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Georgia Society of Clinical Oncology
Conference

**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

RECENT ADVERSE ACTIONS AGAINST IN-OFFICE DISPENSING



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.”

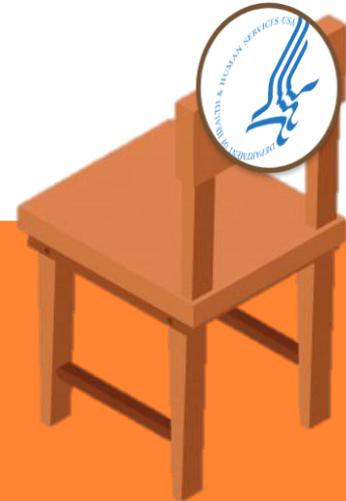
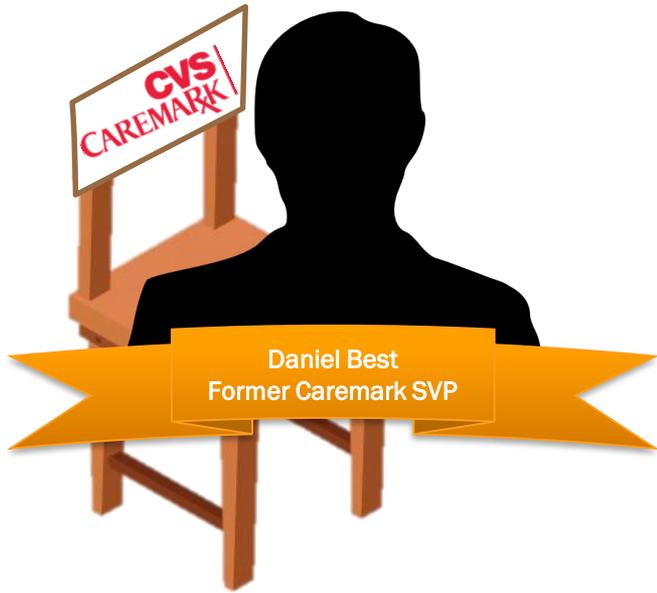


Dispensing Physicians



Reports that MedImpact is similarly not allowing new Dispensing Physicians into its network “at this time”

MEDICARE MUSICAL CHAIRS



WHAT PBMS FEAR: THE TIME I WENT TO A PBM CONFERENCE



WHAT PBMS FEAR: STAR RATINGS

Not meeting customer service requirements can result in regulatory sanction, breach of contract, harm to reputation, and lost business.

- Customer complaints – Health Plan, Department of Insurance, Attorney General, Medicare Ombudsman
- Negative customer reviews– social media, member experience survey, Star Ratings
- Breach of service agreement, including performance guarantees, and violation of the business associate agreement
- Sanction by state and federal agencies

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.



WHAT PBMS FEAR: THE PBM REBATE GAME FROM AN INSIDER

Elimination of the Retrospective Rebate System

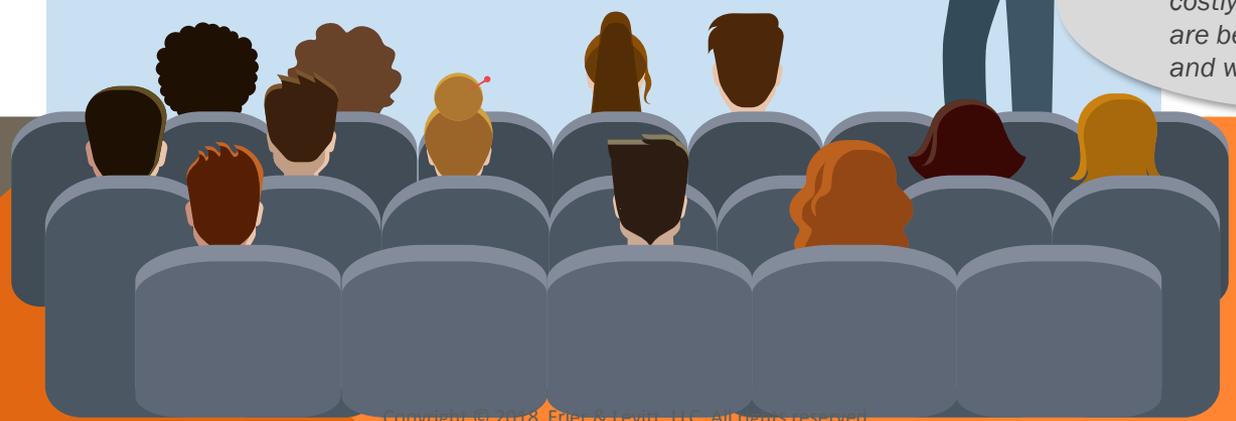
In re Insulin Pricing Litigation, Civ. No. 3:17-cv-00699 (D.N.J.)

