PBM and DIR Fee Updates

Jonathan E. Levitt, Esq.

FRIER LEVITT
ATTORNEYS AT LAW

VIRGINIA ASSOCIATION
OF HEMATOLOGISTS
AND ONCOLOGISTS

Disclaimer

The materials and information provided in this presentation are for informational purposes only and not legal advice. The brief overview should not be construed as legal advice or exhaustive coverage of the topics. Contact your attorney to obtain advice with respect to any particular issue or problem. Statements, opinions and descriptions are based on general experience of Frier Levitt attorneys, and are not meant to be relied upon by anyone. Use of and access to this presentation, materials or information do not create an attorney-client relationship.

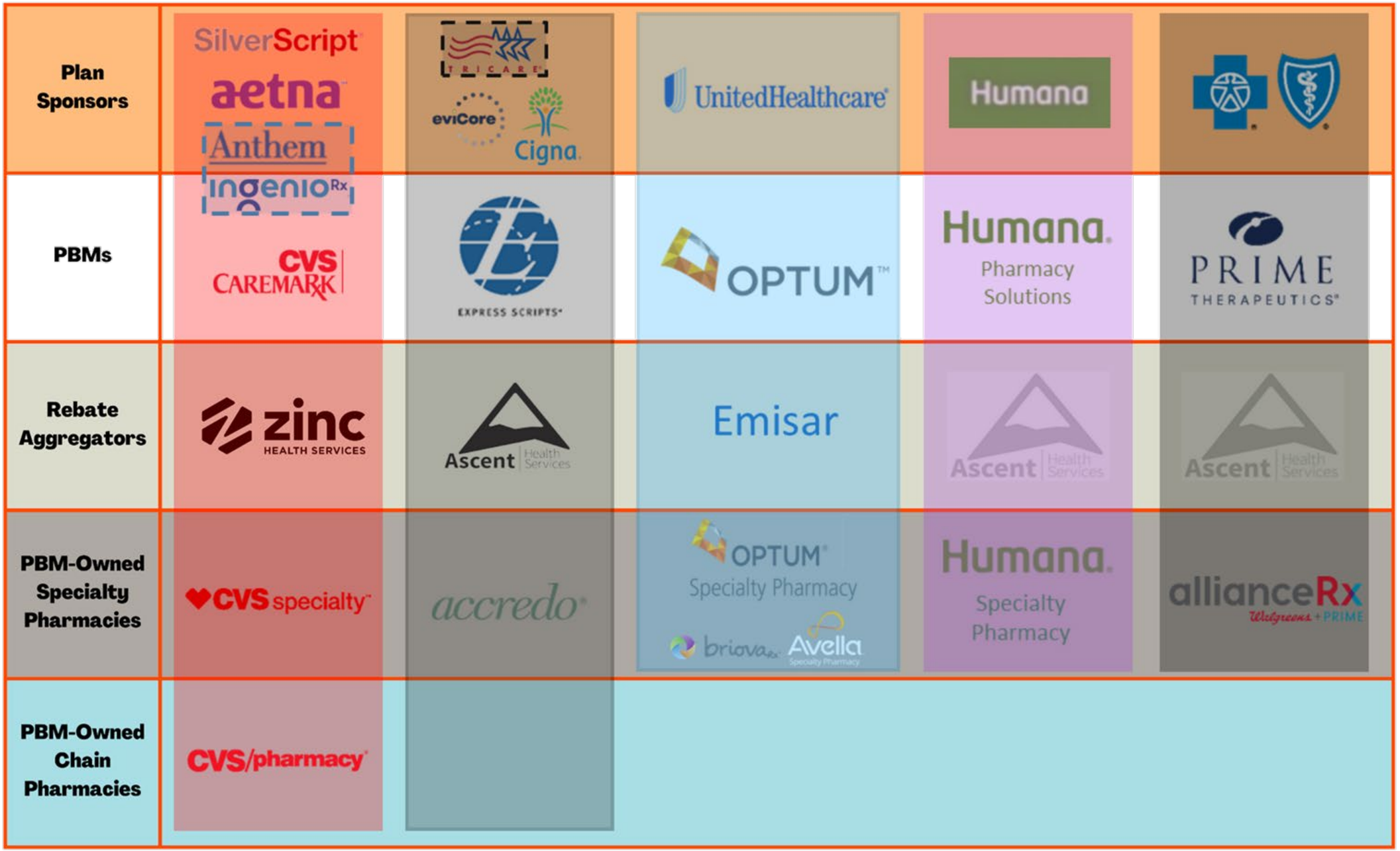
All product and company names are trademarks™ or registered® trademarks of their respective holders. Any use of such marks is for educational purposes and does not imply any affiliation with or endorsement by them.

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Glossary

- ***"Dispensing Physician Practices"*** refers to practices that dispense medication pursuant their plenary medical license, where permitted by law. They do not hold a pharmacy license.
- ***"Physician-Owned Pharmacies"*** refers to practices the dispense medication through a licensed retail pharmacy. The licensed retail pharmacy may be the same entity as the medical practice.
- ***"Community Oncology Practices"*** refers broadly to both Dispensing Physician Practices and Physician-Owned Pharmacies.

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS



VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

NETWORK ACCESS

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Potpourri of Payor Problems

Network Access

- MedImpact and Prime Therapeutics both refusing to admit Dispensing Physicians into networks
- ***FEP-BCBS*** Switch to CVS Caremark and Exclusion of Community Oncology Practices
- ***New York Medicaid FFS*** Carve Out and Exclusion of Dispensing Physicians
- Network Access in ***Self-Funded ERISA Plans***

