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PBM Landscape for Dispensing Physician Providers

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Presented by:

Harini Bupathi, Esq.

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About Frier Levitt

Frier Levitt is a national boutique healthcare law firm located in Pine Brook, New Jersey. Our attorneys bring collective experience and backgrounds in pharmacy, hospital administration, professional licensing, Attorney General actions, clinical practice, and medical billing. Through our experience in representing thousands of pharmacies across the country, we have developed strong relationships with key decision-makers at each Pharmacy Benefit Manager and have successfully fought on behalf of pharmacies and healthcare providers in conducting PBM audit appeals and disputes. Frier Levitt provides directed and uniquely-tailored legal services to community pharmacies including network issues, State and Federal Any Willing Provider laws, regulations. Moreover, Frier Levitt also provides comprehensive legal services to our healthcare clients, including corporate and transactional services, regulatory advice, and litigation support.

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ABOUT OUR PRESENTER

Harini Bupathi, Esq.
Associate

Harini Bupathi, Esq. is an associate in Frier Levitt's Life Sciences practice group. Harini's practice focuses on counseling different types of pharmacy providers, including dispensing physician providers, on their relationships with Pharmacy Benefit Managers (PBMs) and other similar payors. She advises clients in a wide range of PBM-related matters including network access, audits, termination, wrongful recoupment actions, and fraud, waste, and abuse investigations. Harini utilizes her knowledge and experience to counsel on strategies and best practices to avoid any adverse action from payors and PBMs and to prevent action from regulatory agencies.

LEARNING OBJECTIVES

1. Discuss the current pharmacy benefits landscape to identify barriers to entry for various PBM networks
2. Identify payor network admission criteria for various PBM networks and understand the legal tools providers can leverage
3. Examine PBM-imposed terms and conditions, including reimbursement and DIR fees

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.