- Proposed class action against several manufacturers of diabetes drugs as well as CVS Caremark, Express Scripts and OptumRx related to the payment of rebates to PBMs and their failure to disclose their retention of some or all of such rebates to health plans to which they provide PBM services as well as consumers

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.



WHAT PBMS FEAR: MAC PRICING REGULATION

State MAC Laws

PRIME THERAPEUTICS

State Trends – What's Next?

- **Guaranteed profit** – new laws granting pharmacists the right to refuse to fill prescriptions when their costs exceed reimbursement.
- **Reference pricing** – including brand drug pricing information in disclosure requirements.
- **State Involvement** – appeals, licensing requirements.

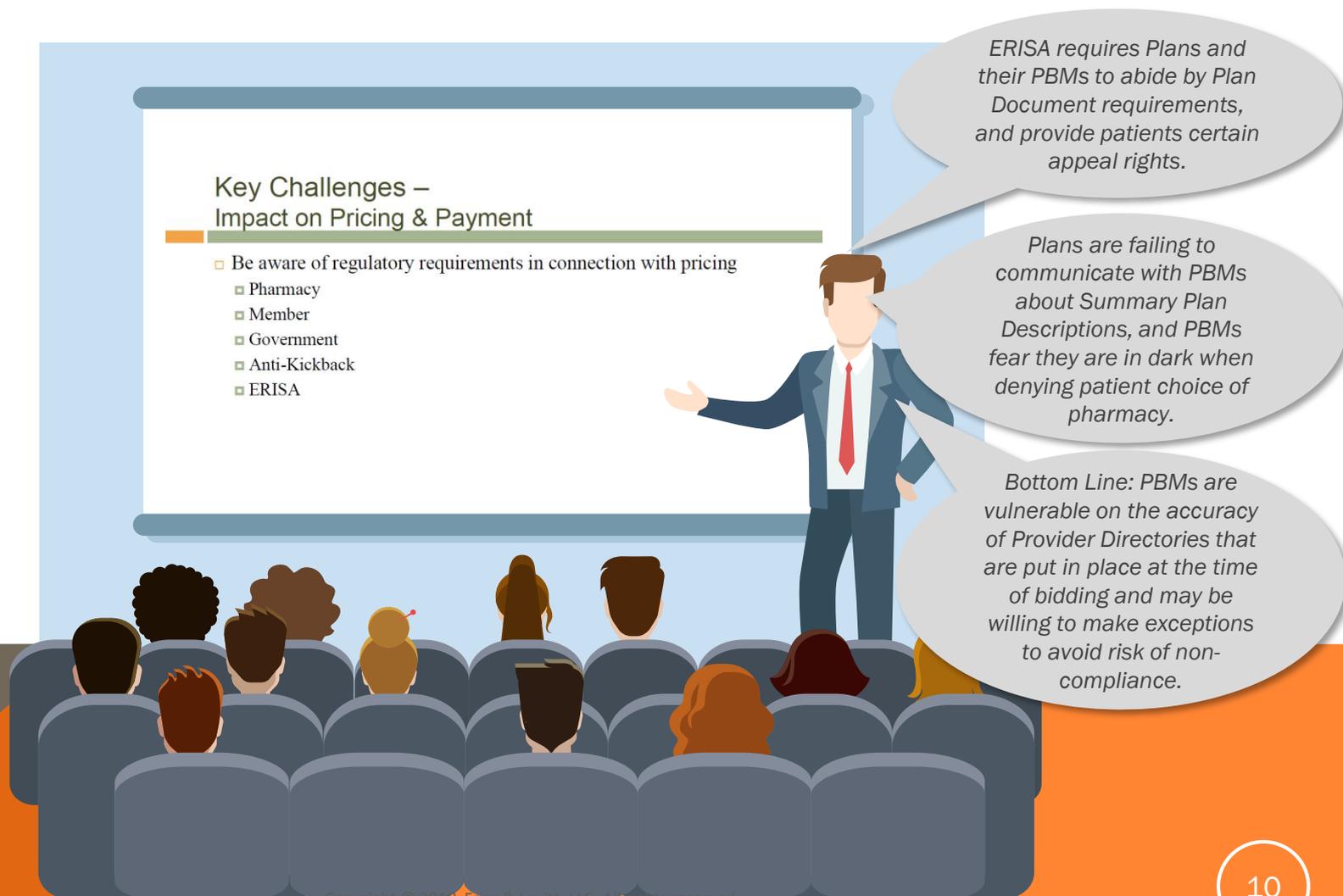
States are not only legislating to protect pharmacies, but now taking a more active role in enforcing that protection.

