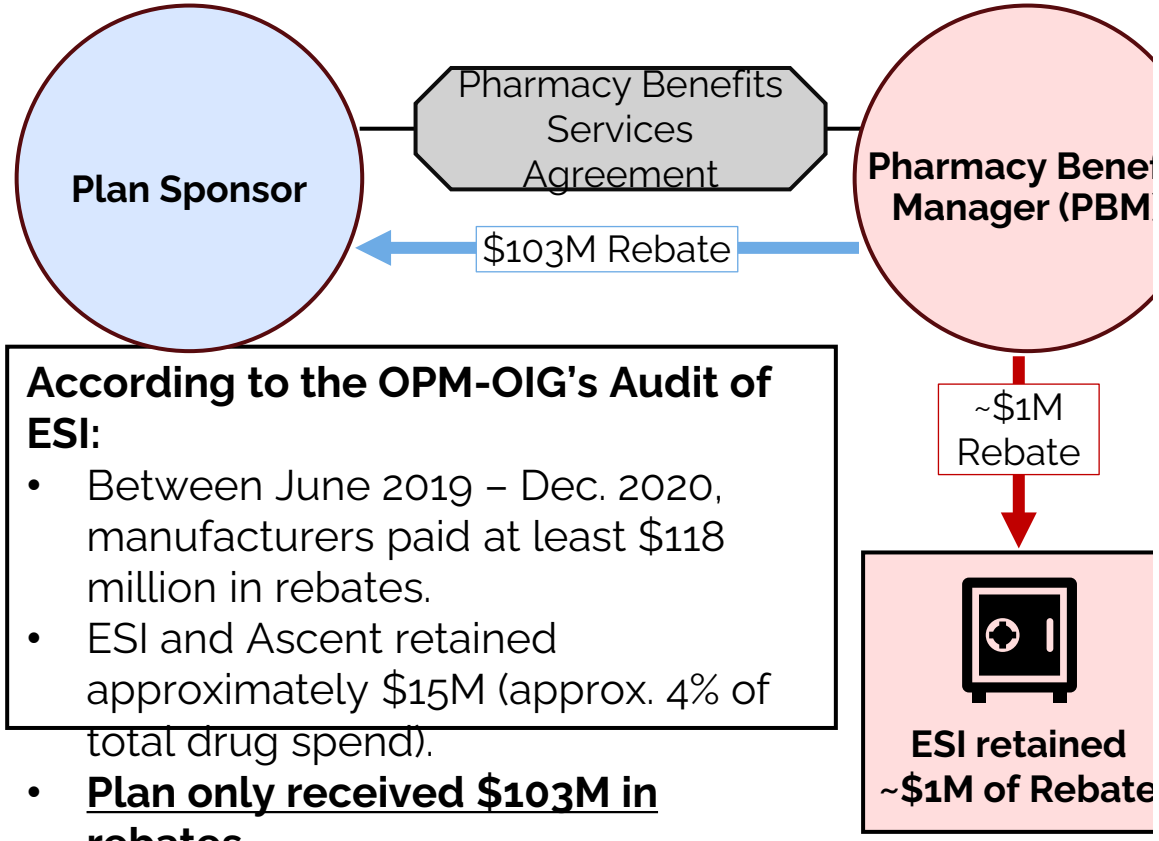
= adjudicated claims

= flow of money

<u>Conclusion</u>:

- Pharmacy Benefits Services Agreement promises "Pass Through Pricing," and no Spread Pricing.
- Triangulation data shows PBM charged Spread Pricing.

Plan Sponsor Alert: Rebate Retention



According to the OPM-OIG's Audit of ESI:

- Between June 2019 – Dec. 2020, manufacturers paid at least $118 million in rebates.
- ESI and Ascent retained approximately $15M (approx. 4% of total drug spend).
- **<u>Plan only received $103M in rebates.</u>**

CVS Caremark Biosimilar Strategy

- CVS Caremark launched Cordavis in 2023, a generic drug and biosimilar "manufacturer" focused on distributing lower-cost products
- Cordavis partnered with Sandoz in late 2023 to produce and distribute a Humira biosimilar called Hyrimoz® (*adalimumab-adaz*)
- In January 2024, CVS Caremark announced that AbbVie's Humira would be excluded from all formularies, and that Hyrimoz would be the only biosimilar covered on most of its formularies
- CVS Caremark also announced Cordavis and AbbVie will produce a co-branded version of Humira that will be identical to Humira in its formulation (i.e., an "authorized biologic")
- While CVS Caremark has limited these activities to top-selling Humira for now, it would not be unexpected if CVS Caremark expanded this strategy to other high-cost cancer biologics