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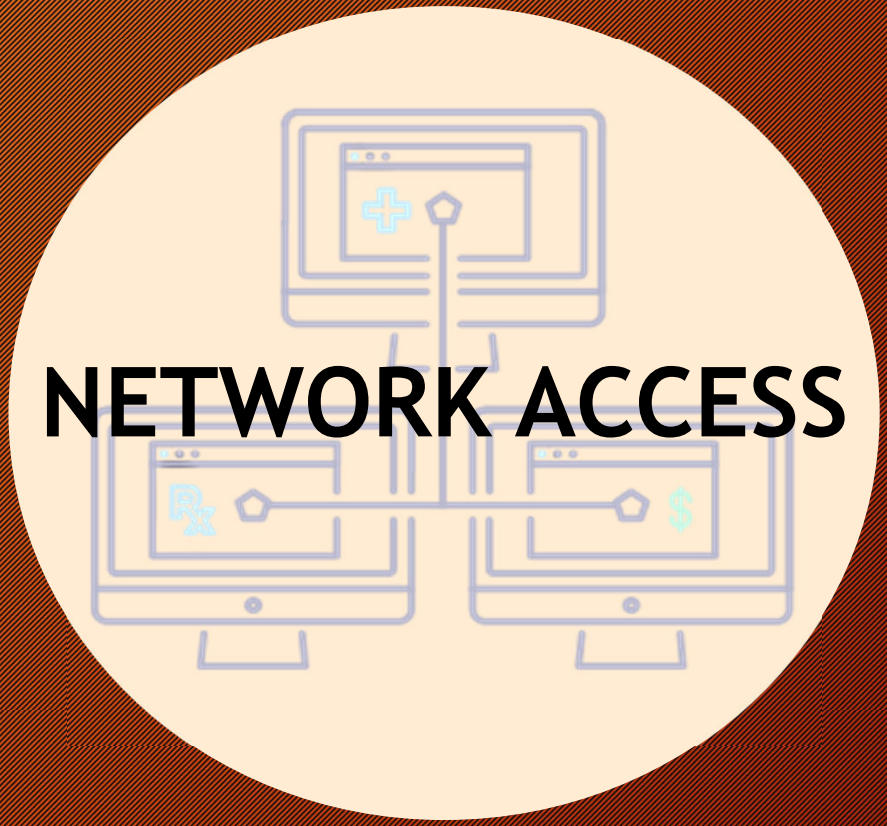
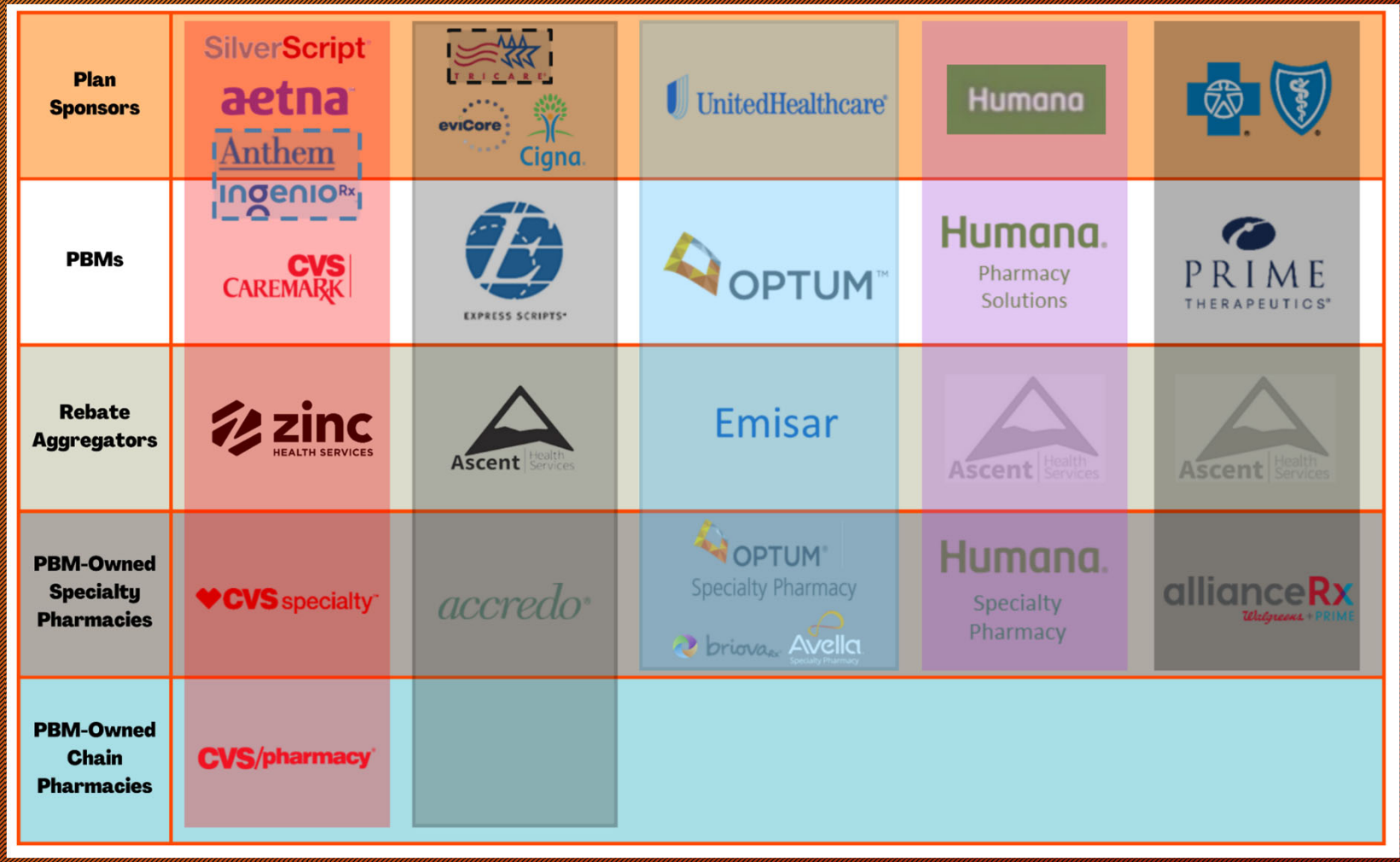