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

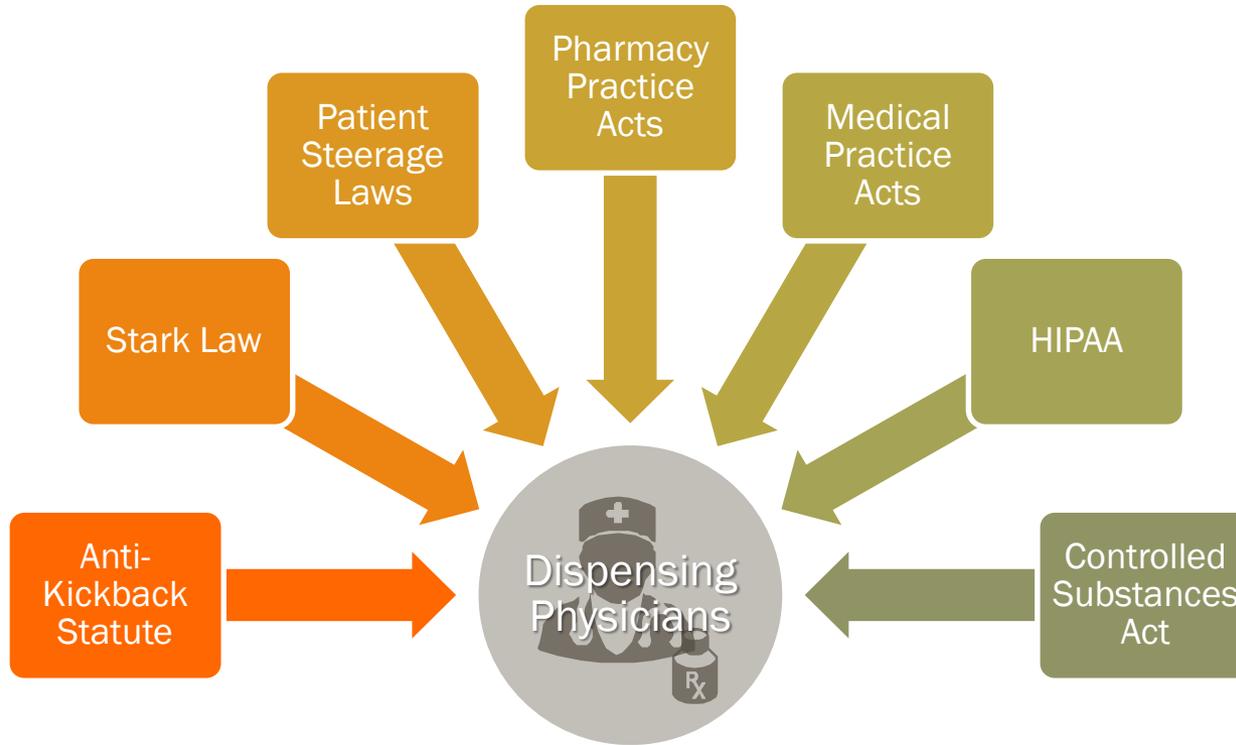
35 States have enacted MAC laws, and can give pharmacies appeal and notice rights, as well as the right to refuse to fill prescriptions at a loss.