Tools and Enforcement

42 U.S. Code § 1395nn

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

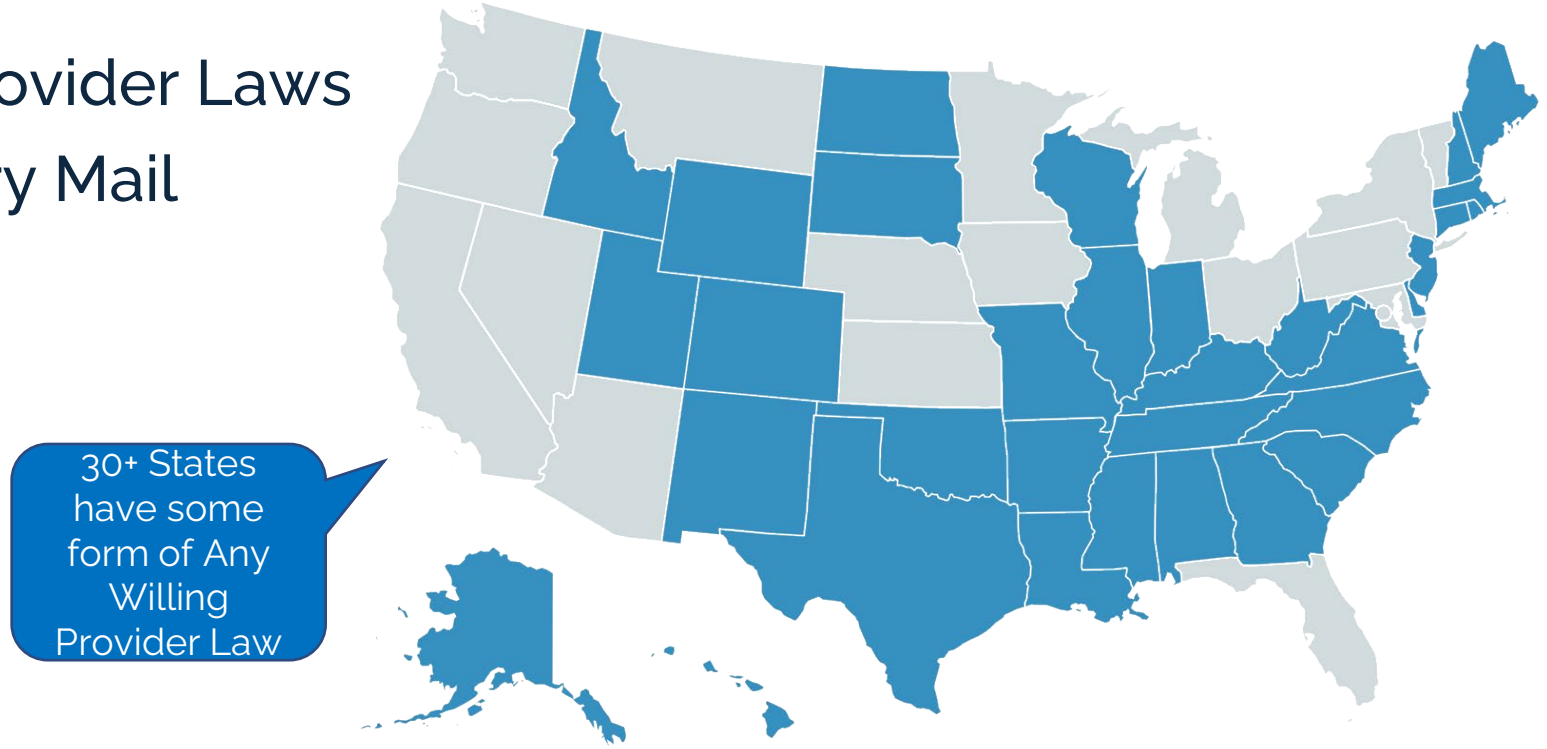
CMS states that the AWPL requires "Part D sponsors must offer *reasonable and relevant reimbursement* terms for all Part D drugs"

"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]".

Source: 42 USCS § 1395w-104

State Any Willing Provider Laws

- State Any Willing Provider Laws
- State Anti-Mandatory Mail Order Laws



Other State Laws

Minimum Reimbursement Laws

- *Minimum "Floor" Reimbursement Laws:* A payor may not "pay or reimburse a pharmacy or pharmacist for the ingredient drug product component of a pharmacist service less than the national average drug acquisition cost, or if the national average drug acquisition cost is unavailable, the wholesale acquisition cost" ((Delaware Ins. Code § 3372A(7))
- *Anti-Price Discrimination Laws:* A PBM "may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the amount the pharmacy benefit manager reimburses itself or an affiliate for providing the same product or service." (Maryland Code § 15-1612(c))
- *Market-Based Pricing Laws:* Requires the PBM to include in contracts a process to resolve pricing and reimbursement disputes. If dispute raised, PBM must identify the NDC of a drug product available for purchase by the appealing pharmacy at a price equal to or less than the applicable pricing. (N.J.S.A. 17B:27F-4)

MAC Appeal Laws

- *V.T.C.A. § 1369.353*
  - A PBM may not include a drug on a MAC list unless the drug is generally available for purchase in the state from a national or regional wholesaler and not obsolete
  - Requires the PBM to allow pharmacies to appeal MAC prices
  - In the event of successful MAC appeal, the PBM must retrospectively adjust the MAC price to all similarly situated pharmacies

Anti-Patient Steering Laws

- *Georgia Code Ann. § 33-64-12:* Imposes a surcharge on PBMs that engage in steering
- *Texas Code Ann., Insurance Code § 1369.554:* Prohibits a plan or PBM from steering or directing a patient to use the issuer's or PBM's affiliated pharmacy through any oral or written communication, including online messaging regarding the provider or patient-specific advertising, marketing, or promotion of the provider
- *La. Stat. Ann. § 40:2870(A)(5)(a):* PBM shall not directly or indirectly engage in patient steering to a pharmacy in which the PBM maintains an ownership interest or control without making a written disclosure and receiving acknowledgment from the patient
- *New Jersey Admin. Code § 13:39-3.10:* Makes it unlawful for a pharmacist to enter into an arrangement with a healthcare provider for the purpose of directing or diverting patients to or from a specified pharmacy or restraining in any way a patient's freedom of choice to select a pharmacy

Unfair Competition Laws

- *Mass. Gen. Laws Chap. 93A*
  - Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are unlawful
  - Violations of Massachusetts' any willing provider law are considered unfair business practices, thereby creating a private right of action
  - A court can award a business plaintiff compensatory or actual damages, as well as double or triple damages if the plaintiff can prove the defendant willfully and knowingly violated Chapter 93A
  - Reasonable attorney's fees and costs incurred in the lawsuit are also available under certain circumstance