NETWORK ACCESS



PBM PAYOR PROBLEMS

- Common “slow-rolling” of network applications to PBM networks (i.e. CVS Caremark)
- Complete barriers of entry into PBM networks (i.e. MedImpact and Prime)
- FEP-BCBS Switch to CVS Caremark and Exclusion of Community Oncology practices
- New York Medicaid FFS Carve Out and Exclusion of Dispensing Physicians
- TRICARE reimbursement rates and provider network terminations

Federal Employee Program (FEP)-BCBS

- As of January 1, 2022, CVS Caremark took over administration of specialty and mail order pharmacy for FEP-BCBS
- Historically, community oncology practices (including PDPs) were able to participate in general networks and could dispense LDDs, particularly were Walgreens + Prime Alliance did not have access.
- Now, there has been an increase in denials and/or directing of patients to CVS Specialty.
- In response, CVS Caremark has claimed that under FEP guidelines, dispensing physician practices cannot be added to FEP networks and can be considered “Non-Preferred Providers.”

Express Scripts and TRICARE

- Express Scripts entered into a new 3-year contract with the Department of Defense to serve as PBM for the TRICARE program.
- As a result, in late July 2022, Express Scripts sent notices to network pharmacies and PSAOs about new network terms and conditions, including reimbursement rates. Express Scripts provided a limited time period to accept the terms.
- Express Scripts has been notifying patients of providers that did not accept the new rates that their provider is no longer in TRICARE networks as of October 24, 2022 and should obtain pharmacy services from Accredo.
- Approximately 15k pharmacies will no longer participate in TRICARE's networks.