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.

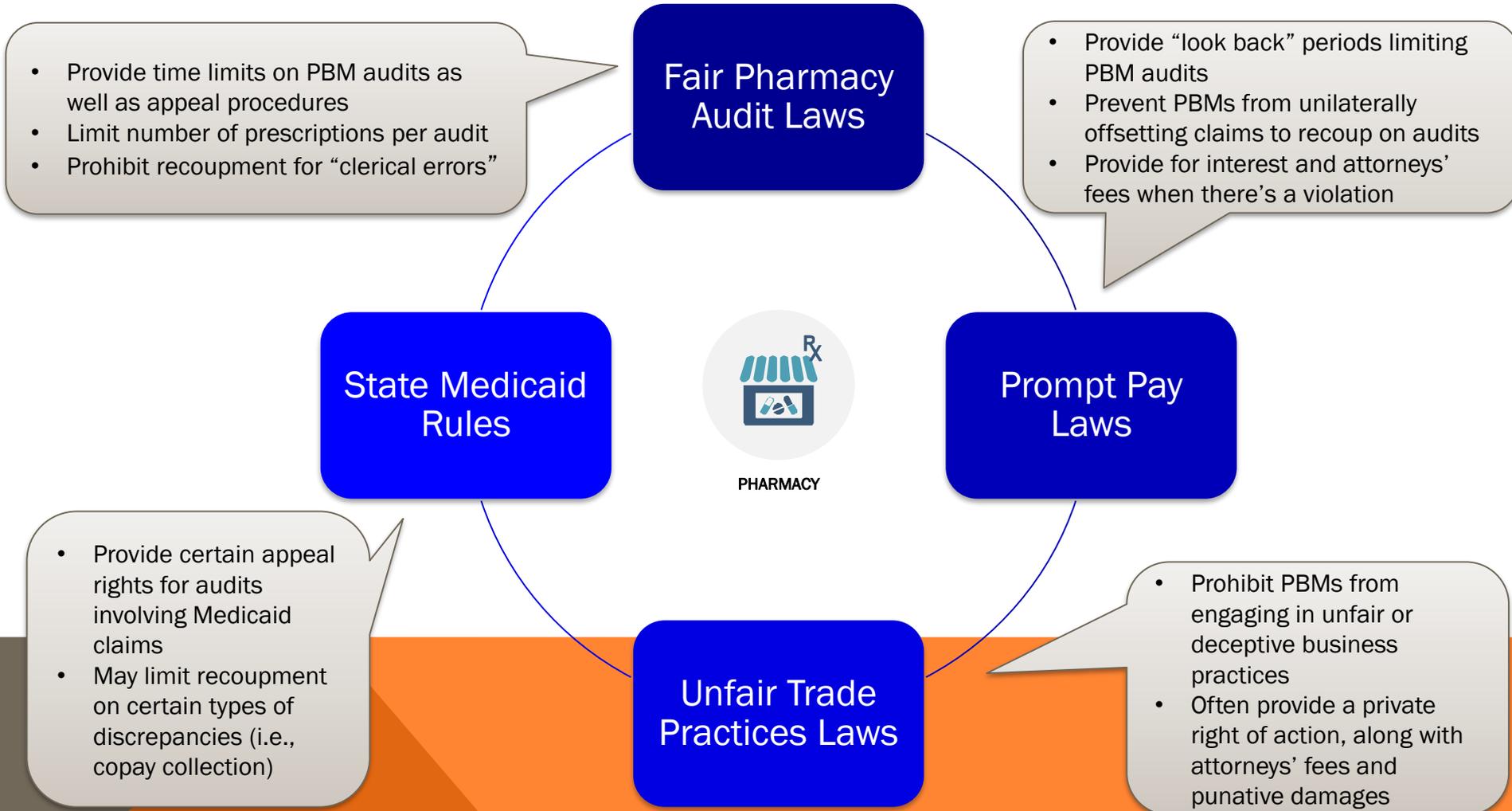
WHAT PBMS FEAR: ERISA CONCERNS AND PROVIDER DIRECTORIES