Patient Rights

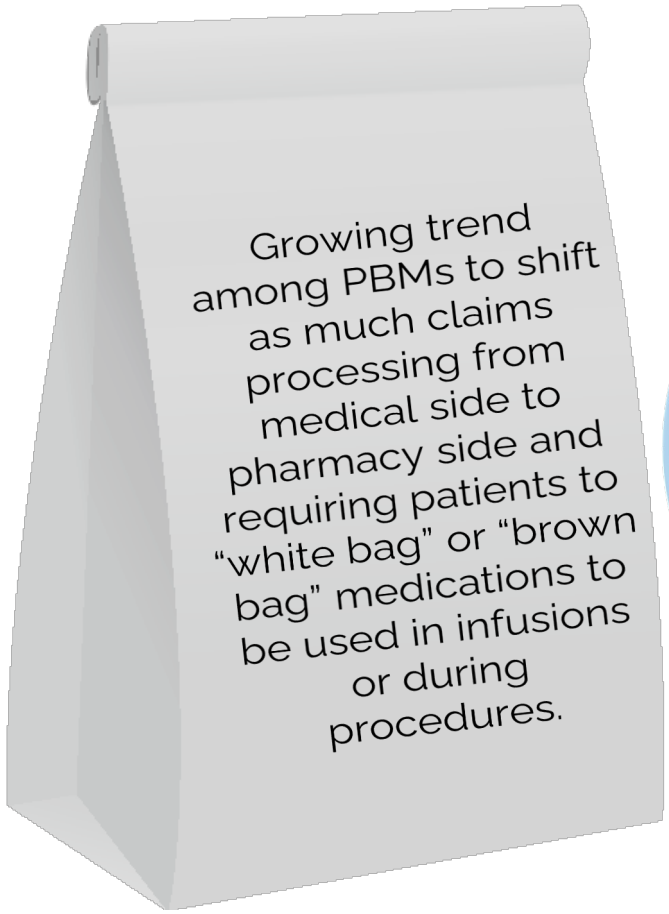
- Summary Plan Document
- *Vanusanik v. PricewaterhouseCoopers LLP and Express Scripts, Inc.*, 8:20-cv-2839-CEH-TGW, (M.D. Fla. Sep. 17, 2021)
- *Doe v. CVS Pharmacy, Inc.*, No. 19-15074 (9th Cir. 2020)

Source: https://ecf.flmd.uscourts.gov/cgi-bin/show_public_doc?2020-02839-56-8-cv (accessed Sept. 11, 2025)
https://cdn.ca9.uscourts.gov/datastore/opinions/2020/12/09/19-15074.pdf (accessed Sept. 11, 2025)