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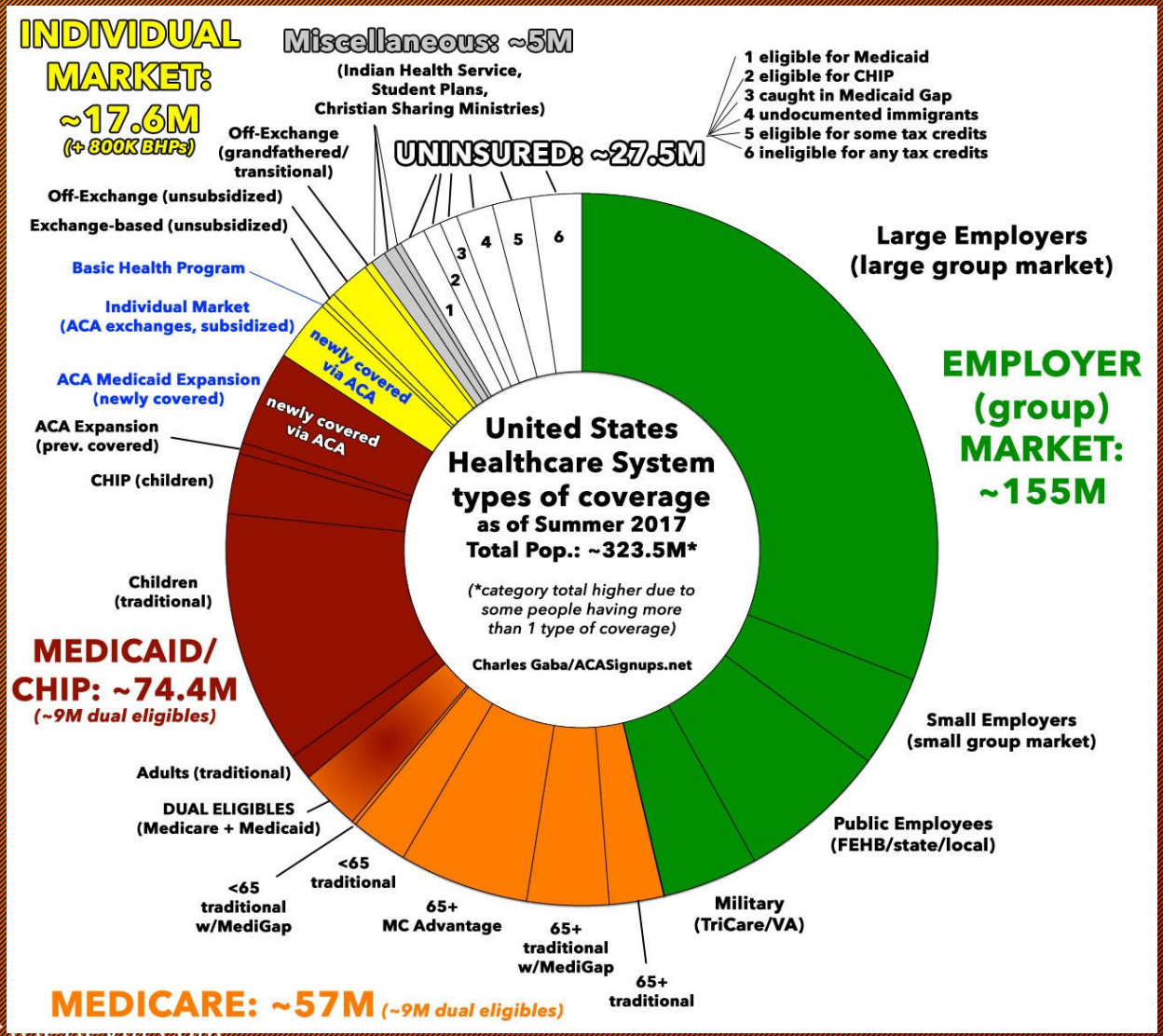
Type of Plan Impacts What Law Applies



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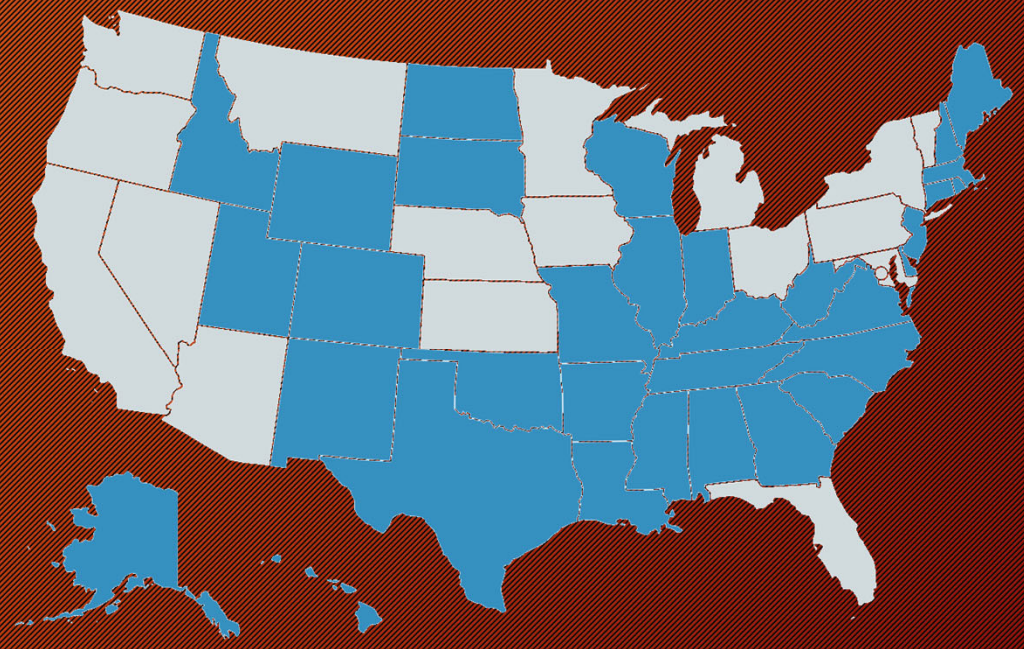
FEDERAL ANY WILLING PROVIDER LAWS