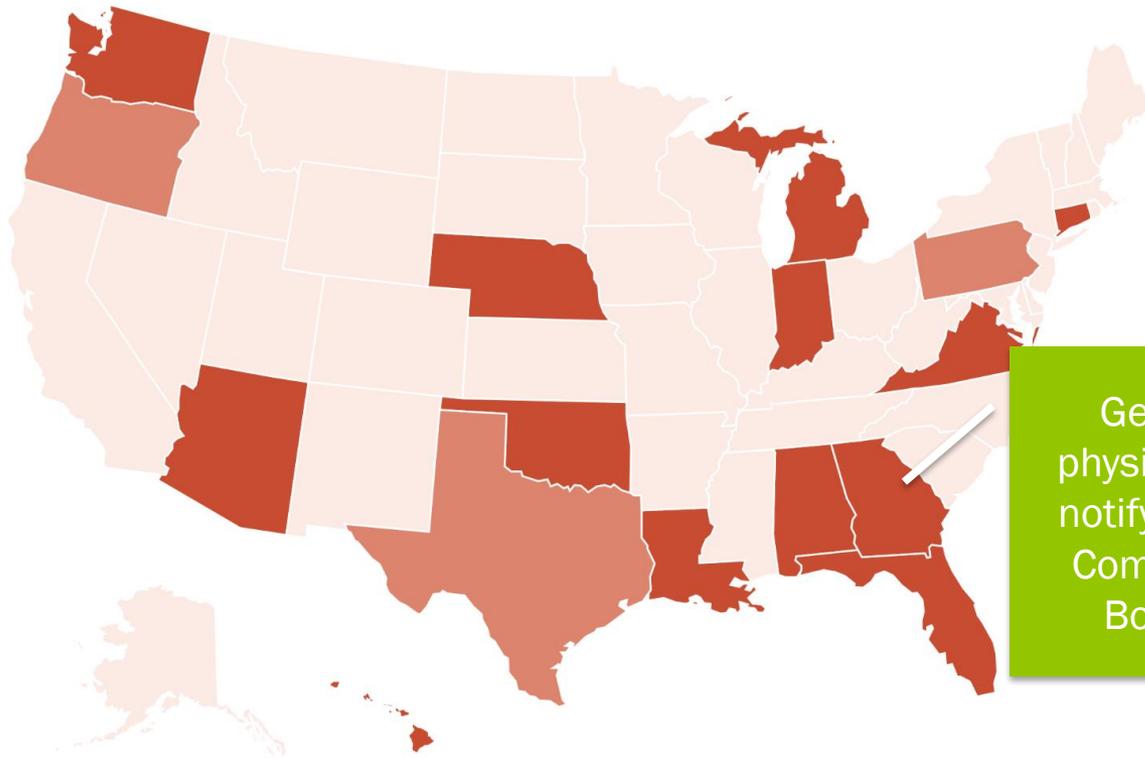
FEDERAL AND STATE LAWS IMPACTING PHYSICIAN DISPENSING



