Prescription Drug Pricing Reform
A proposal to reduce health care costs

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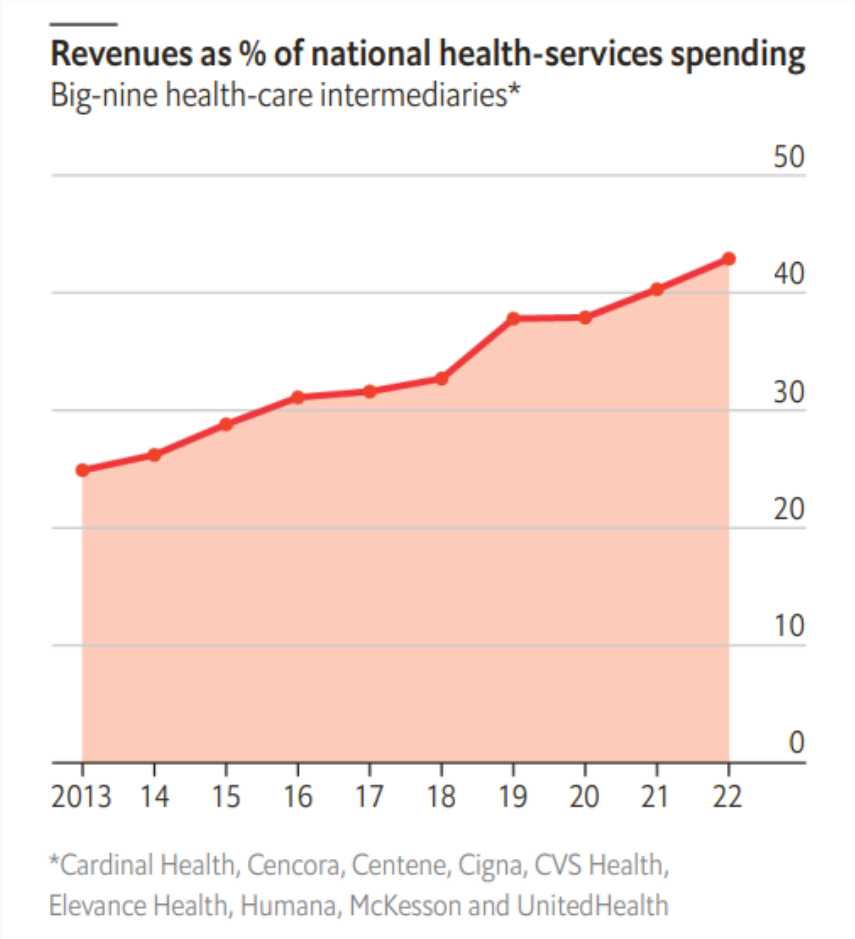
Agenda

- Refresher on Drugs as part of Health Care Costs
- Refresher on PBMs
- What the NM Legislature accomplished last year
- What remains to be done that we could do this year
- Future projects

Who is making the money in Health care

- $4.3 T every year, 17% of GDP
- 45% is controlled by middlemen in 2020, up from 25% in 2013
- Four Health Insurance companies cover 50% of Americans
- Four PBMs generate 60% of drug revenues
- Three PBMs handle 80% of all prescription claims
- Three Wholesalers control 92% of all drugs
  - Amerisource Bergen now Cencora
  - McKesson
  - Cardinal

- The Economist 10/8/23



REVENUES AS % OF NATIONAL HEALTH-SERVICES SPENDING

"Who Profits Most From America's Baffling health-care system? Hint: it isn't big pharma, The Economist, October 8, 2023.