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



NEW JERSEY ANY WILLING PROVIDER LAWS

- New Jersey law requires that insurance companies allow subscribers to select a pharmacy or pharmacist of their choice
  - New Jersey Any Willing Provider Law mandates that "[N]o pharmacy…shall be denied the right to participate as a preferred provider or as a contracting provider, under the same terms and conditions currently applicable to all other preferred or contracting providers" if the pharmacy accepts the terms and conditions. i.e. N.J. Stat. Ann. § 17:48-6j
- New Jersey's AWPL is applicable to Commercial insurance and Medicaid Plans alike
- Limitation on dispensing does not apply to dispensing in the oncological context N.J.S.A. 45:9-22.11

MANDATORY WHITE BAGGING

- In mid-2020, several large payors took virtually identical conduct to require **that in-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.
- Some states have express "Anti-Patient Steering Laws" which generally prohibit healthcare providers from agreeing to send prescriptions to a particular pharmacy. New Jersey law provides that "[i]t shall be unlawful for a pharmacist to enter into an arrangement with a health care practitioner who is licensed to issue prescriptions, or any institution, facility, or entity that provides health care services, 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." *N.J. Admin. Code § 13:39-3.10*

Practices must demand PBM adherence to the law

Practices may inform patients of their rights

Complaints to State and Federal Agencies (including the FTC)

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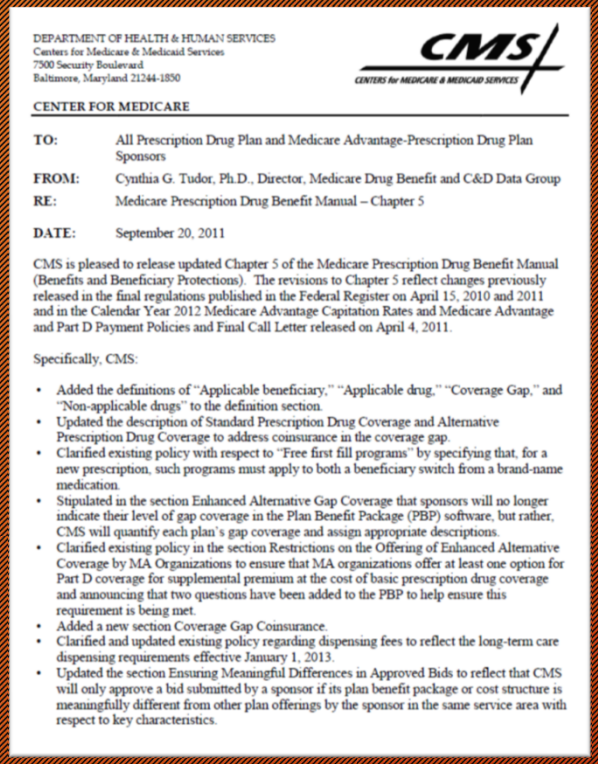
COVERAGE AND REIMBURSEMENT

MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, SECTION 5.50.3



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.

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

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"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

Brianna Hassett | Darrell Willyard

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]

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.[5]

Specialty adherence rates reported for the insurance groups XYZ represents were 82.5%, 87%, 89.6%, 89.75% and 92.54%.[6] 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%.[2,6]

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.[6] 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

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2020 CVS CAREMARK MEDICARE PART D PERFORMANCE NETWORK PROGRAM™: TRIMESTER 3 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%

- 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 Specialty Providers? What Does Caremark Not Measure?

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

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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)

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QUESTIONS?

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Let's continue the conversation

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