LEGAL TOOLS AVAILABLE TO PHARMACY PROVIDERS



DIFFERENT STATE LAWS PROVIDE DIFFERENT RIGHTS

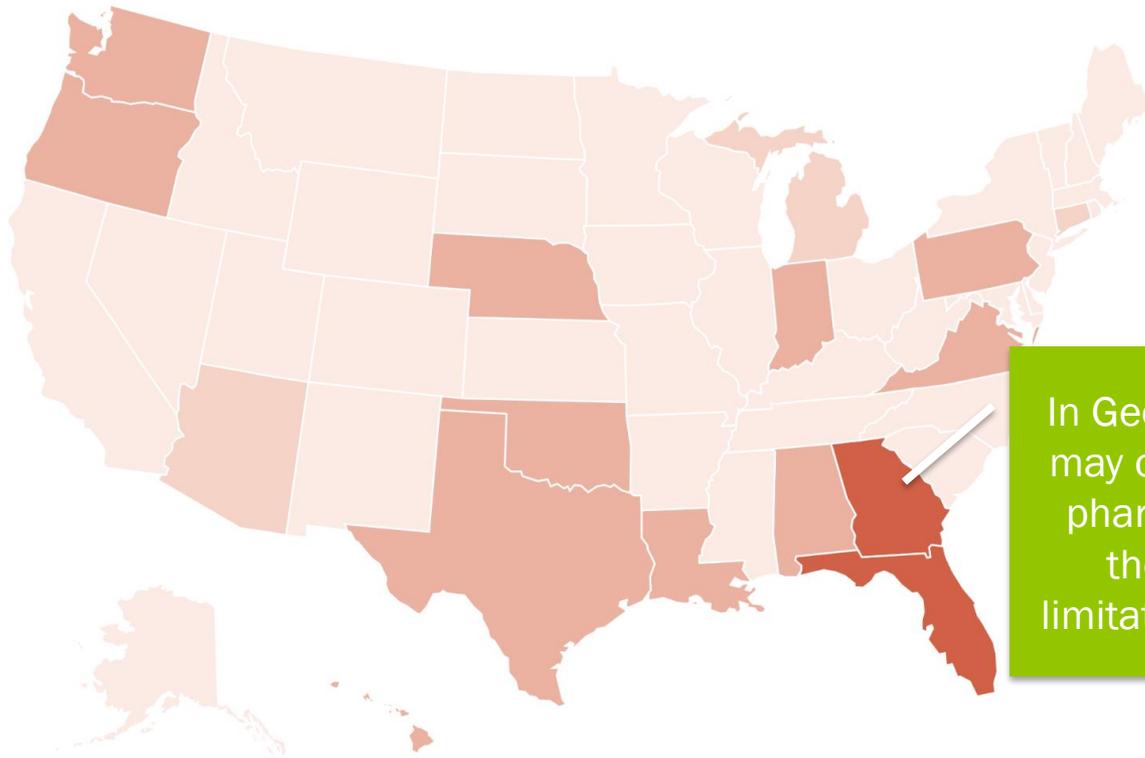


Georgia permits physician dispensing notifying the Georgia Composite Medical Board in writing