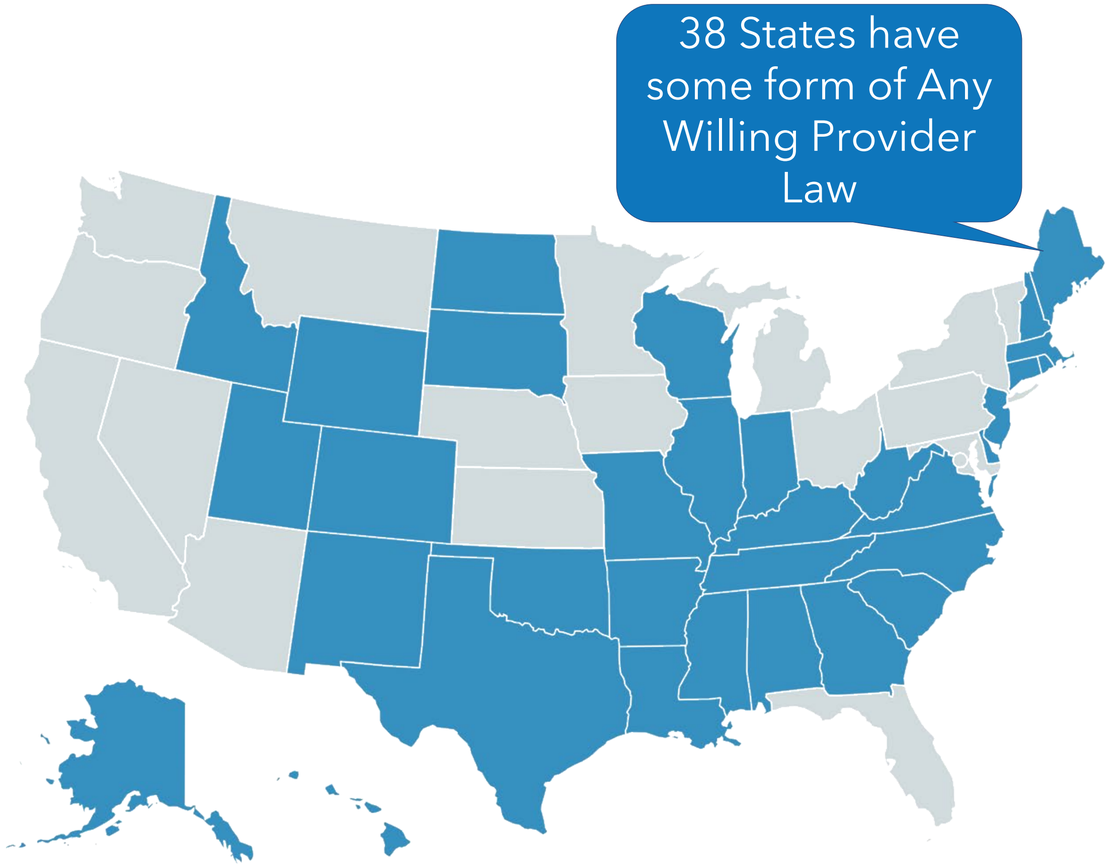
Any Willing Provider

Federal Any Willing Provider Law – 50 States & Washington D.C. (Medicare Part D)

Federal Freedom of Patient Choice Law 50 States & Washington D.C. (Medicare Part D)

State Any Willing Provider Laws

State Anti-Mandatory Mail Order Laws



VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

TRICARE Below Water Reimbursement Rates/ Network Exclusion

TRICARE reimbursement rates have decreased to below acquisition cost

- Providers have multiple ***options to challenge "below water" reimbursement***:
  - Initiate ***litigation against Express Scripts*** (the exclusive PBM for TRICARE benefits) predicated upon a violation of the Sherman Act (unfair restraint on trade), the Clayton Act (predatory pricing), breach of contract for violating the implied covenant of good faith and fair dealing, and tortious interference based on ESI's interference with a provider's relationship with patients.
  - "Associational Standing".
  - Initiate an ***administrative complaint*** against the Department of Defense (DOD)
  - Seek information through ***FOIA requests*** on ESI's contract terms with the DOD and ESI's wholly owned mail order pharmacy to explore wrongdoing. If information isn't turned over pursuant to FOIA request, providers can explore litigation to challenge the failure to turn over certain information
- The Federal and state Any Willing Provider Laws do not apply to TRICARE.

TRICARE®

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

VA's "Any Willing Provider Law"

Va. St. Ann. § 38.2-3407 (applies to broad range of providers):

- ***No*** hospital, ***physician*** or provider listed in § 38.2-3408 willing to meet the terms and conditions offered to it or him ***shall be excluded***.
- Statute is not preempted by ERISA and ***providers are able to bring a cause of action*** against insurers who violate Virginia's Any Willing Provider Law.
  See Stuart Circle Hosp. Corp. v. Aetna Health Mgmt., 995 F.2d 500 (4th Cir. 1993)

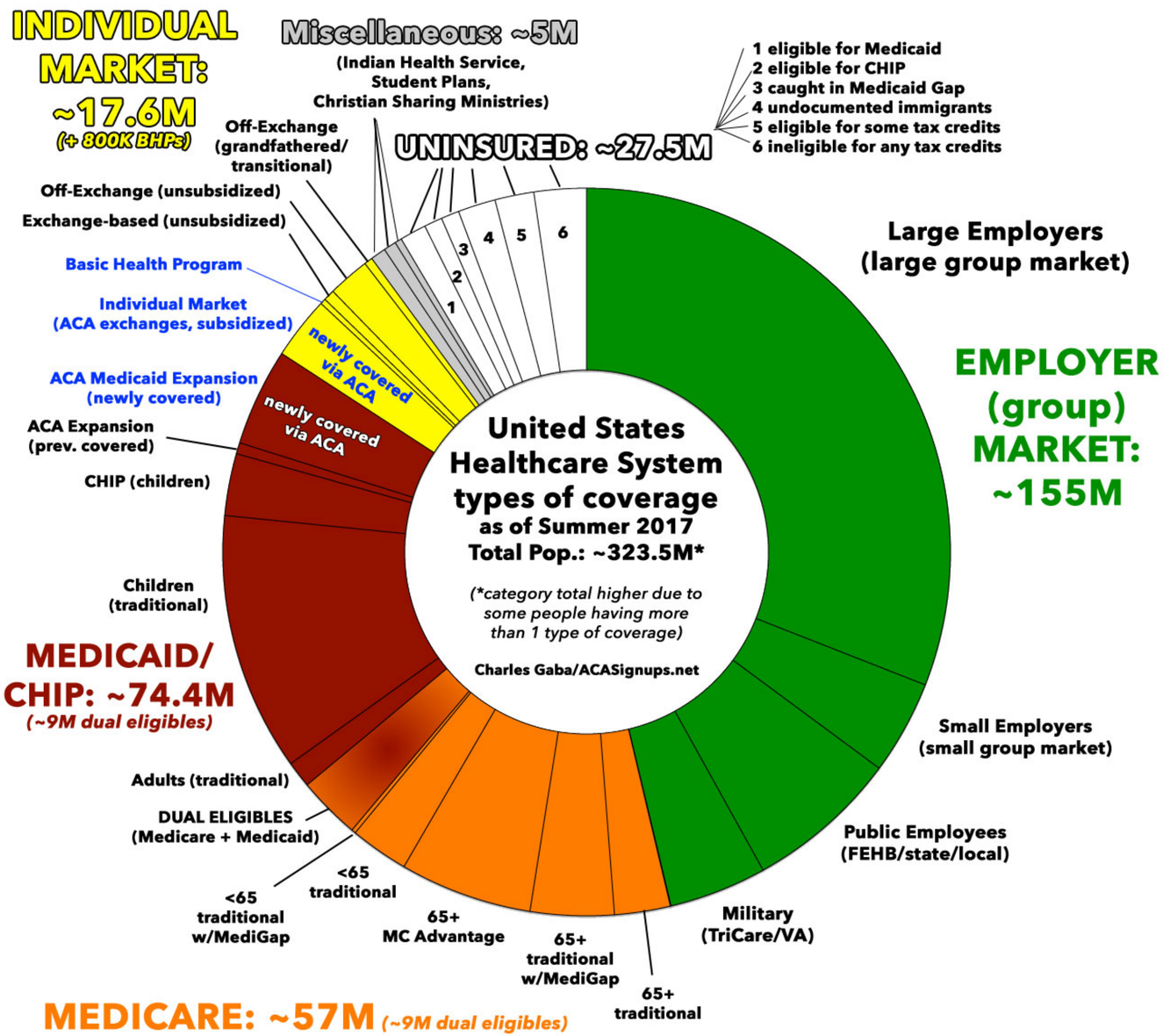
Relevant Provisions of Va. St. Ann. § 38.2-3407.7 (applies to pharmacies):

- ***No insurer*** proposing to issue either preferred provider policies or contracts or exclusive provider policies or contracts ***shall prohibit any person receiving pharmacy benefits from selecting the pharmacy of his choice*** to furnish such benefits.