White Bagging Mandates

42 U.S. Code § 1395nn

Medical Benefit vs. Pharmacy Benefit



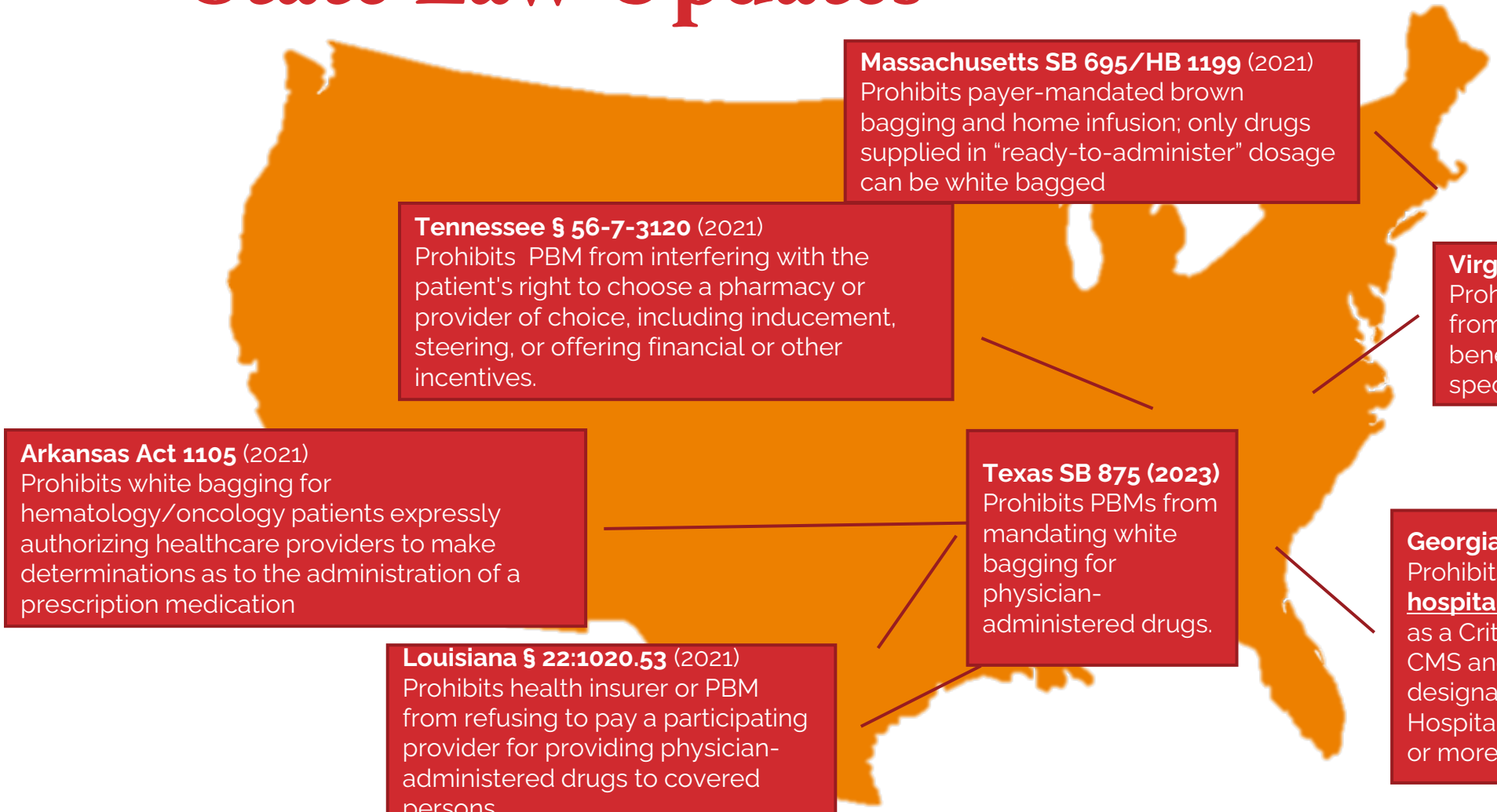
Medical Benefit

- *Processed and reimbursed by the health insurance company under the "medical" side.*
- *Typically more open networks.*
- *Less likely to be rerouted to PBM-owned pharmacy.*
- *Often includes reimbursement for ancillary services.*

Pharmacy Benefit

- Processed and reimbursed by the PBM under the "pharmacy" side.
- More likely to have "restricted" networks.
- More incentive for PBM to direct business to wholly-owned specialty pharmacies.
- Less likely to include reimbursement for ancillary services.

Mandatory White-Bagging State Law Updates



Massachusetts SB 695/HB 1199 (2021)
Prohibits payer-mandated brown bagging and home infusion; only drugs supplied in "ready-to-administer" dosage can be white bagged

Tennessee § 56-7-3120 (2021)
Prohibits PBM from interfering with the patient's right to choose a pharmacy or provider of choice, including inducement, steering, or offering financial or other incentives.

Virginia § 38.2-4312.1 (2021)
Prohibits plans and PBMs from restricting a beneficiaries choice of specialty pharmacy

Arkansas Act 1105 (2021)
Prohibits white bagging for hematology/oncology patients expressly authorizing healthcare providers to make determinations as to the administration of a prescription medication

Texas SB 875 (2023)
Prohibits PBMs from mandating white bagging for physician-administered drugs.

Georgia Directive 22-EX-5 (2022)
Prohibits white bagging at any **hospital** in the state designated as a Critical Access Hospital by CMS and any hospital not designated as a Critical Access Hospital that is located 30 miles or more from another hospital

Louisiana § 22:1020.53 (2021)
Prohibits health insurer or PBM from refusing to pay a participating provider for providing physician-administered drugs to covered persons

Strategies to Combat Mandatory White-Bagging

- Challenging payor policies through negotiation
  - Notice
  - Objection
  - Quantify loss and burden
- Challenge payor policies in court or in arbitration as a breach of contract
  - Reduction in reimbursement
  - Increase in administrative burden
  - Material change to the contract
- Unilateral amendment
- Appealing to legislators as a threat to patient safety and financial security of health care providers
- Appeals to state insurance commissioners
- Complaints to Boards of Pharmacy
- Requiring formal indemnification from specialty pharmacy/health plan before accepting products

Hospital Home Infusion Expansion

42 U.S. Code § 1395nn

Hospital Home Infusion Drivers & Trends

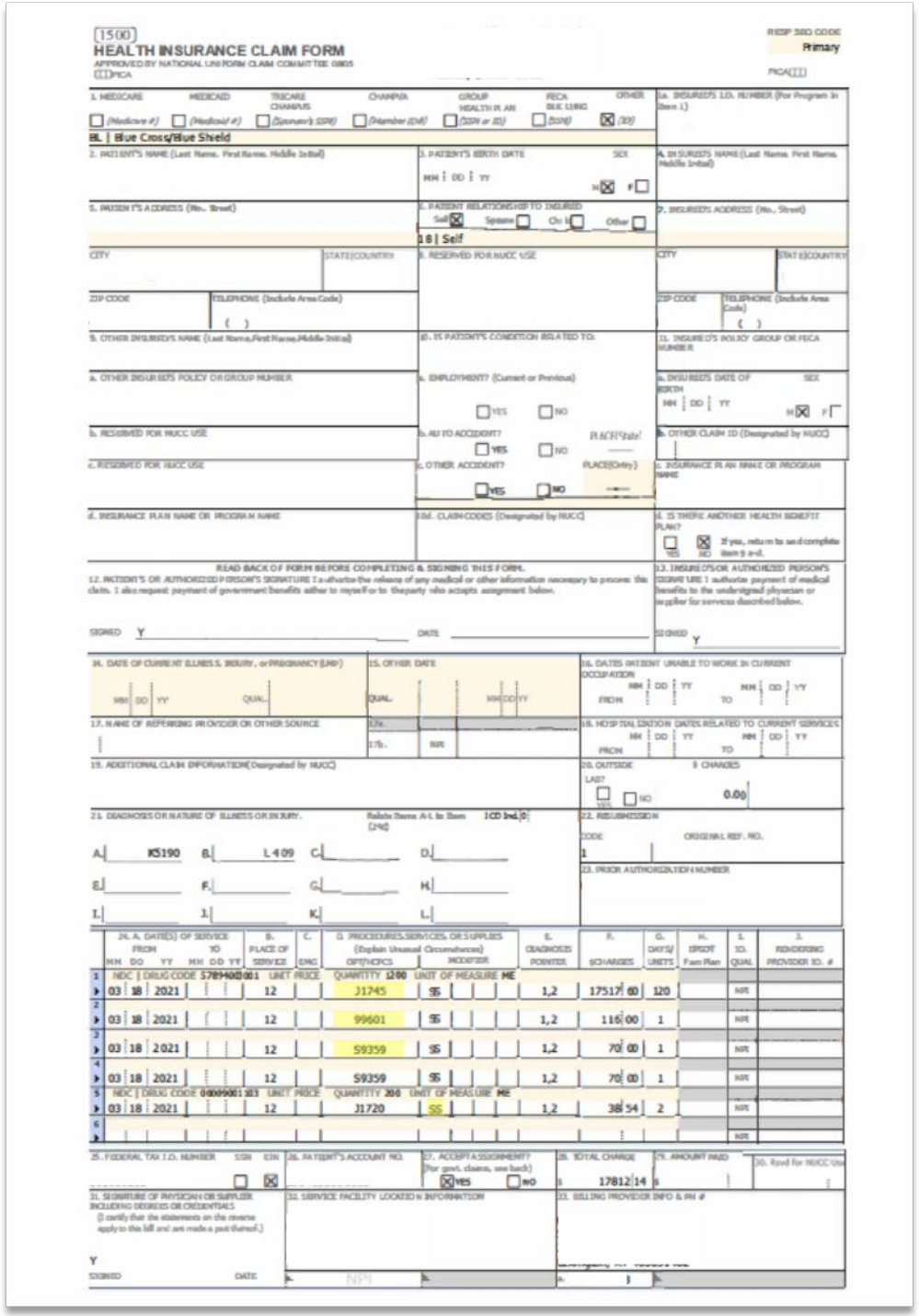
- Shift to site-of service optimization and hospital-at-home initiatives
- Leveraging infusion suites and home infusion to recapture integral parts of continuum of care
  - Hospitals are increasingly moving infusion care away from inpatient/outpatient departments and towards home infusion or infusion suites in an effort to reduce costs and improve patient satisfaction

