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STATE & NATIONAL POLICY UPDATE





WHY CARE ABOUT POLICY?

Policy defines the oncology landscape today
Medicare Modernization Act, Affordable Care Act,
Inflation Reduction Act
Government can and will pick winners and losers
Greater New York Hospital Association

Where will community oncology be in 20 years?



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STATE VS NATIONAL

Congress is increasingly dysfunctional
Healthcare regulation increasingly shifting to state level

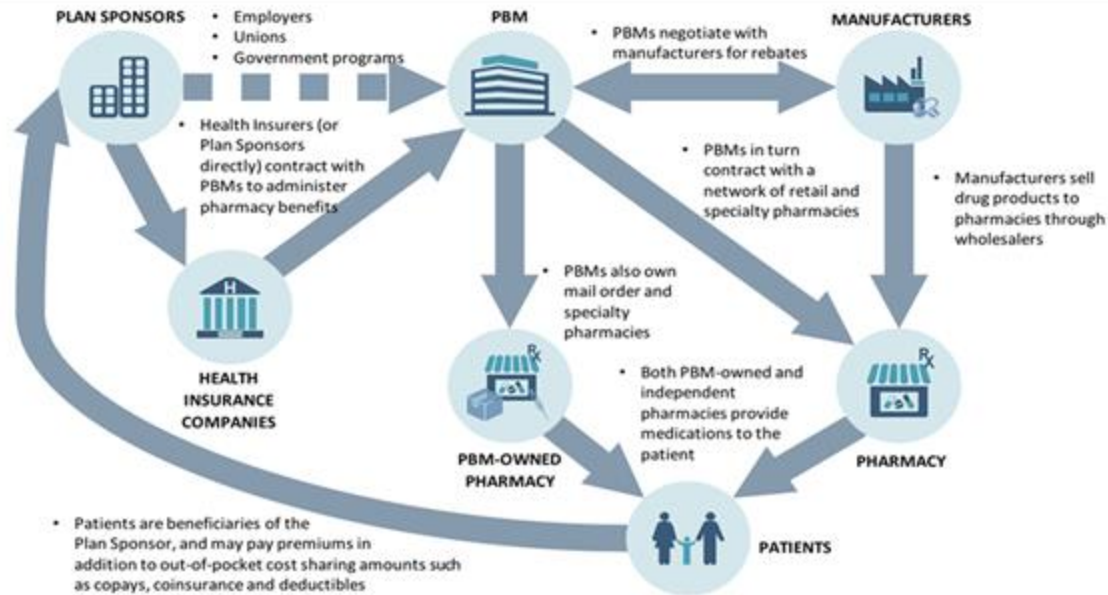
ESHOS more important than ever!



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PHARMACY BENEFIT MANAGERS

Three PBMs control 80%
of the US market





PHARMACY BENEFIT MANAGERS

- Spread pricing
- Gag clauses
- Formulary management - manufacturer rebates
- Narrow networks
- Steering
- Patient copays higher than retail price of drug
- DIR fees/clawbacks



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PHARMACY BENEFIT MANAGERS

Rutledge v Pharmaceutical Care Management Association (PCMA)– US Supreme Court ruled that an Arkansas law regulating PBMs was not subject to federal preemption – December 2020



PHARMACY BENEFIT MANAGERS

Established the Pharmacy Benefits Bureau
Oversight, transparency, and accountability
Can license and unlicense PBMs
Revised law stripped out the private right of
action
Rules and regulations currently being drafted
Slow process
Frier Levitt Comment Letters

REPORT FROM THE NEW YORK STATE SENATE

COMMITTEE ON INVESTIGATIONS AND
GOVERNMENT OPERATIONS

CHAIR
SENATOR JAMES SKOUFIS



**Final Investigative Report:
Pharmacy Benefit Managers in New York**

MAY 31, 2019

This report was produced in coordination with the
COMMITTEE ON HEALTH
CHAIR
Senator Gustavo Rivera

PHARMACY BENEFIT MANAGERS

Medicaid Fee for Service Transition
Oncology practices can continue to dispense oral
oncolytics and supportive care drugs
But.....

Invoice Pricing
Bill through medical benefit

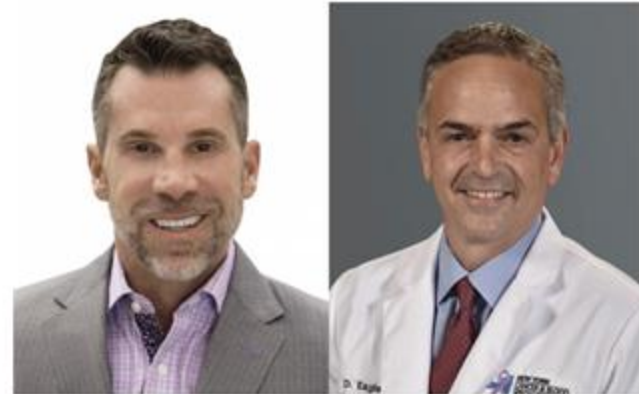
Medically Integrated Dispensing

Value Based Enterprise Program

Allowed NYCBS to become the first private practice in
the state to be approved for a retail pharmacy

Achieving Health Equity for New York Medicaid Patients

By **Dr. Jeff Vacirca** and **Dr. David A.
Eagle** | August 30, 2022



PHARMACY BENEFIT MANAGERS



HOUSE

Congressman Comer demanded
documents from all major PBMs
Multiple hearings



SENATE

Senate Finance Committee PBM
hearings
Legislation being drafted

DRUG MAILING

CMS FAQ with end of public health emergency

Practices at risk of violating Stark self-referral law by mailing drugs to patients

CMS ignored a letter from over 50 Congressional Representatives urging reversal of FAQ

Community Oncology Alliance lawsuit

Representative Harshbarger and Wasserman Schultz introduced HR 5526 - Seniors' Access to Critical Medications Act



INFLATION REDUCTION ACT

Oral drugs begins in 2026

IV Drugs begins in 2028

Initial ten drugs include:

Eliquis

Xarelto

Imbruvica

Includes a technical flaw that ties oncology drug reimbursement to the new manufacturer fair price (MFP) rather than the average sales price (ASP)
Result is an almost 50% reduction in practice revenue

Technical fix bill from Senator Barrasso and Representative Burgess

Hoping for this to go into end of year package

PRIVATE HEALTHCARE TRANSACTION REGULATION

Scrutiny of private healthcare transactions

Particularly when private equity involved

No Surprises Act

Carlyle Group take over of Manor Care

State level review and approval of private healthcare transactions - AG or DOH

New York- currently DOH reporting only

American Independent Medical Practice Association - over 5000 docs and counting

GENERIC DRUG SHORTAGES

You see it first

Manufacturers are not required to disclose the reason for a shortage underlying issues remain opaque

Fix?

More disclosure and regulation

Change underlying payments and financial incentives



PRIOR AUTHORIZATION & STEP EDITS

Continued national and state level battle
New York Clinical Peer Review Law
Gold Card
CMS RFI request on Prior Authorization
Left out drug!

OPINION / COMMENTARY / GUEST ESSAYS

**Prior authorization from insurance companies
often delays treatment for patients**



There are cases in which prior authorization has harmed patients, yet insurers aren't held liable. Credit: Getty Images/Ultak/istock/PhotoLibrary

By Jeff Vachon and David A. Eagle
Guest essay
Updated August 1, 2022

Doctors Push to Protect Patients With Iron Deficiency Anemia

By David Eagle, M.D., Rahul Seth, M.D. | June 7, 2022

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NEW YORK BILLING AND REIMBURSEMENT

Modifier 25

More private insurers denying payment for office visits and injections/infusions on the same day

Clean Claims Act

Insurers must pay within 45 days of receiving a clean claim

Easily circumvent by requesting records for any chemo or high payment amount claim

MSSNY/Heather Lopez have resources and strategy

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NEW YORK STATE

Price Transparency
Non-compete Bill
Wrongful Death

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THANK YOU