Suggestions to Improve VA's State AWPL

Provisions that would strengthen VA's AWPL:

- ***Express Private right of action*** to providers, providing for damages and injunctive relief.
- Add "***reasonable and relevant***" to the phrase "terms and conditions"
- ***Express applicability to dispensing physician practices***, in addition to all types of pharmacies (including mail order, specialty, retail, closed door and physician owned).
  - Currently, Virginia's AWPL suggests that the provisions may extend to dispensing physicians.
- Expressly Provide that the AWPL requirements are applicable ***to PBMs***.
- Provision, tied to state licensure of PBMs and health insurers/plan sponsors, whereby a failure to comply with the AWPL results in financial penalties and loss of license.
- Provide for funding of enforcement agencies to investigate and prosecute violations of the AWPL.



Type of Plan Impacts What Law Applies

ERISA and Preemption: Is VA's AWPL Applicable to All Plans?

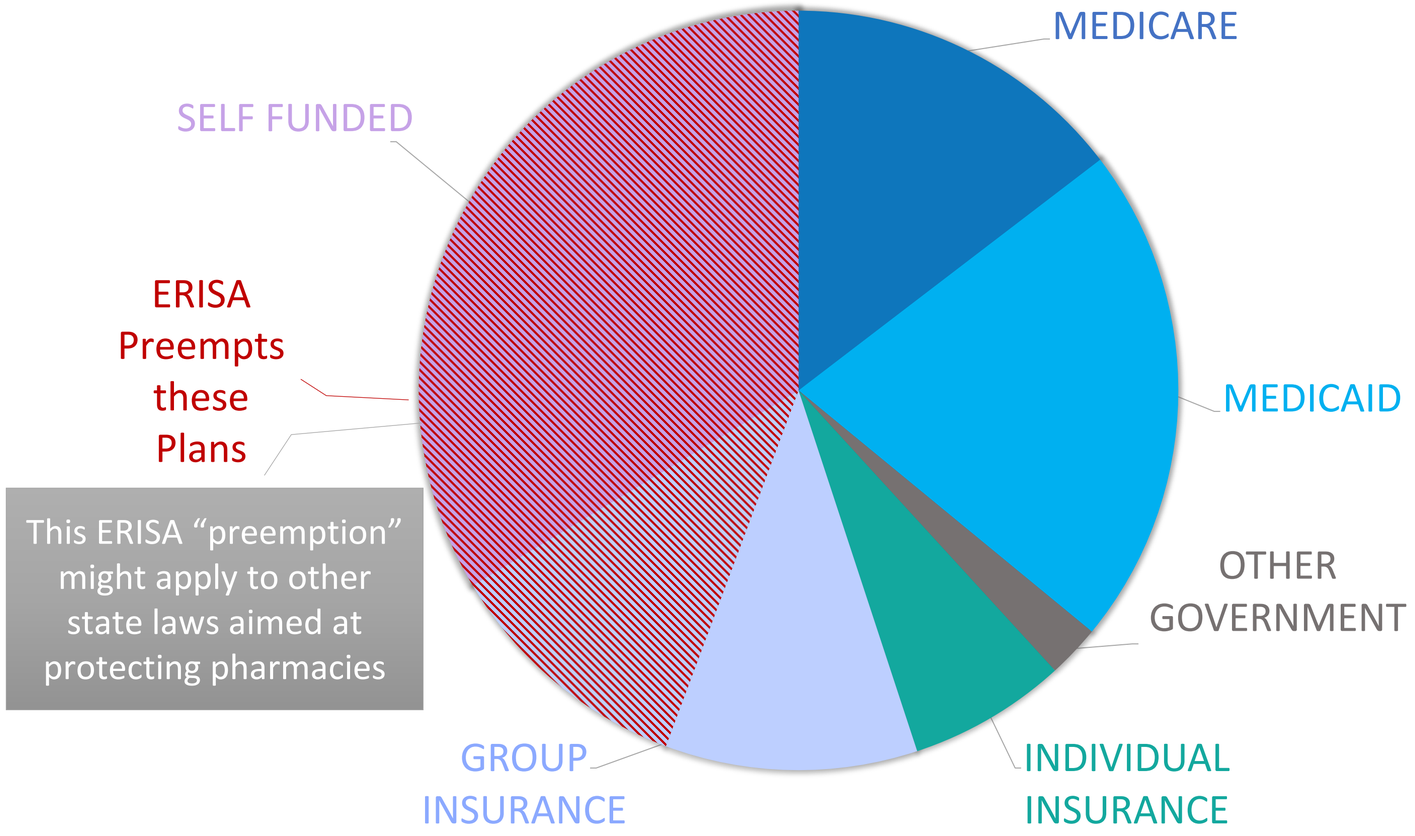
Employee Retirement Security Act ("ERISA"), 29 U.S.C. §§ 1001 – 1461: federal law governing employee **health benefits**

ERISA requires that every Plan include a Summary Plan Description ("SPD")

ERISA preempts state laws, such as AWPL

However, states still have right to regulate "the business of insurance"

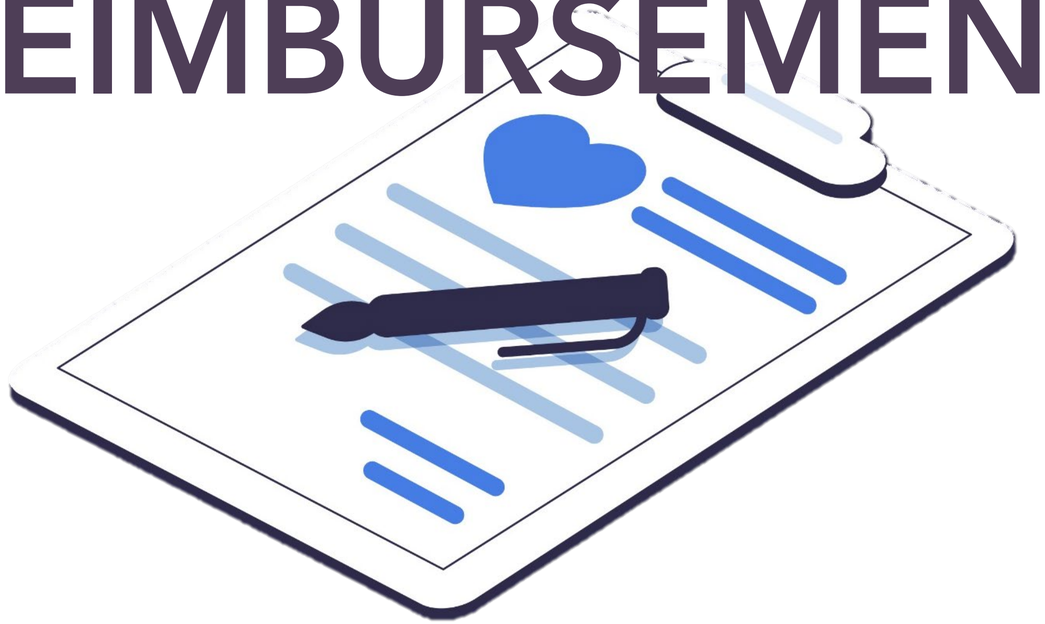
Don't trust PBMs on Plan **"exclusion"** for Self-Funded Plans



This ERISA "preemption" might apply to other state laws aimed at protecting pharmacies

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

COVERAGE & REIMBURSEMENT



VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

VA's Maximum Allowable Cost "MAC" Law:

MAC: a pricing metric, usually defined as the maximum amount a PBM will reimburse for the cost of certain drugs, typically multiple source prescription drugs; often MAC is applied to generics.