Alternative Infusion Sites

- Hospital Outpatient Department
- Provider-Based Infusion Clinic
- Ambulatory Infusion Clinic
- Pharmacy Based Infusion Suite
- Home Infusion

Medical Claims Billing

- Drugs are billed using a J-Code or Q-Code, not an NDC Number
- Drugs are billed “ancillary to” a certain procedure (e.g., CPT code 99601)
- Includes a “per diem” charge for each day infusion is to occur (e.g., HCPCS code S9359)
- This particular claim was administered in an “infusion suite,” as denoted by the “SS” modifier



Legal & Regulatory Barriers

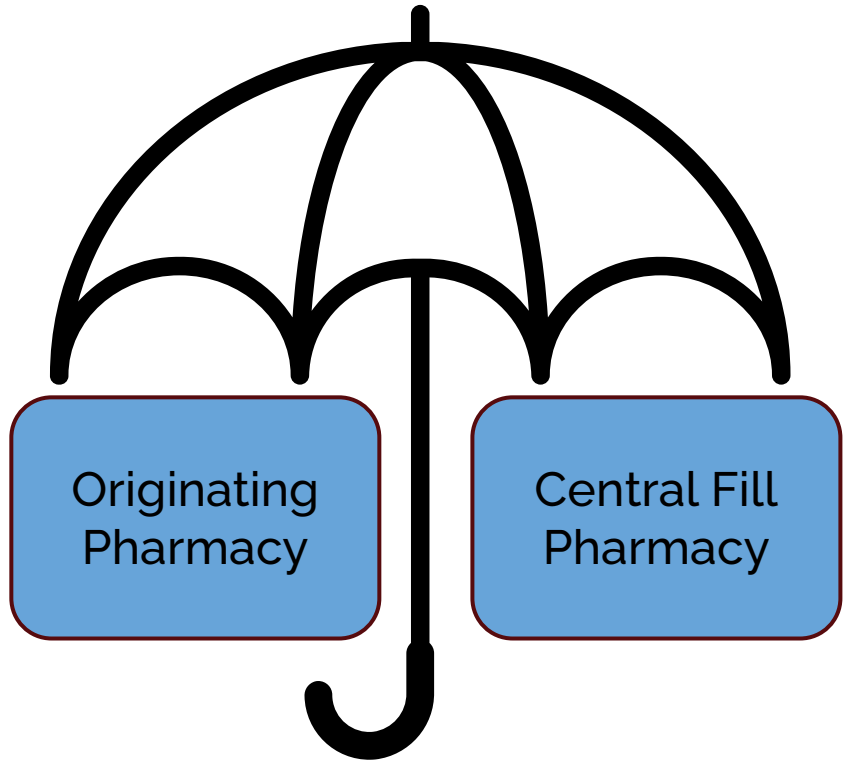
- Home infusion providers must maintain multi-state pharmacy licensures as well as be accredited from a CMS-approved accrediting organization (*ACHC, CHAP, URAC, NABP, TCT or JC) when servicing patients across state lines
- Corporate practice of medicine rules regarding employment of nurses
  - Many states restrict hospitals or corporations from directly employing nurses for professional services to avoid conflicts between care quality and profit motives
- Stark Law** and Anti-kickback Statute ("AKS) implications for in-network referral relationships
  - In-network referral agreements must be structured carefully to avoid prohibited financial incentives
  - Monitoring and compliance program are valuable tools to help mitigate risk of Stark/AKS
- Central fill and shared services can support home infusion scale and efficiency with compounding and distribution across sites, but faces regulatory, logistical, and reimbursement challenges