MARKET SHARE FOR HEALTHCARE INTERMEDIARY SERVICES, %

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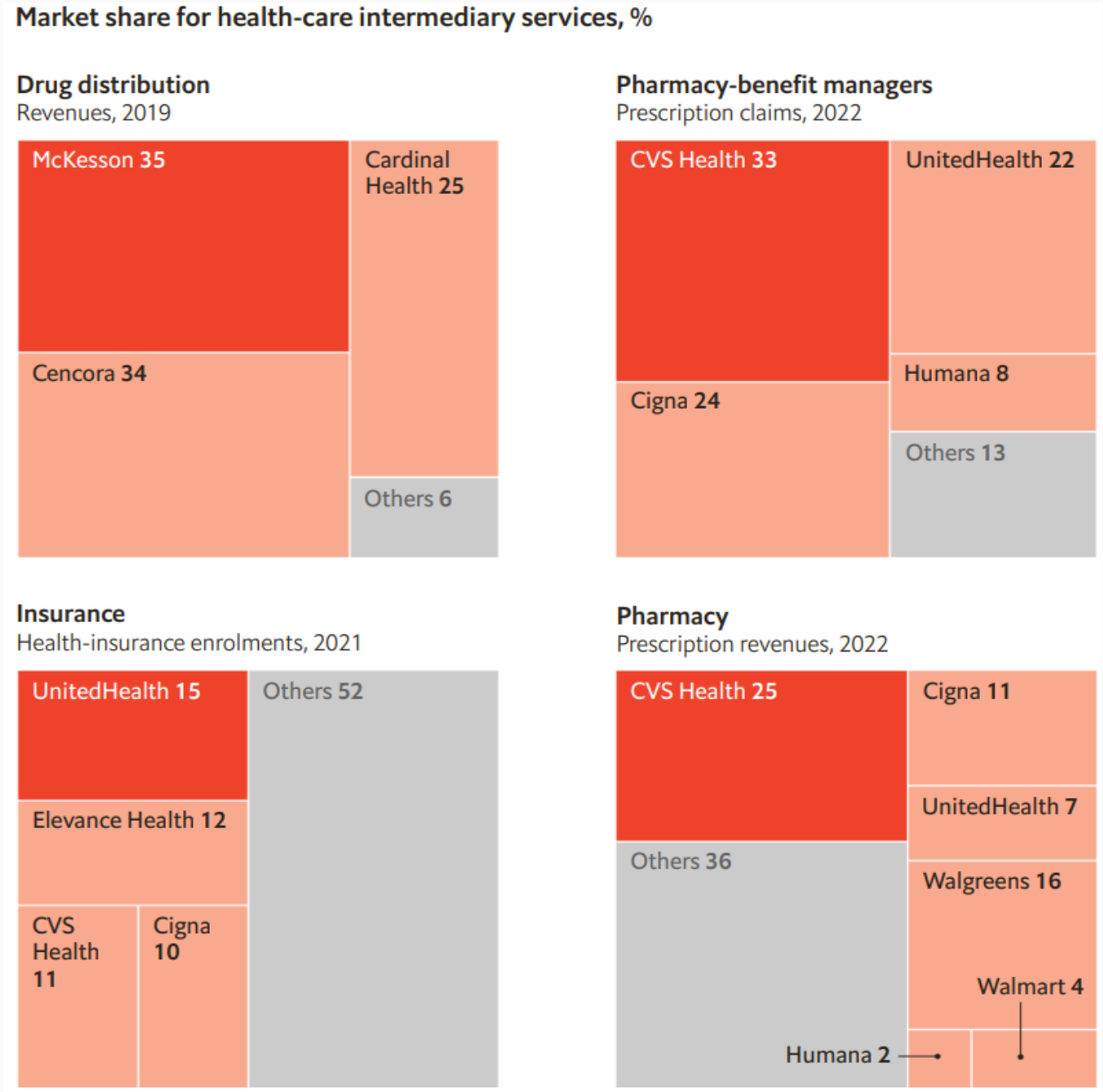
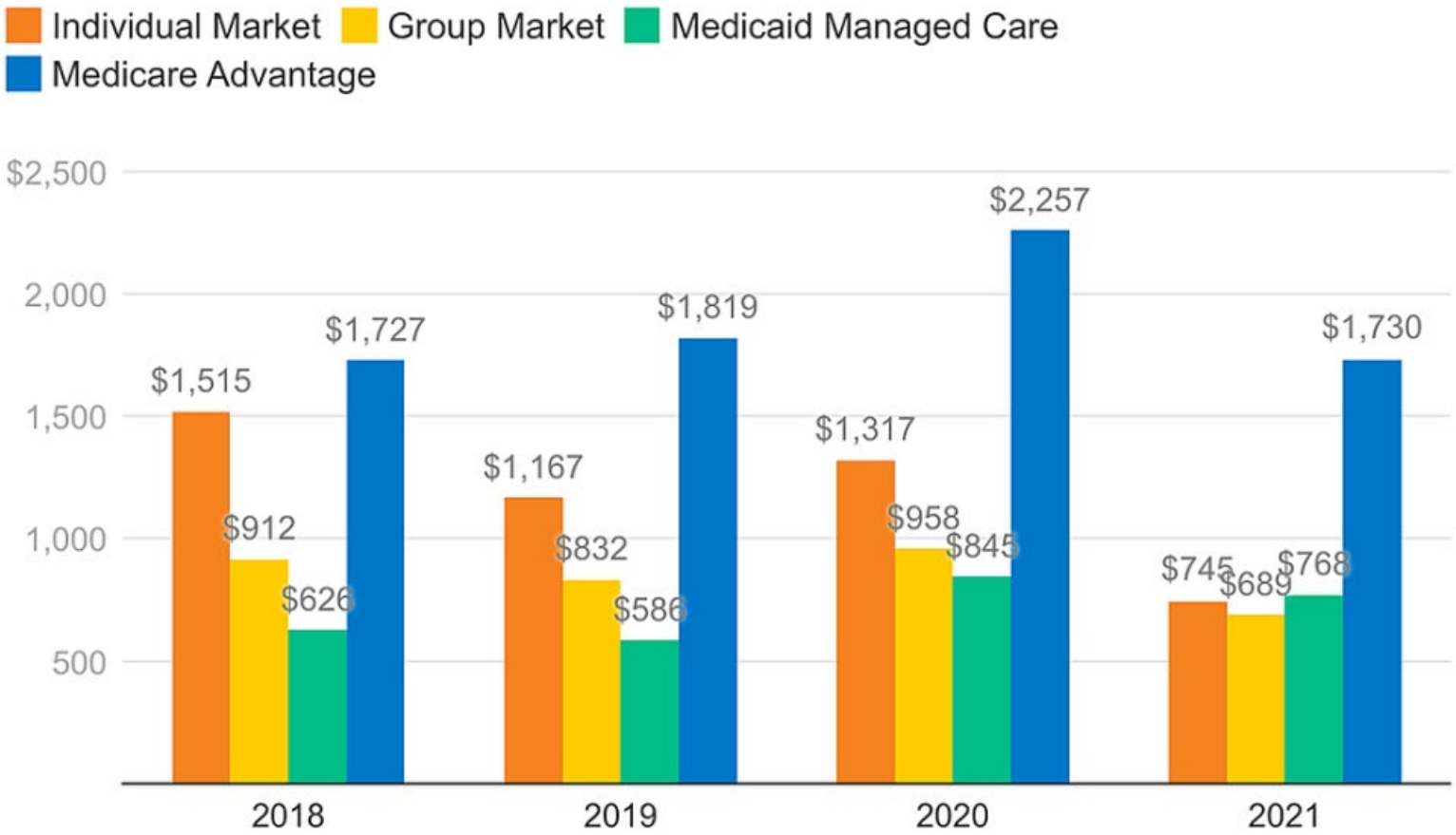


Gross Margins Per Enrollee, 2018-2021



NOTE: Gross margins per enrollee are the amount by which total premium income exceeds total claims costs, divided by the number of enrollees. Gross margins include administrative costs, tax liability, and profits.

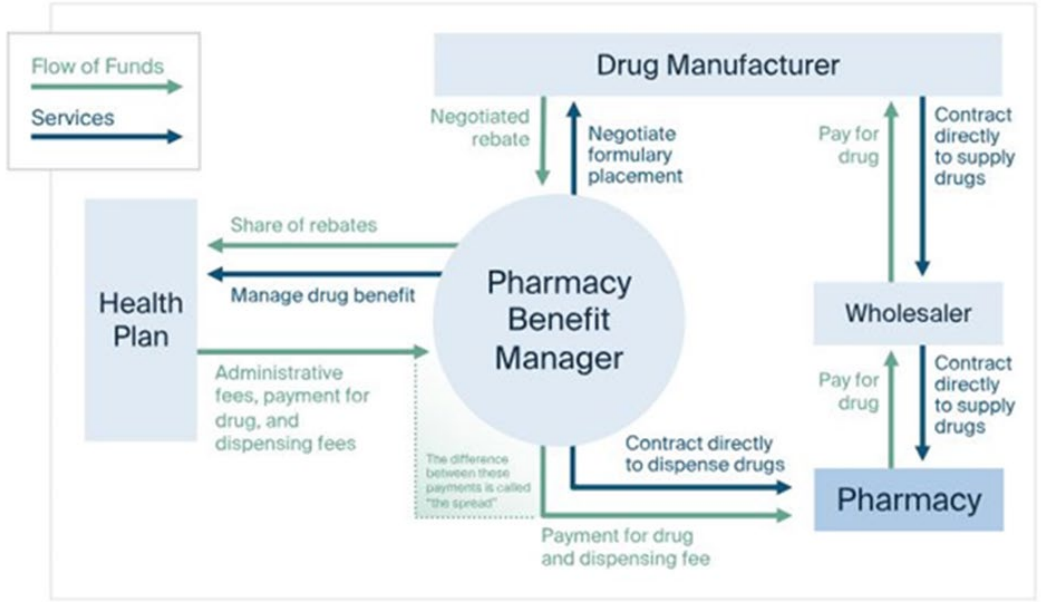
SOURCE: KFF analysis of data from Mark Farrah Associates Health Coverage Portal TM.

KFF

2/23 Kaiser Family Fund 2021

EXHIBIT 2

The Flow of Services and Funds in the Pharmaceutical Distribution Chain



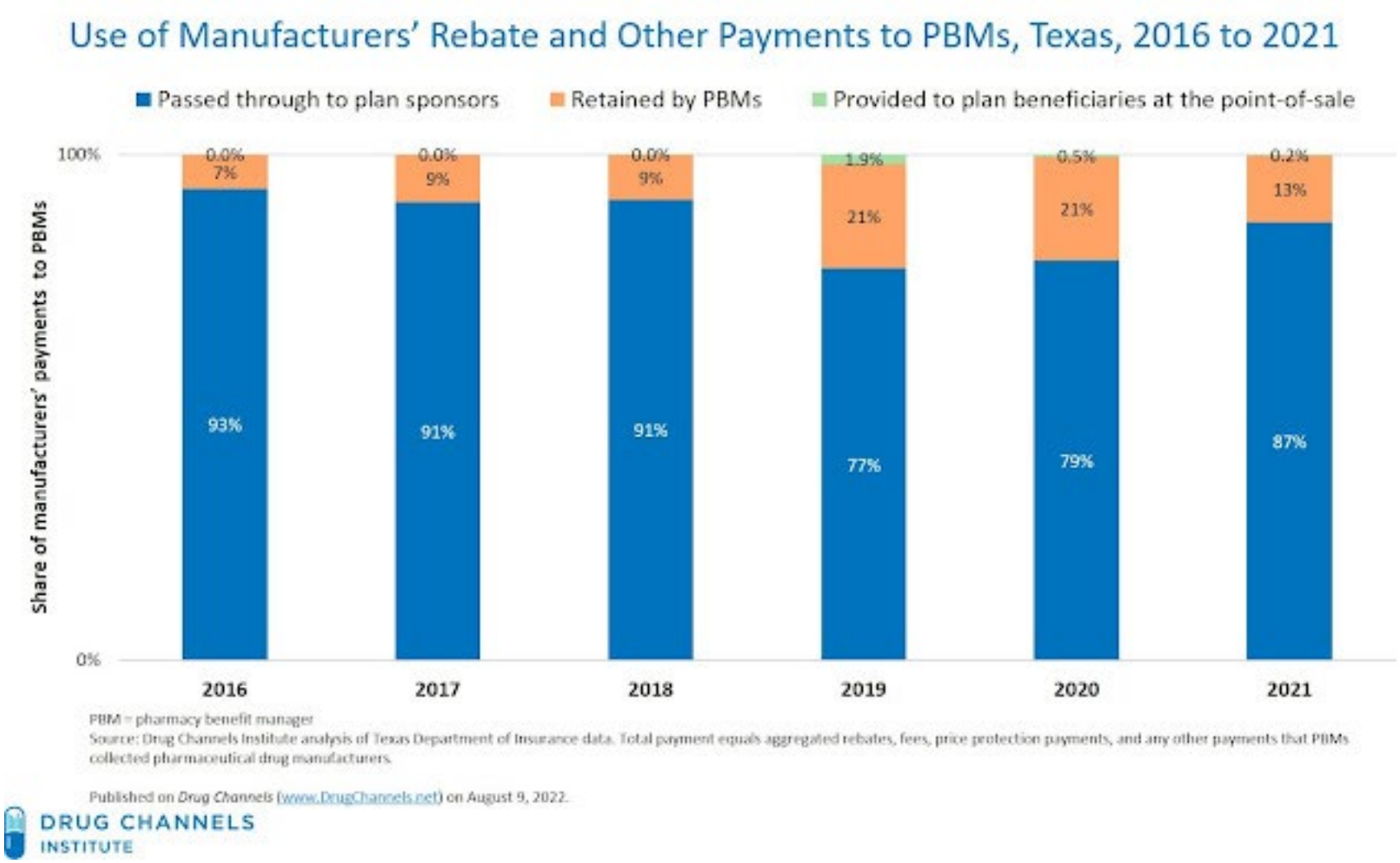
Data: Adapted from Elizabeth Seeley and Aaron S. Kesselheim, *Pharmaceutical Benefit Managers: Practices, Controversies, and What Lies Ahead* (Commonwealth Fund, Mar. 2019).

Source: Elizabeth Seeley and Surya Singh, *The Role of Pharmacies in Making Drug Purchasing More Efficient and in Promoting Access to Preventive Care* (Commonwealth Fund, Aug. 2021). https://doi.org/10.26099/g749-h298

Who are the Pharmacy Benefit Managers

Express Scripts, owned by Cigna, also known as Ascent	100M American Lives
CVS Caremark, purchased Aetna, also known as Zinc	100M American Lives
OPTUM RX, Owned by United Health Group, known as Emisar	65M American Lives 70,000 employed physicians

PBMs: Where do the Rebates go?



PBMs in Texas: From the Drug Channels Institute. Total annual rebate payments

2016	$558M
2019	$857M
2020	$2.4B
2021	$5.7B

COULD WE HAVE THE REBATES GO TO PATIENTS?

Justice Sotomayor opened the door to regulation of PBMs.

- Applying the logic of *Rutledge*, PBM laws are a form of health care cost regulation, and PBMs are not health plans but rather their administrative contractors, so ERISA should not preempt states' PBM regulations.
- Federal and state laws must still avoid regulating the benefits of plans or who is covered, but may regulate contractors like PBMs in regards to the cost of care.

Rutledge v. Pharmaceutical Care Management Association

- ERISA, 1974, Preempts laws that " relate to" employee benefits including health plans
- *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co. 1995 Supreme Court decision*
  - *NY regulations of hospital charges to plans was an indirect effect and did not dictate health plan decisions.*
- Court ruled 8-0 that the Employee Retirement Income Security Act (ERISA) did not preempt Arkansas's law regulating pharmacy benefit managers (PBMs),

What did Rutledge accomplish?

- Reaffirms that the goal of ERISA is to provide security for employee benefits and that the requirement to have uniformity of benefits is just a means to that and not a goal in itself,
- Allows states to affect costs and not benefit design of health plans
- State regulation of an intermediary contracted by a health plan does not “directly regulate health benefit plans at all.”
- *Rutledge* clarifies that states may regulate plans’ contractors, and that cost-control regulation is presumptively beyond ERISA’s preemptive scope

What did we accomplish with SB 51 in 2023?

- Removed Co Pay Accumulators
- Removed Co Pay Maximizers
- Stopped PBMs from acquiring the 340b Discounts
- Required Rebates go to patients

- Disclaimer: This only applies to the state regulated plans: ERISA plans and Medicare Advantage plans do not have to comply

Lowest Cost Distribution Channels

- Studies show that retail pharmacies provide lower generic drug costs than mail order
- Brand names slightly higher at retail pharmacies
- Medicare Part D cannot use lower copays to push patients to mail order but Commercial plans do in about 50%

- Jodi B. Segal et al., "Determinants of Generic Drug Substitution in the United States," *Therapeutic Innovation and Regulatory Science* 54, no. 1 (Jan. 2020): 151–57.
- Norman V. Carroll, "A Comparison of Costs of Medicare Part D Prescriptions Dispensed at Retail and Mail Order Pharmacies," *Journal of Managed Care & Specialty Pharmacy* 20, no. 9 (Sept. 2014): 959–67.

Loss of Independent Pharmacies

- Pharmacists are ideally positioned in their respective communities to address gaps in care by collaborating with other health care providers, which can help eliminate health disparities.
- A 2016 study found as the availability of pharmacies in a given area increased, hospital readmissions for people in Oregon 65 or older decreased.
- In the U.S., it is estimated medication nonadherence is associated with 125,000 deaths, 33%-69% of medication-related hospitalizations, and $100 to $300 billion in health care services annually.
- Pharmacists can help improve medication adherence and management of chronic diseases and potentially reduce costly hospital readmissions.

Patient Limited Access to Local Specialty Pharmacies

- Filling prescriptions at a local specialty pharmacy allows for ideal patient care
- Insurance preferred pharmacies often require patients to utilize mail order/ non-local pharmacies for specialty medications
- Example: Only 25 – 30 % of all new prescriptions for oral oncolytic medications prescribed by a provider from the University of New Mexico Comprehensive Cancer Center are able to be filled at the specialty pharmacy located in the cancer center
  - Including 1 time “courtesy fills” when the insurance allows the patient to use the local specialty pharmacy for the first fill only but must then use the insurance preferred pharmacy for future fills

What the Health Plans will tell you

Prescription drugs are 21.5% of Commercial premiums

PBMs generate $1000/enrollee savings/year

Premiums will rise if PBMs curtailed

Rebates are a response to drug list price increases

Utilization management ensure that physicians prescribe medically appropriate drugs only.

AHIP Letter to FTC 5/25/2022

Other data sources

- Actual pharmaceutical costs net of rebates, as a portion of premium, have remained relatively flat between 2014 and 2018
  - Milliman: The role of pharmacy benefits on ACA market premiums (October 2020

- Net Manufacturer prices,(cost after all discounts and rebates) increased 1.0% in 2021 (below inflation for the 5th year)
- 92% of branded and generic prescriptions have a final out of pocket cost below $20; 0.9% over $125 but out of pocket costs increased $4B in 2021
  - IQUVIA: The Use of Medicines in the US 2022

What Is DIR? (direct and Indirect Remuneration)

- 1.Includes rebates from Manufacturers
- 2. Administrative fees about Fair Market Value
- 3. Price concessions for administrative servicdes
- 4. Legal settlements afftecting Part D Drug costs
- 5. Pharmacy price concessions
  - 4.8% of Part D gross drug costs $9.5B
  - 0.01 % in 2010 $8.9M
- 6. Drug costs for risk sharing settlements

- From National Community Pharmacists Association on CY 2023 Part D Final Rule

CVS Caremark response to Federal removal of DIR fees 4/12/2022, an 8% cut in payment:

- "As Congress considers wide-ranging reforms to pharmacy benefit managers, a top executive at CVS Health, which owns one of the largest PBMs in the country, said the company would find ways to maintain its level of profit if those reforms to things like drug rebates went into effect.
- "There's other ways in the economic model that we can adjust to if one of those things changes," Shawn Guertin, CVS' chief financial officer, said at an industry conference Wednesday. "The other important part of this, if some of these things change, it could lead to higher costs for employers and health plans."

ExpressScripts Part D Network

- the Program essentially lowers reimbursement to all Pharmacy Providers to the average wholesale price ("AWP") discount each Pharmacy Provider would receive if it performed in the lowest possible tier for every DIR Fee performance metric in each common "Network Protocol" ESI offers in its current Broad Part D Network. In addition to these low-ball reimbursement rates, ESI has also implemented a new Performance "Bonus Pool" plan meant to shift the cost of maintaining a performance network away from Plan Sponsors and onto Pharmacy Providers.
- Medicare Part D is under Federal control, but the New Mexico OSI controls the licensing of Brokers. Perhaps requiring transparency from Brokers of how the Part D Plan PBMs work could help New Mexicans choose wisely?

Addressing Pharmacy Discrimination

Defines PBM and requires licensure by SOI and transparency

Not an insurer therefore ERISA does not apply

PBM shall not reimburse a pharmacy less than it reimburses an affiliated pharmacy

PBM must calculate the reimbursement on the day of sale, same drug identifiers (NDC)

PBM cannot reimburse less than the acquisition cost

Includes appeal process

Addressing Pharmacy Discrimination

A PBM shall not be paid a percentage of the cost of the drug but shall be paid a fixed fee in advance

- Cannot negotiating increased prices paired with rebates

A PBM will file a reimbursement transparency report

A PBM auditing a pharmacy must be conducted fairly and may not recoup fees unless overpayment or fraud is found, and cannot charge the pharmacy for the audit

Continues prohibition against discrimination for 340b covered entities

Addressing Pharmacy Discrimination: Prohibits Spread Pricing

Difference between what PBMs pay pharmacies for the drugs and what PBMs charge plan sponsors for generics

PBMs reimburse pharmacies based on Maximal Allowable Cost schedules and Generic Effectiveness Rates.

MAC and GER is in the contract with the payer

Separate from contract with the pharmacy

Payers can let PBMs keep the spread or pass them to the insurer in exchange for a PBM administrative fee

Addressing Pharmacy Discrimination Avoids ERISA concerns

- Requiring a patient to use the PBM's Mail order service
- Includes regulating price concessions
- PBMs may not reduce payment under any reconciliation process other than error. (DIR or other fees)
- PBMs may not force participation in all contracts
- PBMs may not enforce gag rules in contracts
- PBMs may not prohibit pharmacists from informing patients of the options to discuss a lower cost prescription with the prescriber
- PBMs must provide a clear contract with a pharmacy, not requiring unnecessary restrictions

Proposed Addressing Pharmacy Discrimination bill

- PBMs may not
  - require or prefer a brand name drug over a generic
  - require a patient to fill a prescription at an affiliated pharmacy
  - require a physician office or hospital to accept drugs purchased by the PBM
  - Require infusion drugs to be administered at home, unless the ordering physician determines that the home is a safe infusion site.
  - Charge a fee for claims submission or data collections or to be credentialed in the network
  - Base payment on patient outcomes or plan star ratings
  - Withhold payment based on quality metrics without a contracted method to comply

Addressing Pharmacy Discrimination Appropriation

- $700,000
- Superintendent will require staff to enforce for monitoring, compiling data