Legal Issues:

- MAC is a pricing metric but ***set entirely by the PBM***.
- Application of MAC pricing/reimbursement to Brands/Single Source ***Generics***.
- Two commonly used pricing metrics: AWP and WAC—the basis for AWP and WAC are known; publicly available—we at least have agreement on a starting point.
- By contrast, ***basis for MAC is kept secret by PBMs***—each PBMs' MAC prices are "black box" (pharmacies/public do not have access.)
- PBMs create ***two MAC lists:*** A ***Plan*** MAC List and a ***Provider*** MAC List
  - Allows PBMs to collect more from the Plan and reimburse less to Providers—this is "Spread Pricing", and MAC is a key tool used by PBMs to effectuate Spread Pricing.
- VA state law Prohibits ***Spread Pricing*** (discussed further below).

Suggested Improvements to VA's MAC Law

Existing MAC Law: Va. St. Ann. § 38.2-3407.15.3:

- **PBMs must:** At least every 7 days, ensure MAC listed drugs are readily available and that MAC list is current with up-to-date information (cannot use outdated lists/information with pricing that favors PBM)
- **Provide MAC Appeal Process which includes:**
  - Minimum 14 days to appeal; PBM must respond in 14 days

Improve Law by adding additional Legal Tools for Providers:

- PBMs' minimum MAC must be ***equal or greater than Providers' acquisition cost***.
- If MAC appeal is successful, PBM must adjust reimbursement ***for all similarly situated Providers*** in the Network.
- PBM failure to comply with MAC Law to be considered a violation of the State's unfair trade practices act (or other similar state specific law/legislation).
- Add an ***express Private Right of Action*** to pursue private civil remedies directly against PBM for violating MAC law.

Virginia Spread Pricing Law

Spread Pricing occurs where a PBM charges MORE to a health plan for prescription drugs than the PBM pays the pharmacy to dispense that drug

- Va. St. Ann. § 38.2-3467 ***prohibits PBMs from engaging in spread pricing.***
  - "No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall conduct spread pricing in the Commonwealth."
- Va. St. Ann. § 38.1-325 Prohibits Spread Pricing on Commonwealth's Medicaid managed care program.

What should pharmacies do?

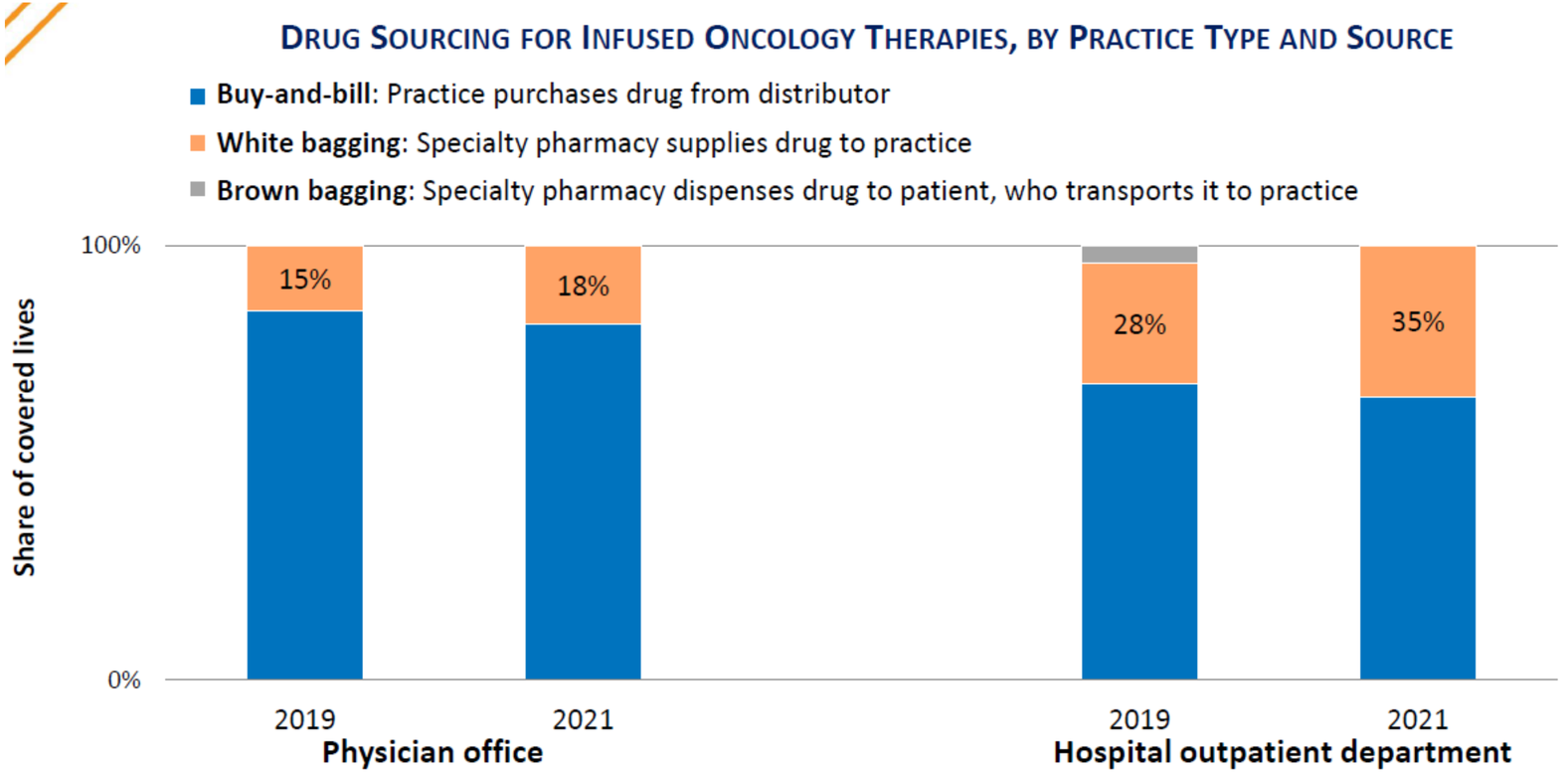
- Fight PBMs engaged in illegal spread pricing.

Plan Sponsors should be encouraged to utilize this law and audit PBMs to discover an illegal spread.

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Mandatory White Bagging

In mid-2020, several large payors took virtually identical conduct to require that i***n-office infused medications*** be ***filled at the Payor's wholly-owned specialty pharmacies*** or removing the ability altogether of providers to source and seek reimbursement for medications administered in their facilities.