** Accreditation Commission for Health Care (ACHC), Community Health Accreditation Partner (CHAP), National Association of Boards of Pharmacy (NABP), The Compliance Team (TCT) or The Joint Commission (JC)*

*** 42 U.S. Code § 1395nn*

Shared Pharmacy Services

- Operational Efficiency
  - Allows pharmacies under common ownership to streamline inventory management and staffing to reduce costs while improving service delivery
- State Law Regulations
  - Trend of greater recognition
  - Governance of shared services is subject to state-specific laws
- General Requirements
  - Common electronic file, policies and procedures, and identification of pharmacy staff responsible for each task
- PBM Considerations
  - Explicit recognition may be required for reimbursement



Billing & Coverage Challenges: Medicare and Commercial Payors

- Medicare Coverage Landscape
  - Medicare Part B provides coverage for certain home infusion drugs {mainly DME therapies) while Part D coverage is broader but excludes nursing and equipment fees
  - CMS reimbursement structures and “home infusion therapy services” billing rules remain complex and often inadequate for hospital-based infusion programs
- Commercial Payor Variability
  - Commercial insurers have varying policies on coverage, reimbursement rates, bundled fees, and prior authorization which leads to operational and financial unpredictability
  - Many commercial payors require “white bagging,” which decreases hospitals’ ability to control and coordinate patient care

The 340B Program

42 U.S. Code § 1395nn

340B Claims Submission

- NCPDP Field 420-DK and Submission Clarification Code "20"
  - Indicates that, prior to providing service, the pharmacy has determined the product being billed is purchased pursuant to rights available under the 340B Program
  - But how do contract pharmacies handle claims that aren't immediately identifiable as 340B that are reconciled after-the-fact?
- Several PBMs have begun requiring pharmacies to identify 340B claims at the point-of-sale
- Many Medicaid fee-for-service and managed care plans have long required the modifier
- Is it lawful to omit the Submission Clarification Code?

Source: https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf

340B-Specific Pricing

- 340B-specific pricing:
  - AWP minus 33% (when normal reimbursement is AWP minus 15% for non-340B claims)
  - 340B actual acquisition cost plus a dispensing fee of +/- $10
- PBM “clawbacks” over 340B pricing reconciliation
- State legislation prohibiting PBMs from imposing additional charges on hospitals that qualify for the 340B Program

340B Program: Manufacturer-Imposed Contract Pharmacy Restrictions

- Overview of Restriction Types:
  - Contract Pharmacy Count Limits: limits number of contract pharmacies a covered entity can use (e.g., one or very few)
  - Geographic Proximity Limitations: restricts contract pharmacies to certain distances from parent hospital sites (e.g., within 50 miles)
  - Data Provision Requirements: mandates covered entities submit contract pharmacy claims data to access 340B pricing
- Key Litigation:
  - *Novartis v. Johnson* (D.C. Cir., 2024):*
    - Court ruled manufacturers may impose restrictions on contract pharmacy use, including count and geographic limits
  - *Sanofi v. HHS* (3rd Cir., 2023):**
    - Court ruled manufacturers may limit 340B pricing to selected pharmacy arrangements; challenged HRSA's advisory opinion supporting unlimited contract pharmacies

*https://law.justia.com/cases/federal/appellate-courts/cadc/21-5299/21-5299-2024-05-21.html (accessed September 11, 2025)
**https://www2.ca3.uscourts.gov/opinarch/213167p.pdf (accessed September 11, 2025)

State Laws on 340B Price Discrimination

- Over 30 states have enacted some form of legislation prohibiting 340B price discrimination prohibiting manufacturers from restricting or discriminating against 340B pricing for contract pharmacies or prohibiting PBMS from imposing discriminatory reimbursement or network restrictions on 340B providers
- Some states with active 340B protection include: Arkansas (2021), Mississippi (2023), Missouri (2023), Kansas (2023), Maryland (2024), Minnesota (2020), Utah (2023), Tennessee (2023), Louisiana (2023), West Virginia (2024), New Mexico (2023), and South Dakota (2022)

Source: https://www.nachc.org/wp-content/uploads/2025/06/06_20_25_nachc_state-level-340b-laws-and-legislation_tracker.pdf

Overview of Pending Litigation Surrounding State Laws

- Arkansas (status: PhRMA lost the challenge at the 8th Circuit and SCOTUS denied cert.)
- Mississippi (status: S.D. Miss. denied PhRMA's preliminary injunction application; appeal pending before 5th Circuit)
- West Virginia (status: D. W.V. granted PhRMA's preliminary injunction application; appeal pending before 4th Circuit; Frier Levitt submitted amicus on behalf of COA in this case)
- Maryland (status: D. Md. denied PhRMA's preliminary injunction application)
- Kansas (status: D. Kan. denied PhRMA's challenge; 8th Circuit affirmed; PhRMA dropped the suit)
- Louisiana (status: W.D. La. denied PhRMA's preliminary injunction application)
- Minnesota (status: Minnesota state court dismissed PhRMA's challenge)
- Missouri (status: W.D. Mo. dismissed parts of PhRMA's challenge)