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

DIFFERENT STATE LAWS PROVIDE DIFFERENT RIGHTS

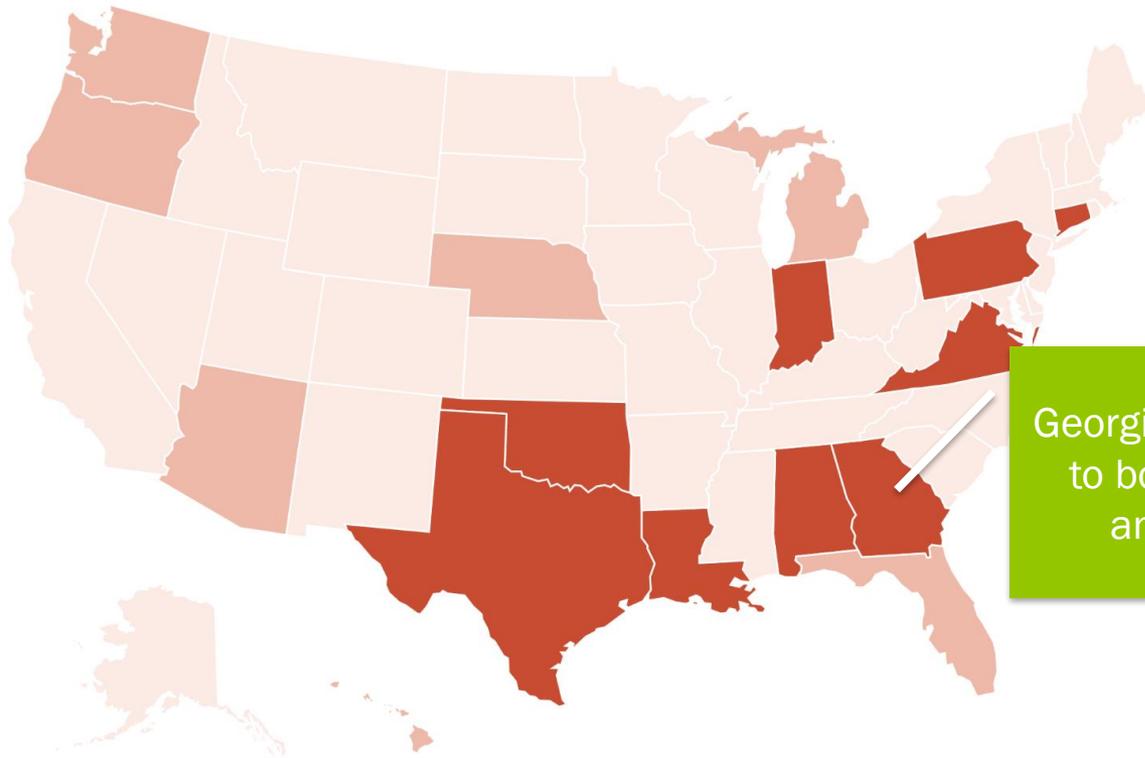


In Georgia, physicians may own or operate a pharmacy, although there are some limitations on referrals

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

DIFFERENT STATE LAWS PROVIDE DIFFERENT RIGHTS



Georgia's AWPL applies to both pharmacies and physicians

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 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

IMPORTANT POINTS TO REMEMBER ABOUT GEORGIA MAC LAW

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



SELF-FUNDED PLANS



HEALTH INSURANCE COMPANY



When contracting with PBMs...

Insurance company bears no risk and provides "Administrative Services" only

Insurance company bears actuarial, financial risk

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

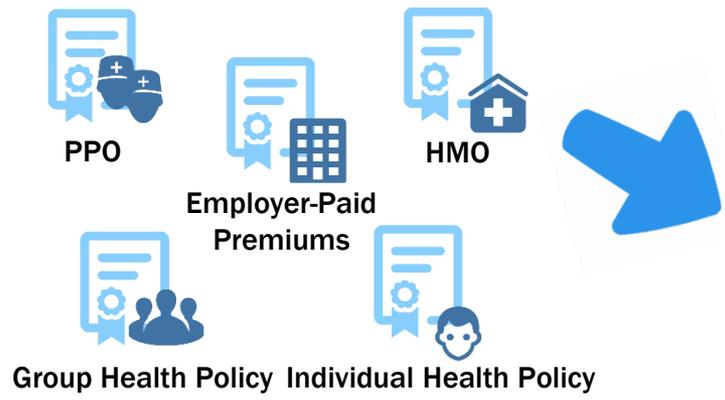
Sometimes include purposely worse or sub-market terms to compensate for better-than-market terms on the risk-bearing side



PBM

DIRECT ARRANGEMENTS WITH PLAN SPONSORS

PREMIUM PAYING PLANS



SELF-FUNDED PLANS



HEALTH INSURANCE COMPANY



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



PBM

PHYSICIAN



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

DIRECT ARRANGEMENTS WITH PLAN SPONSORS

PREMIUM PAYING PLANS



HEALTH INSURANCE COMPANY



SELF-FUNDED 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



PBM



PHYSICIAN

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

DIR FEES: CONTINUING DEVELOPMENTS



BUT WHAT DOES THE LAW SAY?

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Scott Gottlieb

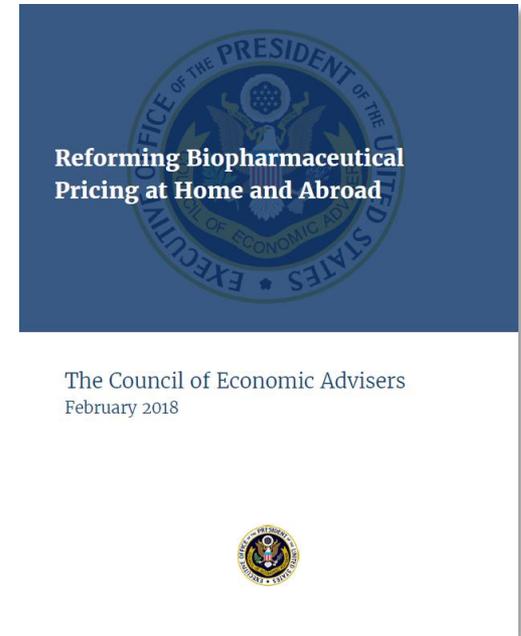
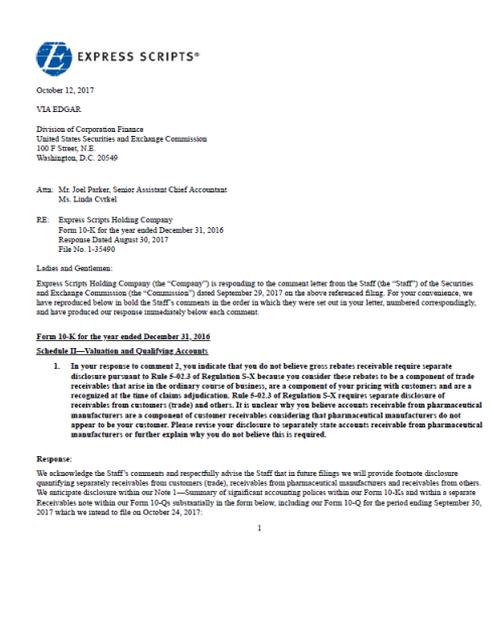
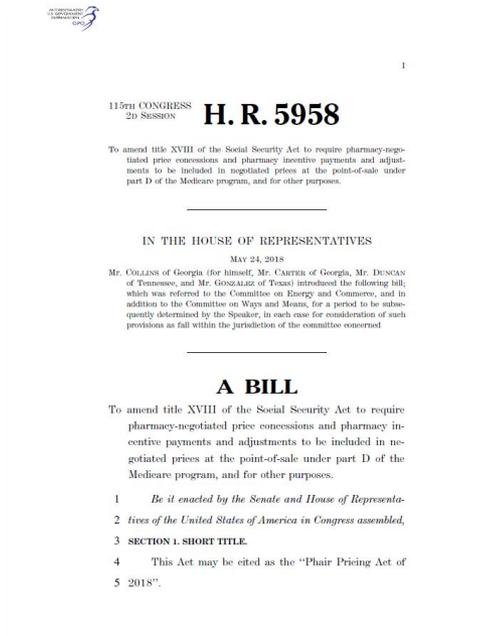


“Are these DIR fees essentially taxes imposed differentially and unpredictably on those independent pharmacies in a way that puts them at a competitive disadvantage from the owned ones?” Azar asked during testimony before the Senate Appropriations HHS subcommittee

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

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 prohibit 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



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