Source: *The 2021-22 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors*, Exhibit 42. Figures for 2019 based on 48 commercial plans representing 126.6 million covered lives. Figures for 2021 based on 51 commercial plans representing 124.9 million covered lives. See White Bagging Update: PBMs' Specialty Pharmacies Keep Gaining on Buy-and-Bill Oncology Channels. Drug Channels. October 2021.

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Mandatory White Bagging

18 VAC 110-20-275 regulates White Bagging

- White bagging is permitted in Virginia, but certain requirements must be met.
- ***VA's White Bagging law would be Improved if it:***
  - Prohibited PBM from forcing patients to fill prescriptions at PBM affiliated pharmacy.
  - Prohibited PBMs from requiring physicians to accept White Bagged medications.
  - Prohibited pharmacies from dispensing chemotherapy or any hazardous drugs directly to their patients, their representatives, or their private residences.

What can providers do?

- Although VA's regulation of White Bagging doesn't prevent mandatory white bagging, other VA state laws help prevent similar patient steering tactics and protect a patient's right to receive treatment from a provider of their choice.
- Va. St. Ann. § 38.2-3467 ***prohibits PBM interference with an individual's right to choose*** a provider.
  - Providers should ***encourage their patients to utilize Virginia's Freedom of Choice laws*** to combat common PBM patient steering tactics.

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Preventing Patient Steering

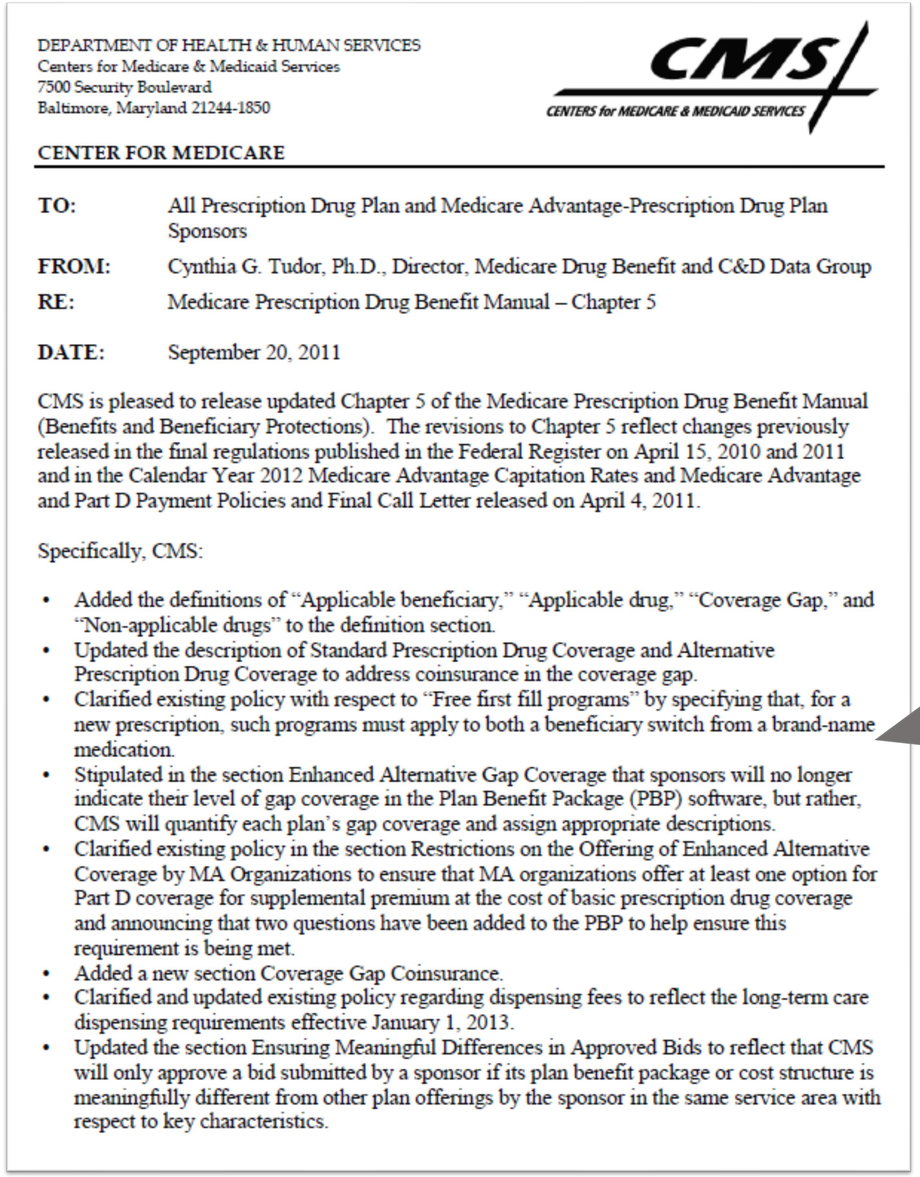
Practices Must Demand PBM Adherence to the Law

Practices May Inform Patients of Their Rights

Complaints to State and Federal Regulatory Agencies (including FTC)

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS



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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

CENTER FOR MEDICARE

TO: All Prescription Drug Plan and Medicare Advantage-Prescription Drug Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C&D Data Group

RE: Medicare Prescription Drug Benefit Manual – Chapter 5

DATE: September 20, 2011

CMS is pleased to release updated Chapter 5 of the Medicare Prescription Drug Benefit Manual (Benefits and Beneficiary Protections). The revisions to Chapter 5 reflect changes previously released in the final regulations published in the Federal Register on April 15, 2010 and 2011 and in the Calendar Year 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter released on April 4, 2011.

Specifically, CMS:

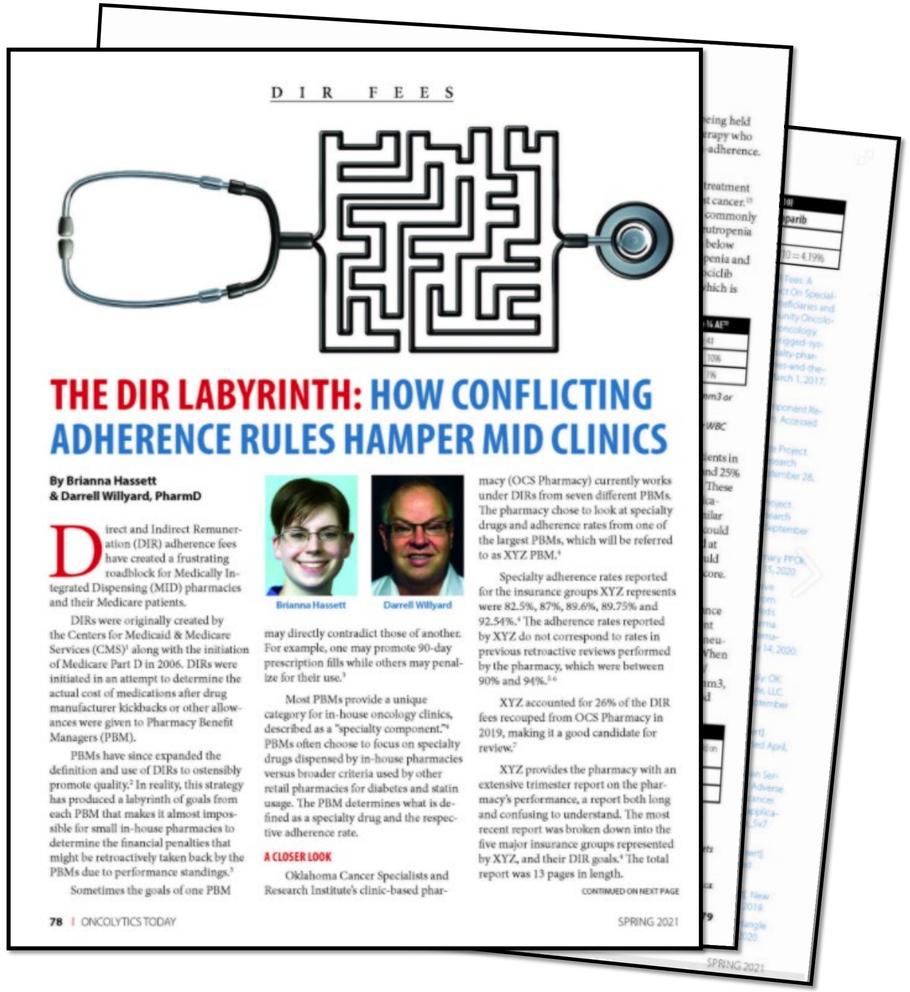
- Added the definitions of "Applicable beneficiary," "Applicable drug," "Coverage Gap," and "Non-applicable drugs" to the definition section.
- Updated the description of Standard Prescription Drug Coverage and Alternative Prescription Drug Coverage to address coinsurance in the coverage gap.
- Clarified existing policy with respect to "Free first fill programs" by specifying that, for a new prescription, such programs must apply to both a beneficiary switch from a brand-name medication.
- Stipulated in the section Enhanced Alternative Gap Coverage that sponsors will no longer indicate their level of gap coverage in the Plan Benefit Package (PBP) software, but rather, CMS will quantify each plan's gap coverage and assign appropriate descriptions.
- Clarified existing policy in the section Restrictions on the Offering of Enhanced Alternative Coverage by MA Organizations to ensure that MA organizations offer at least one option for Part D coverage for supplemental premium at the cost of basic prescription drug coverage and announcing that two questions have been added to the PBP to help ensure this requirement is being met.
- Added a new section Coverage Gap Coinsurance.
- Clarified and updated existing policy regarding dispensing fees to reflect the long-term care dispensing requirements effective January 1, 2013.
- Updated the section Ensuring Meaningful Differences in Approved Bids to reflect that CMS will only approve a bid submitted by a sponsor if its plan benefit package or cost structure is meaningfully different from other plan offerings by the sponsor in the same service area with respect to key characteristics.

Medicare Prescription Drug Benefit Manual Chapter 5, Section 50.3

CMS stated that "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 the AWPL

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

“Willyard Analysis” – The Impact of Improper Adherence Measurements on DIR Fees



DIR FEES

THE DIR LABYRINTH: HOW CONFLICTING ADHERENCE RULES HAMPER MID CLINICS

By Brianna Hassett & Darrell Willyard, PharmD

Direct and Indirect Remuneration (DIR) adherence fees have created a frustrating roadblock for Medically Integrated Dispensing (MID) pharmacies and their Medicare patients.

DIRs were originally created by the Centers for Medicaid & Medicare Services (CMS)[1] along with the initiation of Medicare Part D in 2006. DIRs were initiated in an attempt to determine the actual cost of medications after drug manufacturer kickbacks or other allowances were given to Pharmacy Benefit Managers (PBM).

PBMs have since expanded the definition and use of DIRs to ostensibly promote quality.[2] In reality, this strategy has produced a labyrinth of goals from each PBM that makes it almost impossible for small in-house pharmacies to determine the financial penalties that might be retroactively taken back by the PBMs due to performance standings.[3]

Sometimes the goals of one PBM may directly contradict those of another. For example, one may promote 90-day prescription fills while others may penalize for their use.[3]

Brianna Hassett

Darrell Willyard

Most PBMs provide a unique category for in-house oncology clinics, described as a "specialty component."[4] PBMs often choose to focus on specialty drugs dispensed by in-house pharmacies versus broader criteria used by other retail pharmacies for diabetes and statin usage. The PBM determines what is defined as a specialty drug and the respective adherence rate.

A CLOSER LOOK

Oklahoma Cancer Specialists and Research Institute's clinic-based pharmacy (OCS Pharmacy) currently works under DIRs from seven different PBMs. The pharmacy chose to look at specialty drugs and adherence rates from one of the largest PBMs, which will be referred to as XYZ PBM.[4]

Specialty adherence rates reported for the insurance groups XYZ represents were 82.5%, 87%, 89.6%, 89.75% and 92.54%.[4] The adherence rates reported by XYZ do not correspond to rates in previous retroactive reviews performed by the pharmacy, which were between 90% and 94%.[5-6]

XYZ accounted for 26% of the DIR fees recouped from OCS Pharmacy in 2019, making it a good candidate for review.[7]

XYZ provides the pharmacy with an extensive trimester report on the pharmacy's performance, a report both long and confusing to understand. The most recent report was broken down into the five major insurance groups represented by XYZ, and their DIR goals.[4] The total report was 13 pages in length.

CONTINUED ON NEXT PAGE

- PBMs use “Adherence” measurements to calculate DIR fees
  - Poor Adherence increases DIR fees
- Dr. Darrell Willyard article: PBMs use patient adverse events and appropriate drug holidays, to inappropriately hurt "adherence rating"
- Failure to accurately measure true adherence violates provider contracts and applicable law
- Providers can successfully challenge DIR fees based on flawed adherence measurements

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Sample Caremark Trimester Report

2020 CVS Caremark Medicare Part D Retail Performance Network Program™: Trimester 3 Report

Financial Results

Performance Plan Name	Final Overall Performance Score	Network (Variable Rate Range %)	Variable Rate	Est Total Ingredient Cost (IC) Paid	Est Total IC Paid Times Variable Rate
WellCare Health Plans	82.70%	72 B (7.5-9.5)	8.3%	$ 87,102	$ 7,229
		72 G (14.0-16.0)	14.8%	$ 403	$ 60
		73 B (10.0-12.0)	10.7%	$ 445,690	$ 47,689
		73 G (8.0-10.0)	8.7%	$ 52	$ 5

Performance Results

Category	Medication Adherence					Other Categories			Final Overall Performance Score
Performance Criteria	RAS Antagonists[1]	Statins[2]	Diabetes[3]	Non-Specialty Component	Specialty Component[4]	Gap Therapy (Statin)[5]	CMR Completion Rate MTM)[6]	Formulary Compliance[7]	
Volume					8			177	
Score				84.78%	86.93%	80.52%	50.55%	100.00%	
Criteria Weight				28.13%	46.88%	10.00%	10.00%	5.00%	
Weighted Score				**23.84%**	**40.75%**	**8.05%**	**5.05%**	**5.00%**	**82.70%**