340B Litigation

- Claims Reconciliation
  - Disputes and litigation between Contract Pharmacies and Covered Entities
  - Disputes and litigation between Contract Pharmacies and PBMs
  - Disputes and litigation between Covered Entities and PBMs
- State Law Litigation
  - *Pharmaceutical Research and Manufacturers of America (PhRMA) v. McClain, et al.*, No. 4:21-cv-00864 (E.D. Ark. 2021)
  - *PhRMA v. Morrisey, et al.*, No. 2:24-cv-00271 (S.D. W.Va. 2024)
  - *People of the State of New York v. CVS Health Corp.*, No. 452197-2022 (Supreme Court of New York)
- Federal Law Litigation
  - *Novartis Pharmaceuticals Corp. v. Johnson*, No. 21-5299 (D.C. 2024)
  - *Genesis Health Care, Inc. v. Becerra*, 4:19-cv-01531 (D.S.C. 2023)

https://340breport.com/wp-content/uploads/2022/09/Intervenors.pd
https://law.justia.com/cases/federal/district-courts/west-virginia/wvsdce/2:2024cv00271/239355/68/
https://340breport.com/wp-content/uploads/2022/09/452197_2022_People_of_the_State_of_v_People_of_the_State_of_MEMORANDUM_OF_LAW_I_11.pdf
https://law.justia.com/cases/federal/appellate-courts/cadc/21-5299/21-5299-2024-05-21.html
https://law.justia.com/cases/federal/appellate-courts/ca4/20-1701/20-1701-2022-07-01.html

340B Implications: ERISA and PBM Contracting

- State 340B pricing laws typically do not apply to self-funded ERISA plans due to federal preemption
- Pharmacies face challenges negotiating with PBMs imposing lower 340B reimbursement rates
- Negotiation Strategies:
  - Request transparent reimbursement terms
  - Advocate for fair market rates, not discriminatory pricing
  - Collaborate with covered entities to demonstrate the 340B program value

Rebate-Based 340B : Overview & Litigation

- Johnson & Johnson (J&J) and other manufacturers proposed replacing upfront 340B discounts with rebate-based models, where hospitals pay full price upfront, then file for rebates as it improves program integrity by reducing duplicate discounts
- HRSA is in opposition of rebate models asserting that the 340B statute requires upfront discounts
- Key Litigation:
  - *Johnson & Johnson v. HHS/HRSA* (D.C. Dist. Ct., 2025)
  - June 27, 2025: Court ruled against J&J, affirming HRSA's authority to reject rebate models and require prior approval
- *Sanofi-Aventis Rebate Model* (ongoing):
  - Court ordered HRSA to reconsider Sanofi's rejected rebate model due to insufficient justification
- Other manufacturers (e.g., Eli Lilly, Bristol Myers Squibb) have similar proposals pending review

https://law.justia.com/cases/federal/district-courts/district-of-columbia/dcdce/1:2024cv03188/274772/59/ (accessed Sept. 11, 2025)

"Convener" and Employer-Sponsored Models

Background

- Emerging model with employer-sponsored plans where third-party organizations such as some transparent PBMs steer patients to specific covered entities or contract pharmacies
- The goal in this model is to maximize 340B pricing eligibility and generate 340B savings which benefits the employer-sponsored plan

Legal Scrutiny

- Potential 340B diversion violations (patient definition issues)
- Anti-kickback and fee-splitting risks
- Triggering of state 340B discrimination statutes
- Public relations and program integrity optics

61 Fed. Reg. 55156; 42 U.S.C. § 256b(a)(5)(B); 42 U.S.C. § 1320a-7b(b); OIG Special Advisory Bulletins; Ark. Code Ann. § 23-92-604; W. Va. Code § 33-51-11; NCSL 340B State Law Summary;HRSA 340B Program Integrity Page; OIG Report OEI-05-13-00431

340B Alternative Distribution Models

- Continued manufacturer restrictions on 340B drug pricing available via the traditional “bill to/ship to” contract pharmacies
- Covered entities/contract pharmacies are becoming increasingly creative in finding alternate ways to capture 340B benefits
- Alternative Distribution Model (“ADM”): in order to navigate certain contract pharmacy restrictions placed on hospital pharmacies, we have seen covered entities attempt to have 340B drugs physically shipped to in-house/entity-owned pharmacies for further distribution to contract pharmacies

340B Alternative Distribution Models: Key Legal Risks and Considerations

- State Boards of Pharmacy (BOP) Rules and Regulations
  - Varying rules/exceptions for requirements on obtaining a wholesaler license based on the state of the covered entity/contract pharmacy
  - Exceptions to wholesaler licensure
- Drug Supply Chain Security Act (DSCSA)
  - Inconsistent wholesaler license requirements under DSCSA rules
  - Need to meet T3 requirements to meet DSCSA policies during the transferring of the drugs

340B Alternative Distribution Models: Key Legal Risks and Considerations (cont.)

- Payor Network Participation
  - Can lead to violations of network participation if wholesaler licensure and other state/regulatory requirements are not followed
  - BOP actions from any violations for noncompliance could potentially negatively affect network in the payer's network
- 340B Program
  - Ensure 340B policies and procedures provide sufficient details about the ADM
  - Ensure ADM is in compliance with 340B Program requirements
  - Diversion risk under HRSA guidance

340B Alternative Distribution Models: Manufacturer Risks and Considerations

- Increased complexity associated with tracking and tracing compliance
  - More complicated for manufacturers to track where 340B-eligible drugs are ultimately dispensed thus risking non-compliance with 340B program rules
- Potential for duplicate discounts and lost revenue
  - Unable to accurately identify and track 340B-eligible prescriptions thus leading to loss in revenue
- Added compliance burden/manufacturer pushback and possible retaliation
  - Increase manufacturer audits and inquiries
  - Disputes over 340B pricing and eligibility

Summary

- Proactive monitoring reduces compliance risk and supports strategic decision-making
- Strong internal controls help maximize program benefits while avoiding regulatory penalties
- Comprehensive documentation and clear processes minimize audit exposure and support reimbursement
- Flexible frameworks enable hospitals to manage legal risk while maintaining operational efficiency

