PBMS: LEGAL UPDATE & WHAT YOU SHOULD BE DOING

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ABOUT THE SPEAKER

JONATHAN E. LEVITT, ESQ.

- Co-Founder and Chair of the Life Sciences and Pharmacy Practice Group
- Litigated multiple Class Action lawsuits against PBMs on behalf of providers
- Elected by peers as a Super Lawyer and is Certified by the Supreme Court of New Jersey as a Civil Trial Attorney
Dispensing Physicians are permitted to apply, but CVS Caremark creates delays at every interval

“Starting January 29, 2018, Prime Therapeutics (“Prime”) will no longer be accepting PSAO additions with a pharmacy type of Dispensing Physician. Prime is no longer seeking new pharmacies with this dispensing classification.”

Reports that MedImpact is similarly not allowing new Dispensing Physicians into its network “at this time”
WHAT PBMS FEAR: THE TIME I WENT TO A PBM CONFERENCE

Hey PBMs...
LISTEN UP!
Medicare uses a Star Rating System to measure how well PDPs perform in various categories, including customer service and quality of care.

Even a small number of patient complaints can impact Star Rating, and going from 4 to 3 stars is “circling the toilet bowl”

Bottom Line: Star Rating System is a weapon to counterbalance weapons used by PBMs and Plan Sponsors.

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Rebates are “mystical” and most Plans have low level of knowledge and have little transparency or tools to track rebates.

PBMs utilize rebates to manipulate utilization and coverage for drugs, with highly-rebated drugs getting formulary placement, while other drugs may get PA’s.

Bottom Line: Rebates can promote inferior and more costly products and plans are becoming more savvy and willing to take action.
Maximum Allowable Cost, or “MAC,” refers to the upper limit of what a PBM will reimburse for a multisource prescription drug.

35 States have enacted MAC laws, and can give pharmacies appeal and notice rights, as well as the right to refuse to fill prescriptions at a loss.

Bottom Line: Pharmacies must take advantage of MAC laws that have onerous requirements for PBMs and can jeopardize the PBM’s licensure if not followed.
WHAT PBMS FEAR: ERISA CONCERNS AND PROVIDER DIRECTORIES

ERISA requires Plans and their PBMs to abide by Plan Document requirements, and provide patients certain appeal rights.

Plans are failing to communicate with PBMs about Summary Plan Descriptions, and PBMs fear they are in dark when denying patient choice of pharmacy.

Bottom Line: PBMs are vulnerable on the accuracy of Provider Directories that are put in place at the time of bidding and may be willing to make exceptions to avoid risk of non-compliance.
FEDERAL AND STATE LAWS IMPACTING PHYSICIAN DISPENSING

- Dispensing Physicians
  - Anti-Kickback Statute
  - Patient Steerage Laws
  - Pharmacy Practice Acts
  - Medical Practice Acts
  - HIPAA
  - Controlled Substances Act

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**Legal Tools Available to Pharmacy Providers**

- **Fair Pharmacy Audit Laws**
  - Provide time limits on PBM audits as well as appeal procedures
  - Limit number of prescriptions per audit
  - Prohibit recoupment for “clerical errors”

- **State Medicaid Rules**
  - Provide certain appeal rights for audits involving Medicaid claims
  - May limit recoupment on certain types of discrepancies (i.e., copay collection)

- **Unfair Trade Practices Laws**
  - Provide “look back” periods limiting PBM audits
  - Prevent PBM from unilaterally offsetting claims to recoup on audits
  - Provide for interest and attorneys’ fees when there’s a violation

- **Prompt Pay Laws**
  - Prohibit PBMs from engaging in unfair or deceptive business practices
  - Often provide a private right of action, along with attorneys’ fees and punitive damages
Physician Dispensing Laws

- Each of the applicable States permit physician dispensing in some form
- However, three of the States apply certain limitations to the scope and nature of in office dispensing

Georgia permits physician dispensing notifying the Georgia Composite Medical Board in writing.
Physician Ownership of Pharmacy Laws

• Only two of the applicable States explicitly permit physician ownership of a licensed pharmacy
• Nine States are “silent” on the issue
• The remaining three States outright prohibit the practice

In Georgia, physicians may own or operate a pharmacy, although there are some limitations on referrals.
DIFFERENT STATE LAWS PROVIDE DIFFERENT RIGHTS

Any Willing Provider Laws
• Practices located in nine of the States may make use of AWPLs
• Certain AWPLs apply to “pharmacies” while others specifically apply to “providers,” including physicians

Georgia's AWPL applies to both pharmacies and physicians
GEORGIA MAXIMUM ALLOWABLE COST (“MAC”) LAW

General Overview of MAC Law—Ga. Code Ann. § 33-64-9:

Maximum Allowable Cost or “MAC” refers to upper limit of what a PBM will reimburse for a multisource prescription drug.

MAC is a critical issue for pharmacies throughout the country—PBMs throughout the country are taking advantage of the opaque MAC pricing model to under-reimburse pharmacies for MAC drugs.

Approximately 35 states have enacted MAC laws, many of which give pharmacies substantive legal rights, including notice rights and appeal rights.

Georgia’s MAC Law is an example of a MAC law that provides a very specific Appeals Process that must be followed by the PBM:

- Legally Required Georgia MAC Appeals Process:
  - PBM contracts must “include a process to internally appeal, investigate, and resolve disputes regarding multi-source generic drug pricing.”
  - The process must include at least the following:
    - Pharmacy’s right to appeal is limited to 14 calendar days following reimbursement of claim;
    - PBM must respond to appeal no later than 14 calendar days after the date the appeal was received by PBM.
PBMs are obligated to respond regardless of whether an appeal is successful or denied:

- **If appeal is denied:**
  - PBM must provide the (1) **reason for the denial** and (2) **identify the national drug code of a product that may be purchased by contracted pharmacies at a price at or below** the MAC.

- **If appeal is successful:**
  - PBM must adjust the MAC price that is the subject of the appeal effective on the day after the date the appeal is decided;
  - Apply the adjusted MAC price to all similarly situated pharmacists and pharmacies as determined by the PBM;
  - Allow the pharmacy that succeeded in the appeal to reverse and rebill the claim giving rise to the appeal.

PBM’s response should never be: “the Pharmacy is being paid at MAC” or “the current MAC price is appropriate and does not need to be adjusted at this time” or any similar variation.

If a pharmacy is appealing, it is because they received less than what it paid for the drug, so a PBM does not fulfill its obligations by saying, “don’t worry, our MAC is correct”—more is required: PBM must tell the pharmacy the NDC of a product that can be purchased by the pharmacy at a price at or below the PBM’s MAC price.
DIRECT ARRANGEMENTS WITH PLAN SPONSORS

PREMIUM PAYING PLANS

- PPO
- HMO
- Group Health Policy
- Individual Health Policy

Insurance company bears actuarial, financial risk

Better terms on many issues including pricing, rebates, etc. for their risk-bearing lines of business

SELF-FUNDED PLANS

- Union Plans

Insurance company bears no risk and provides “Administrative Services” only

Sometimes include purposely worse or sub-market terms to compensate for better-than-market terms on the risk-bearing side

When contracting with PBMs...
DIRECT ARRANGEMENTS WITH PLAN SPONSORS

PREMIUM PAYING PLANS

- PPO
- HMO
- Employer-Paid Premiums

Group Health Policy  Individual Health Policy

HEALTH INSURANCE COMPANY

PHYSICIAN

Vertical integration and common ownership between insurers, PBMs, and mail-order pharmacies will make it impracticable to “carve in” dispensing services (for now)

For oncology practices seeking to integrate drug benefits into Value Based Contracting...

SELF-FUNDED PLANS

- Union Plans
- EXON
- Pepsi
- CAT

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DIRECT ARRANGEMENTS WITH PLAN SPONSORS

PREMIUM PAYING PLANS

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HEALTH INSURANCE COMPANY

SELF-FUNDED PLANS

- Union Plans

However, Self Funded Plans provide unique opportunity for oncology practices to integrate physician dispensing and take prescription volume away from PBM-owned pharmacies at an overall savings to the Plan Sponsor

PHYSICIAN

For oncology practices seeking to integrate drug benefits into Value Based Contracting...
DIR FEES: CONTINUING DEVELOPMENTS

- Part D plans and PBMs have expanded percentage-based DIR fees
- Existential crisis for many dispensing physicians
- CMS issued new guidance on DIR reporting requirements for PDPs
- Multiple providers have commenced actions against PBMs and plan sponsors
- Industry organizations release multiple white papers
“Are these DIR fees essentially taxes imposed differentially and unpredictably on those independent pharmacies in a way that puts them at a competitive disadvantage from the owned ones?” Azar asked during testimony before the Senate Appropriations HHS subcommittee.

It is an “important issue worthy of study” because “there should be a level playing field” and “good competition,” Azar stated in directing the Inspector General at HHS to look into this issue.

Scott Gottlieb stated that the top three PBMs controlled 80% of the market, preventing market optimization and preventing savings (such as DIR) from being passed to sponsors and patients, and calling the PBM model a “shell game.”
DIR FEES REMAIN UNDER ATTACK

The Phair Pricing Act of 2018 (H.R. 5958) is Congress’ current attempt to prohibits retroactive "DIR fees" on pharmacies

The SEC forced ESI to break out a seemingly benign number from its balance sheet having to do with the DIR it collects from pharmaceutical firms

White House Panel of Economic Advisors issues White Paper stating that the “list price” of drugs is “artificially inflated” by the rebate/DIR game