Specialty Performance Results

Category	Specialty Medication Adherence									
Performance Criteria	HIV	Immune Inflammatory Disorders	Lipid Disorders PCSK9 Inhibitors	Multiple Sclerosis	Oncology	Osteoporosis	Pulmonary Arterial Hypertension	Renal Disease	Transplant	Specialty Component[4]
Volume	0	0	0	0	8	0	0	0	0	8
Score	0.00%	0.00%	0.00%	0.00%	86.93%	0.00%	0.00%	0.00%	0.00%	86.93%
Criteria Weight	0.00%	0.00%	0.00%	0.00%	46.88%	0.00%	0.00%	0.00%	0.00%	46.88%
Weighted Score	0.00%	0.00%	0.00%	0.00%	40.75%	0.00%	0.00%	0.00%	0.00%	**40.75%**

Available at: https://communityoncology.org/wp-content/uploads/2021/06/COA_EnC_DIRFees_04-7-21_FINAL-C.pdf

- How Does Caremark Calculate the Final Overall Performance Score (***FOPS)***?
- How Does Caremark Calculate the ***Variable Rate***/DIR Fee %?
- What Portion of Your FOPS is Based on *Your Data*?
- What is the Impact of ***Blank Cells*** and Mean Imputation?
- How does Caremark Calculate Specialty Medication Adherence for Oncology Providers? What Does Caremark Not Measure?

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Express Scripts DIR Fees

DIR Fees collected prior to payment as adjustments

- Program based on opaque performance metrics that may not be relevant to specialty oncology providers
- DIR Fees based on a percentage of Average Wholesaler Price (AWP)
- Up to 6% of AWP and is more consequential to specialty providers dispensing high priced medications
- Potential return of DIR Fees, but only for the top 1% of providers Express Scripts deems “high performers”
  - Not anticipated to include specialty providers due to utilization of inapplicable metrics

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Recent Unsealed DIR Fee Case Victories Highlight Unfairness of Performance Metrics

- *Senderra Rx Partners, LLC v. CVS Health Corporation et al.*, No. 2:19-cv-05816 (D. Ariz.)
  - ***$3.1*** million award returning DIR Fees to the pharmacy, along with attorneys' fees, interest, and costs

- *Caremark et al. v. AIDS Healthcare Foundation*, No. 2:21-cv-01913 (D. Ariz.)
  - ***$23*** million award including 100% of DIR Fees, reasonable attorneys' fees and costs
  - Caremark has not paid this award, and instead has sought to vacate the judgment

- *Mission Wellness Pharmacy, LLC v. Caremark, LLC et al.*, No. 2:22-cv-00967 (D. Ariz.)
  - ***$3.6*** million award including 100% of DIR Fees, pre-judgement interest, attorneys' fees and costs
  - Caremark has not paid this award, and instead has sought to vacate the judgment (Caremark also unsuccessfully fought efforts to unseal the federal court proceedings)

- PBMs employ a variety of tactics to suppress any effort to hold them accountable:
  - Confidential arbitrations
  - Prohibitions on class, coordinated, consolidated or even multiparty actions
  - Fee shifting provisions (including requirement for providers to place $50,000 or more into escrow to initiate a dispute)
  - Panel of three arbitrators' costs of which must be borne equally by provider
  - Discovery limitations (including limitations on depositions and paper discovery, and prohibitions on seeking discovery on other disputes with other providers)
  - 6-month statute of limitation to bring claims
  - Contractual attempts to limit damages and interpretation of laws (including any willing provider law)

CURRENT DIR FEE ENVIRONMENT

Federal Action:

- Greater Momentum at Federal Level for Oversight and Regulation of PBMs
- On June 7, 2022, FTC announces investigation into 6 largest PBMs including Caremark, ESI, and OptumRx
- Significant development; unanimous 5-0 vote to investigate after Public Comment period; statements from FTC commissioners reflect serious concerns: "***Something is rotten in the state of the U.S. pharmaceutical market, and it warrants serious investigation***."
- Sens. Chuck Grassley and Maria Cantwell introduce legislation to empower FTC to increase drug pricing transparency and hold PBMs accountable for unfair and deceptive trade practices that increase costs of prescription drugs

State Level Action:

- States have been reinvigorated to challenge PBMs (due mostly to Rutledge v. PCMA outcome)
- New York State (previously declined to enact PBM bill due to preemption concerns pre-Rutledge)
    - Early 2022, new legislation takes effect governing and regulating PBMs in New York
    - On May 11, 2022, Governor announces establishment of Pharmacy Benefits Bureau
    - Bureau has already solicited Public Comments on two areas related to PBMs
        - Public Comment on Duty, Accountability, and Transparency of PBMs to Health Plans
        - Applicability of NY Insurance Law Article 29 and Public Health Law 280-a to PBMs in Medicare

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Issue of Co-Pay Accumulators:

Definition of Co-Pay Accumulators:

- Copay Accumulator is a strategy used by PBMs to stop manufacturer-sponsored copayment cards or other manufacturer-assistance programs from counting towards a patient's deductible and/or annual out-of-pocket maximum.
- By using Copay Accumulators, PBMs reduce the value of manufacturer-assistance programs by exhausting such funds and also requiring patients to pay deductibles and co-insurance up to their out-of-pocket maximums.

Some of the Negative Effects:

- Lower Medication Adherence
- Decreased Use of Specialty Drugs

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Prohibitions on Co-Pay Accumulators

At the Federal Level:

- New ***CMS Final rule*** directly addresses the issue of co-pay accumulators. How so?
  - ***45 CFR § 156.130***, entitled "***cost-sharing requirements***," provides:

    (h) Use of manufacturer coupons. For plan years beginning on or after January 1, 2020:

    (1) Notwithstanding any other provision of this section, and to the extent consistent with state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs ***that have an available and medically appropriate generic equivalent are not required to be counted*** toward the annual limitation on cost sharing (as defined in paragraph (a) of this section).
  - Rule strikes a balance b/w encouraging adherence to medications where copayments may be unaffordable to many patients and there are no affordable alternatives and discouraging physicians and patients from choosing an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available.

Prohibitions on Co-Pay Accumulators:

At the State Level:

- VA was one of the first states to take action to address co-pay accumulator issue.
- VA enacted H.B. 2515, essentially banning PBM co-pay accumulators and forcing PBMs to count any payments made on an enrollee's behalf toward their deductible.
- Va. St. Ann. § 38.2-3407.20
  - Requires insurers to account for any payments made on an insured's behalf in addition to the payments made by the insured when calculating the overall out-of-pocket cost sharing.
- VA is on the frontline of this issue and VA providers/residents are well positioned on this issue.