References

- https://acasignups.net/estimates/coverage
- https://www.thebignewsletter.com/p/the-red-wedding-for-rural-pharmacies
- https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/memopdbmanualchapter5_093011.pdf
- https://www.cms.gov/newsroom/fact-sheets/cms-letter-plans-and-pharmacy-benefit-managers
- https://www.oversight.gov/sites/default/files/documents/reports/2024-10/2022-SAG-029.pdf
- 42 USCS § 1395w-104
- https://cdn.ca9.uscourts.gov/datastore/opinions/2020/12/09/19-15074.pdf
- 42 U.S. Code § 1395nn (Lexis)
- https://law.justia.com/cases/federal/appellate-courts/cadc/21-5299/21-5299-2024-05-21.html (accessed Sept. 11, 2025)
- https://www2.ca3.uscourts.gov/opinarch/213167p.pdf (accessed Sept. 11, 2025)
- https://www.nachc.org/wp-content/uploads/2025/06/06_20_25_nachc_state-level-340b-laws-and-legislation_tracker.pdf
- https://www.ncpdp.org/NCPDP/media/pdf/340B_Information_Exchange_Reference_Guide.pdf
- https://law.justia.com/cases/federal/district-courts/district-of-columbia/dcdce/1:2024cv03188/274772/59/ (accessed Sept. 11, 2025)
- https://340breport.com/wp-content/uploads/2022/09/Intervenors.pd (accessed Sept. 11, 2025)
- https://law.justia.com/cases/federal/district-courts/west-virginia/wvsdce/2:2024cv00271/239355/68/ (accessed Sept. 11, 2025)
- https://340breport.com/wp-content/uploads/2022/09/452197_2022_People_of_the_State_of_v_People_of_the_State_of_MEMORANDUM_OF_LAW_I_11.pdf (accessed Sept. 11, 2025)
- https://law.justia.com/cases/federal/appellate-courts/cadc/21-5299/21-5299-2024-05-21.html (accessed Sept. 11, 2025)
- https://law.justia.com/cases/federal/appellate-courts/ca4/20-1701/20-1701-2022-07-01.html (accessed Sept. 11, 2025)
- https://cdn.ca9.uscourts.gov/datastore/opinions/2020/12/09/19-15074.pdf (accessed Sept. 11, 2025)
- *https://www.sec.gov/Archives/edgar/data/1402479/000162828020013237/exhibit1023-sx4xpharma.htm*
- *https://www.wellcare.com/en/providers/medicare-bulletins/express-scripts-transition*

Thank You

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Presentation Title: Legal Considerations for Health Systems Pharmacies: White Bagging, 340B, and More

Presenter Name: Jesse C. Dresser

Learning Objectives:

1. Describe state laws and current litigation efforts relating to contract pharmacy restrictions.
2. Discuss potential barriers to utilizing such models and/or why such models may be permissible.
3. Describe current rebate model policies and litigation efforts.

Test Question	Corresponding Learning objective	Corresponding text or slide number with answer	Rationale for correct/incorrect answers
1. Which of the following best describes a recent legal development affecting 340B contract pharmacy arrangements? A) Manufacturers must allow unlimited contract pharmacies B) Manufacturers can restrict contract pharmacy use C) PBMs are prohibited from auditing 340B claims D) All state laws override federal 340B rules	Describe current rebate model policies and litigation efforts	NASP 2025.pptx (340B Program: Manufacturer-Imposed Contract Pharmacy Restrictions; Novartis v. Johnson, D.C. Cir. 2024) Slide 42	Correct answer: B. Novartis v. Johnson confirmed manufacturers can restrict contract pharmacy use. Other options are incorrect or not supported by current law.
2. What is a key compliance risk when using alternative distribution models (ADMs) for 340B drugs? A) Enhanced patient access B) Diversion risk under HRSA guidance C) Guaranteed higher reimbursement D) Exemption from DSCSA requirements	Describe current rebate model policies and litigation efforts	NASP 2025.pptx (340B Alternative Distribution Models: Key Legal Risks and Considerations (cont.)) Slide 51	Correct answer: B. ADMs can increase diversion risk, which is a major compliance concern. Other options are either benefits or incorrect.
3. Which state law provision is designed to combat mandatory white bagging practices? A) Prohibiting PBMs from steering patients	Discuss potential barriers to utilizing discriminatory pricing models and/or why they may be permissible	NASP 2025.pptx (Mandatory White-Bagging State Law Updates) Slide 30	Correct answer: A. Several states have enacted laws prohibiting PBMs from steering patients or mandating white bagging. Other

B) Requiring all drugs to be brown bagged C) Mandating exclusive use of PBM-owned pharmacies D) Allowing only out-of-state pharmacies to dispense specialty drugs			options are not accurate or not supported by law.
4. When facing below-acquisition-cost reimbursement from a PBM, which of the following is a recommended strategy? A) Ignore the issue B) File a complaint with CMS C) Accept the rate without dispute D) Only appeal to the PBM's internal process	Describe state laws and current litigation efforts relating to contract pharmacy restrictions	NASP 2025.pptx (Strategies to Combat Below Water Reimbursement Rates (cont.)) Slide 16	Correct answer: B. Filing a complaint with CMS is a recommended step, along with other dispute processes. Ignoring or accepting the rate is not advised.
4. When facing below-acquisition-cost reimbursement from a PBM, which of the following is a recommended strategy? A) Ignore the issue B) File a complaint with CMS C) Accept the rate without dispute D) Only appeal to the PBM's internal process	Describe state laws and current litigation efforts relating to contract pharmacy restrictions	NASP 2025.pptx (Strategies to Combat Below Water Reimbursement Rates (cont.)) Slide 16	Correct answer: B. Filing a complaint with CMS is a recommended step, along with other dispute processes. Ignoring or accepting the rate is not advised.