How to Challenge Copay Accumulators

Use the federal and state laws but also:

- Review Summary Plan and Plan documents
- Under most plans, patients can either make a grievance or a coverage determination:
  - A ***coverage determination*** is the decision the insurer will make as relates to payments for the patients' benefits, prescriptions costs, and other coverage issues
  - A ***grievance*** is a general statement of dissatisfaction about the plan (i.e. copay accumulator)
- ***Providers can pursue*** action against an insurer *on behalf of a patient* if the patient does either of the following:
  - ***Assigns*** his/her benefits to the provider
  - ***Appoints the provider*** as the patient's Power of Attorney

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

REGULATORY THREATS

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

In Office Ancillary Services Exception and Mailing

- IOAS Exception has traditionally been used by IODs/MIDs to protect their in-office dispensing or physician owned pharmacy models

- Based on a CMS FAQ last year, this may no longer be available
  - CMS indicated that the location requirement of the exception is ***not*** met if a prescription drug is *mailed* to a patient

- Strategies for Moving Forward
  - File FOIA request to CMS
  - Request clarification from CMS regarding couriers
  - Pursue lobbying efforts
  - Explore applicability of other exceptions

Rebate "Aggregator" Payments for in Office Dispensing

- Rebate aggregator arrangements are being presented to physician dispensers. The aggregator offers ***to obtain manufacturer rebates*** on behalf of the practice for certain products that have been dispensed or, more commonly, administered *to patient in office*
- Regulatory Concerns
  - HIPAA – PHI cannot be shared with manufacturers
  - ***Fee splitting*** – the aggregators typically request a % fee based on the rebates collected
  - ***Kickback*** – the rebate (no matter how many intermediaries between prescriber and manufacturer) may constitute remuneration in exchange for a referral (ordering/administering the drug) and does not meet a safe harbor
- These models offer little transparency and require careful regulatory review to assess applicable exposure.

Physician Dispensing vs. Retail Pharmacy in Virginia

Permitted as a Pharmacy

- Pursuant to Va. Code § 54.1-3304, Board of Pharmacy may issue a pharmacy license to physician practice
- May be issued when good cause is shown that pharmacy services are not otherwise readily available (i.e., there is not a pharmacy within 15 to 20 miles)
- Few of these licenses still remain

Physicians Selling Drugs

- Pursuant to Va. Code § 54.1-2914, a physician my obtain a permit from the Board of Pharmacy to "sell" "controlled substances" ("controlled substances" extends to all prescription drugs)
- Requires compliance with other rules applicable to licensed pharmacies
- Every physician in the practice must be individually licensed
- More common method of physician dispensing

Physician Dispensing vs. Retail Pharmacy in Virginia

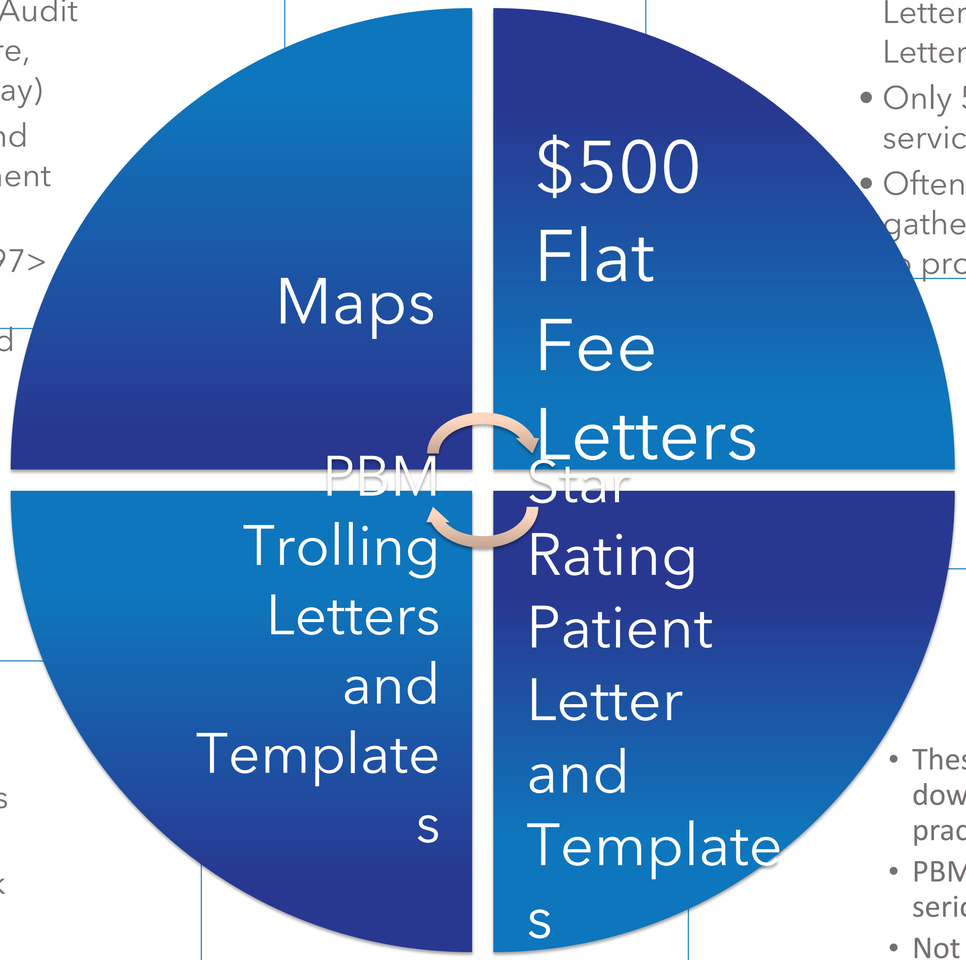
Licensed Retail Pharmacy		Dispensing Physician	
Pro's	***Con's***	***Pro's***	***Con's***
• May freely employ pharmacists and pharmacy technicians without issue	• Must employ full time pharmacist-in-charge	• Not required to employ pharmacist-in-charge	• Potentially limited in ability to employ pharmacy technicians as support staff
• Able to obtain access to PBM networks only allowing licensed retail pharmacies	• Limited to locations where another pharmacy provider is not readily nearby	• Potentially have access to better class of trade pricing based on dispensing physician status	• Certain PBMs (i.e., Prime Therapeutics, MedImpact) have refused access to or terminated dispensing physician practices on the basis that they are not licensed retail pharmacies
• Potentially able to get access to certain Medicaid fee-for-service pharmacy programs limiting access to licensed pharmacies		• Solo practitioners exempt from certain licensing fees	• Certain Medicaid plans have taken position that fee-for-service is only available to licensed pharmacies or otherwise required dispensing physicians to be reimburse at actual invoice cost
• Permitted to dispense to patients who are not necessarily patients of the medical practice			• Limited to dispensing to patients of the medical practice
			• Limited in the ability to sell devices or appliances to patients

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Legal Strategies for Practices

- 50+ state surveys on 6 topics (AWPL, DIR, Audit Laws, PBM Licensure, MAC and Prompt Pay)
- Pointers on gaps and areas for improvement
- Propose additional surveys on USP <797> and <800> implementation and compliance



- PBM Network Exclusion Letter and First Fill Only Letter
- Only 5 have utilized service
- Often issues with gathering necessary data to prosecute claim

- These are available for download and use by practices on their own
- Includes complaints to agencies
- Not much feedback on use or effectiveness

- These are available for download and use by practices on their own
- PBMs take Star Ratings seriously
- Not much feedback on use or effectiveness

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

Questions?

Thank You!

JONATHAN E. LEVITT, ESQ.
jlevitt@frierlevitt.com

FRIER LEVITT
ATTORNEYS AT LAW

FrierLevitt.com
973.618.1660

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS