



## Rx: Matters of Law

### PROVIDER CONTRACTS:

*R.S. 22:1007*

Prohibits a condition to contract with an organization that pharmacies must participate in all of its associated health plan networks and prohibits terminating a pharmacy's contract that chooses not to participate.

### LIMITATION OF PATIENT PAYMENT:

*R.S. 22:1060.6*

Prohibits a patient from being required to pay for a higher priced pharmacy service when the pharmacy has a less expensive payment option available.

### PBM REGISTRATION:

*R.S. 22:1657*

Requires that Pharmacy Benefit Managers be licensed and regulated by the Commissioner of Insurance.

### PROMPT PAY:

*R.S. 22:1854*

Requires pharmacies to be paid for prescription drugs, products, and supplies within 15 days of electronic claim.

### AUDIT PERIOD; REMITTANCE ADVICE:

*R.S. 22:1856*

Health insurance issuers that limit the period of time a pharmacist or pharmacy have to submit a claim for payment shall have the same limited period of time to perform any review or audit for purposes of reconsidering the validity of such paid claims.

Remittance advice must be generated and be postmarked by a health insurance issuer to a pharmacy within 7 business days of payment and include:

1. Unique enrollee or insured identification number.

2. Patient claim number or patient account number.
3. Date that the prescription was filled.
4. National Drug Code.
5. Quantity dispensed.
6. Price submitted to the health insurance issuer or its contractor.
7. Amount paid by the health insurance issuer or its contractor.
8. Dispensing fee.
9. Provider fee.
10. Taxes.
11. Enrollee or insured liability, specifying any coinsurance, deductible, copayment, or non-covered amount.
12. Any amount adjusted by the health insurance issuer or its contractor and the reason for adjustment.
13. Any other deduction or charge, listed separately.
14. Network Identifier
15. A toll-free telephone number for assistance with the remittance advice.

### AUDITS & RECOUPMENTS:

*R.S. 22:1856.1*

Audit process rules and appeals process:

1. Audits cannot take place during the first three business days of the month
2. No more than one on-site audit in per year
3. At least two weeks notification required prior to on-site audit
4. Clerical or record-keeping error shall not constitute fraud
5. Pharmacy may provide records for supporting documentation
6. Each pharmacy shall be audited under same standards as others
7. Audit report shall be delivered to pharmacy within 90 days of conclusion with a minimum of 30 days for appeal discrepancy of finding
8. Audit with clinical judgment must be conducted by or in consultation with a licensed pharmacist

No pharmacy shall be subject to recoupment of any portion of a reimbursement unless one of the following has occurred:

1. The pharmacy has engaged in fraudulent activity
2. The pharmacy has engaged in dispensing in excess of the benefit design, as established by the plan sponsor.
3. The pharmacy has not filled prescriptions in accordance with the prescriber's order.
4. The pharmacy has received an actual overpayment.

### PRESCRIPTION DRUGS, USE OF INDEX FOR PRICING:

*R.S. 22:1857*

Requires reimbursement for prescription drugs calculated using a nationally recognized pricing reference based on the most current nationally recognized reference price. Requires updated prices or amounts used for calculation of reimbursement no less than every three business days.

### CONTRACTING:

*R.S. 22:1857.1*

Any organization that negotiates with a pharmacy or pharmacies, and an organization that represents an independent pharmacy or a group of independent pharmacies, shall provide each pharmacy that the organization represents a copy of any new contract, provider agreement, amendment to such contract or agreement, or other provider documentation concerning the pharmacy's network participation with a third-party payor.

### RECOUPMENT:

*R.S. 22:1859*

Requires that a pharmacy is provided written notification of a planned recoupment that includes:

1. Name of the patient
2. Date or dates of provision or prescription drugs, other products and supplies, and pharmacist services
3. Explanation of the reason for recoupment

Provides pharmacies with an appeal window of 30 days from receipt of notification.

### PROVIDER FEE; CLAIM FEES:

*R.S. 22:1860.1- 22:1860.2*

Health insurer or agent are obligated to reimburse pharmacist or his agent for each ten-cent provider fee.

Insurance commissioner may fine a health insurer or its agent up to \$250,000 for failure to reimburse pharmacy in a timely manner. A health insurance issuer or a pharmacy benefit manager may not directly or indirectly charge or hold a pharmacist or pharmacy responsible for any fee related to a claim:

1. That is not apparent at the time of claim processing.
2. That is not identified on the remittance advice.
3. After the initial claim is adjudicated.

### MAXIMUM ALLOWABLE COST LISTS:

*R.S. 22:1863-22:1865*

PBMs must provide pharmacies with access to MAC lists.

Requires MAC list updating no less than every seven days.

Requires implementation of appeals process for pharmacies to challenge negative margin reimbursements.

Requires PBM response to MAC inquiry within seven days.

### PHARMACIST-ADMINISTERED IMMUNIZATION:

*R.S. 37:1218 –37:1218.1*

Allows appropriately credentialed pharmacists to administer influenza immunizations to persons seven years of age or older, and all other immunizations and vaccines to persons 17 years of age or older, according to CDC recommendations.

### INTERCHANGEABLE BIOLOGICAL PRODUCTS:

*R.S. 37:1226.1*

Pharmacy must provide the Prescriber with specific interchangeable biological product data within five days of dispensing, unless:

1. There is no FDA approved interchangeable or therapeutically equivalent available
2. The prescription is an unchanged refill
3. The prescriber indicates dispense as written

### LICENSING AND REGULATION OF PHARMACIST:

*R.S. 37:1241(A) (23-24)*

Prohibits pharmacies from paying independent marketing contractors based on volume or value of prescriptions filled by the pharmacy  
Prohibits filling of prescriptions from a prescriber that pharmacy or immediate family members have a financial relationship, unless all current requirements of physician patient referrals law are met

### OPIOID LIMITATIONS:

*R.S. 40:978*

Limits a first-time opioid prescription for adult patient to no more than a seven-day supply.  
Limits minors from having access to more than a 7-day supply of opioids.

Allows pharmacists to dispense less than what is considered the full recommended quantity upon request of the patient, later allowing the patient to request no greater than the remaining quantity be filled prior to the expiration of the prescription. If so, pharmacists will be required to update the record in the prescription monitoring program within seven days.

### MEDICAID PHARMACY REIMBURSEMENT RATE FLOOR:

*R.S. 46:460.36*

No Medicaid managed care organization shall reimburse a local pharmacy at a rate less than the Fee for Service Rate for prescription drug claims.

### SALES TAX EXEMPTION:

*R.S. 47:337.9*

Exempts from all local sales and use taxes prescription drugs purchased through or pursuant to a Medicare Part D plan.

### OCCUPATIONAL LICENSE TAX:

*R.S. 47:359*

Limits the occupational license tax fee for independent community pharmacies to 1/10th of 1% of gross sales, minimum \$50, but never more than \$2000.

# Louisiana Pharmacy Legislation

- ACT 527 (SB 131) 2016 Regular Session Johns
  - Provides that an individual shall not be required to make a payment for pharmacists services in an amount greater than the pharmacist or pharmacy providing the services may retain from all payment sources.
- ACT 597 (HB 436) 2018 Regular Session Johnson
  - Prohibits a pharmacy benefit manager, insurer, or other entity that administers prescription drug benefits programs in La. from prohibiting by contract a pharmacy or pharmacist from informing a patient of all relevant options when acquiring his prescription medication, including but not limited to the cost and clinical efficacy of a more affordable alternative if one is available and the ability to pay cash if a cash price for the same drug is less than an insurance copayment or deductible payment amount.
  - Requires a pharmacy benefit manager to reimburse a pharmacy or pharmacist in this state an amount not less than the amount that the pharmacy benefit manager reimburses an affiliate of the pharmacy benefit manager for providing the same services.
  - Law requires a pharmacy benefit manager, for every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, to make available to all pharmacies both of source information. Authorizes a pharmacist or pharmacy to file a complaint with the commissioner of insurance following a final decision of the pharmacy benefit manager and provides for the investigation of the complaint.
  - New law permits the commissioner to promulgate rules and regulations, in accordance with the Administrative Procedure Act, that are necessary or proper to carry out the provisions of new law.

# Louisiana Pharmacy Legislation Cont.

- ACT 317 (SB 241) 2018 Regular Session Morrell
  - Prior law provided for licensure of pharmacy benefit managers by the commissioner of insurance. New law prohibits pharmacy benefit managers licensed in Louisiana from imposing "gag orders" by contract on pharmacies or pharmacists which prevent them from informing the patient of cheaper alternatives when filling their prescription drug. New law prohibits these provisions in contracts and retroactively makes void any provisions in place on August 1, 2018.
  - New law authorizes pharmacists to inform patients that a cheaper alternative may be available, including cash payment if a cash payment is cheaper than the patient's insurance copayment or deductible amount. New law provides immunity for a pharmacist who does not provide the information to a patient.
  - Effective August 1, 2018.

California's Drug Transparency Law: Navigating

Trump Says Drug Prices Will Drop ` Really,  
Really, Substantially

**High hopes for President Trump's**

Sol **HEALTH CARE**

(2018)

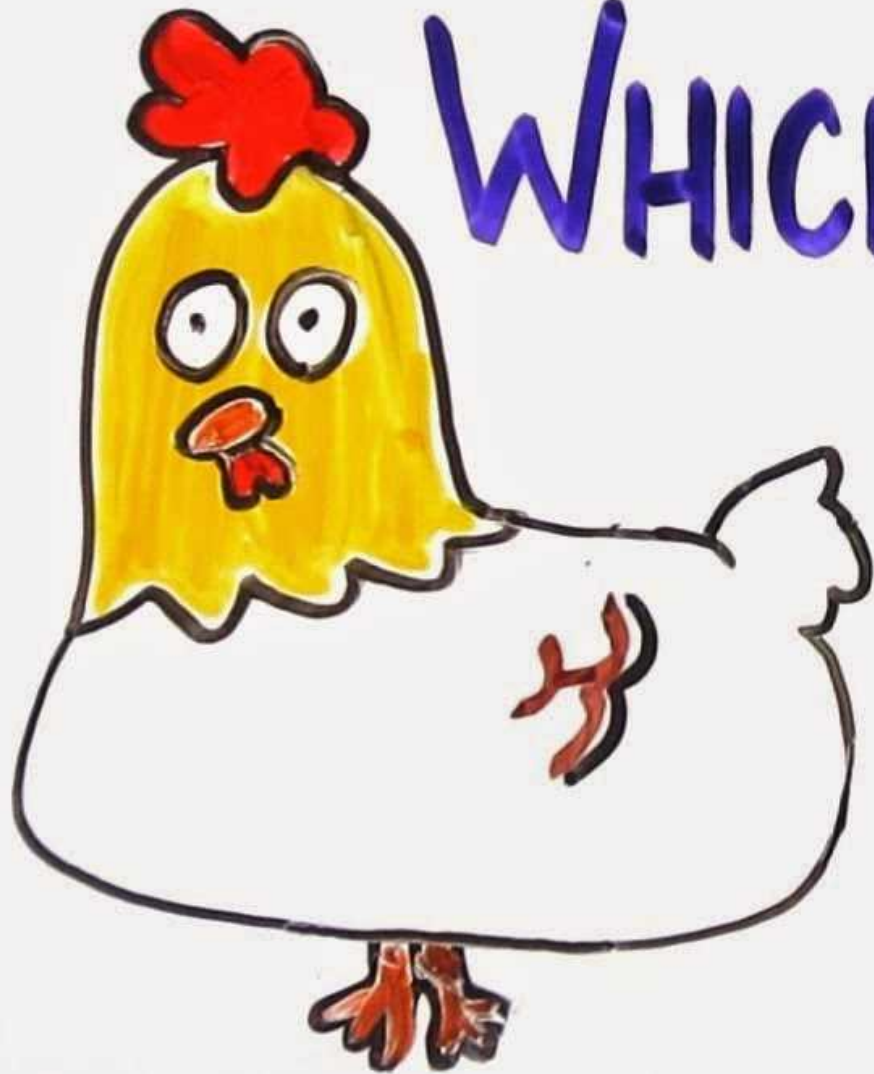
**Trump set to force drugmakers to post  
prices in ads**



### EpiPen® Auto-Injector Estimated Profitability

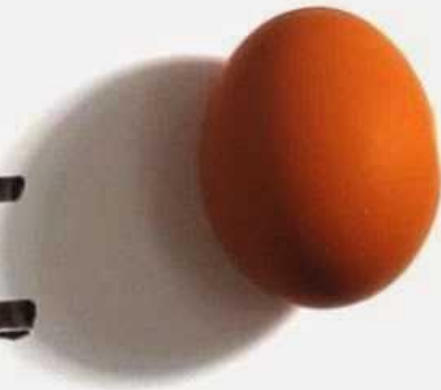
Wholesale Acquisition Cost Price	\$608
- Rebates & Allowances	- \$334
Mylan Revenue	\$274
- Cost of Goods Sold	- \$ 69
	\$205
- Direct EpiPen® Auto-Injector Costs	- \$105
Mylan Approx. Profit per Two-Pack	\$100
Mylan Approx. Profit per Pen	\$ 50

**MS. BRESCH**  
MYLAN, Inc



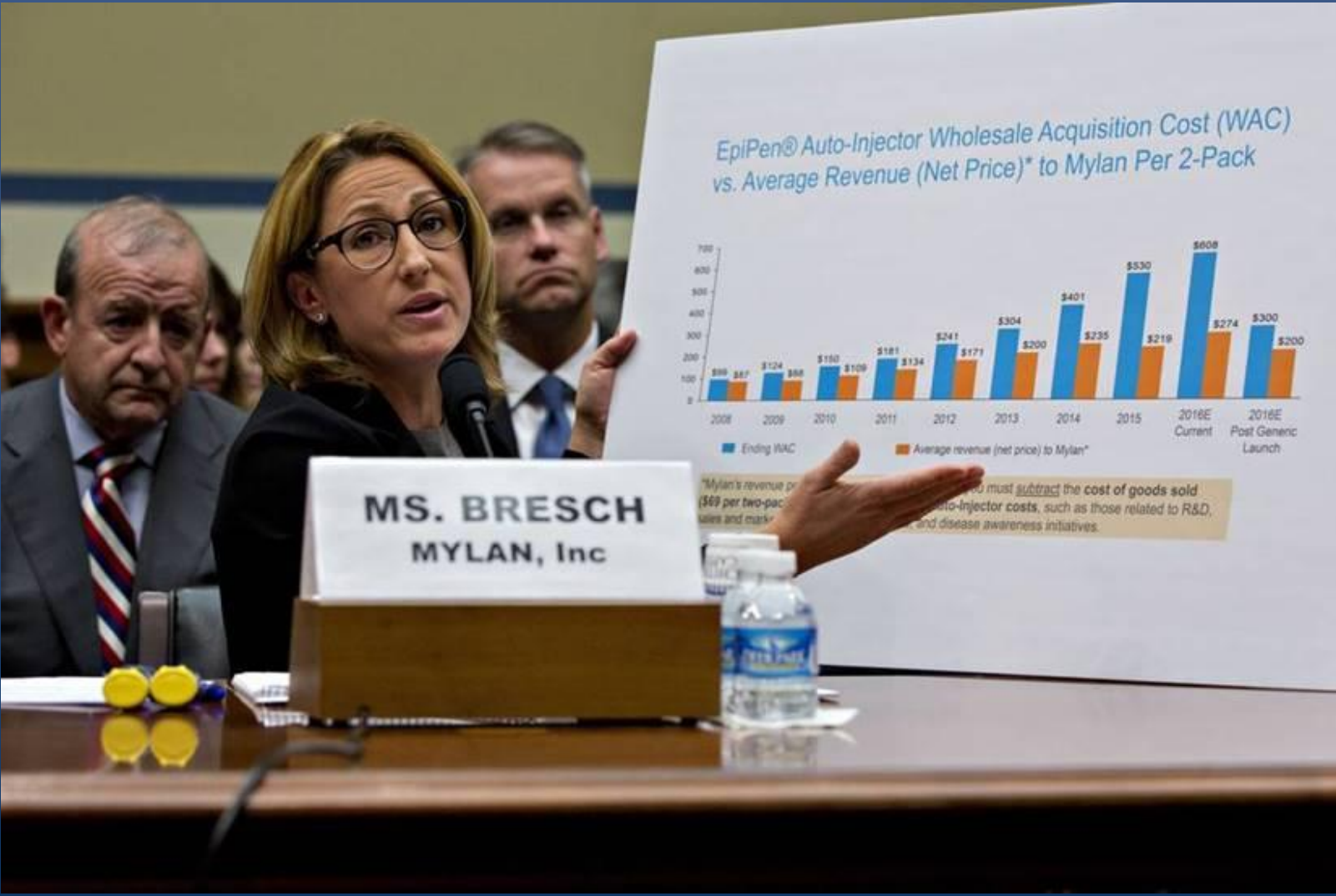
WHICH CAME FIRST

OR  
THE



## Extra PBM Revenue Streams

- 1. PBMs do not include all brand NDCs for rebate aggregation; they retain them for the PBM rather than the client.
- 2. PBMs do not pay on OTC rebates, although they collect and retain them.
- 3. PBMs do not pay on insulin rebates, although they collect and retain them.
- 4. PBMs collect and retain rebates on nonformulary drugs.
- 5. PBMs do not pay on all diabetes supplies, although they collect and retain said cost.
- 6. In relation to Pre & Post AWP – PBMs pay pharmacies Post AWP pricing but charge the client PreAWP pricing. Spread is created as a result.
- 7. PBMs may charge an admin fee on reversed claims.
- 8. PBMs adjust the number of drugs available for the guaranteed per Rx rebate guarantee by changing the denominator of drugs rebated.
- 9. PBMs only provide a portion of a “point of sale” rebates.
- 10. PBMs uses multiple MAC lists: One for the client and one for the pharmacy.
- 11. DIR Fees, also known as a clawbacks, is revenue collected from the pharmacy 90 days after a paid claim. This is 100% retained by the PBM.
- 12. MTM – They collect DIRs fees for not performing MTM to their satisfaction.
- 13. PBMs are responsible for manipulation of the Most-Favored Nations pricing.
- 14. PBMs affect the overall effective generic discount by manipulating the following:
  - 15. Reversed/Rejected Claims
  - 16. Compound Claims
  - 17. 340B claims
  - 18. OTC claims NOT covered as part of the plan benefit
  - 19. Devices
  - 20. Vaccines
- 21. PBMs do not confirm that all pricing will be based on the AWP on the actual date the drug is dispensed, for the actual package size dispensed, and for the actual quantity dispensed.
- 22. PBMs do not pass-through U&C claims.
- 23. PBMs take spread on compound claims.
- 24. PBMs charge the client a professional administration fee for a vaccination, but do not pay the pharmacy the fee.
- 25. PBMs may create spread on repackaged NDCs.
- 26. PBMs negotiate a lower rebate, but request lower acquisition cost for the drug at their in-house pharmacy.
- 27. PBMs negotiate a higher rebate by allowing leaner early refill rules that increase the chance for an additional fill per year.
- 28. PBMs dispense 90 day supplies, but charge the client for a 100 day supply.
- 29. PBMs waive copays to steer towards mail order pharmacy.
- 30. PBMs reclassify the generic as a brand. As a result, they pay the pharmacy as a generic and charge the client a brand rate.
- 31. PBMs switch the NDC. As a result, they pay the pharmacy the lower cost NDC and charge the client the more expensive NDC.
- 32. Zero Balance Due – shift 100% patient pay into the contractual guaranteed agreement.



EpiPen® Auto-Injector Wholesale Acquisition Cost (WAC) vs. Average Revenue (Net Price)\* to Mylan Per 2-Pack



MS. BRESCH  
MYLAN, Inc

\*Mylan's revenue price must subtract the cost of goods sold (\$69 per two-pack) and other auto-injector costs, such as those related to R&D, sales and marketing, and disease awareness initiatives.



## Arkansas Legislation

- PBMs to be licensed by Department of Insurance as of 9/1/18
- Application/Renewal and Fees TBD via Rulemaking--Arkansas Proposed Rule 118 "Pharmacy Benefit Managers"
- PBM network must be adequate and accessible-- within "reasonable distance" from consumer's home-- as determined by Insurance Commissioner; mail order availability is not considered in determination of network adequacy; reimbursement must be "fair and reasonable" to provide adequate pharmacy network.
- Rulemaking to spell out details of required PBM Network Adequacy Report
- PBM and their reps prohibited from causing or knowingly permitting the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading;
- Cannot charge a pharmacist or pharmacy a fee related to the adjudication of a claim, including receipt/processing, development or management of claims services in PBM network or inclusion in PBM network unless approved by Commissioner of Insurance
- PBMs cannot have accreditation requirements to network participation that are more restrictive than (or in addition to) those of AR Board of Pharmacy (unless approved by Insurance Commissioner in coordination with Board of Pharmacy)
- Cannot reimburse a pharmacy or pharmacist in the state an amount less than the amount that the PBM reimburses a PBM affiliate for providing the same pharmacist services.
- The amount shall be calculated on a per-unit basis using the same generic product identifier or generic code number



## Arkansas Legislation Cont.

- A claim for pharmacist services shall not be retroactively denied or reduced after adjudication of the claim, (unless submitted fraudulently, duplicate payment or pharmacy services were not properly rendered)
- Termination of a pharmacy or pharmacist from a PBM network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for services properly rendered.
- Commissioner may issue a rule establishing prohibited practices of PBMs providing claims processing services or other prescription drug or device services for health benefit plans
- Pharmacists/pharmacies may provide info to consumers on total cost for pharmacy service for a prescription drug; PBM cannot prohibit pharmacy from discussing information regarding the total cost for pharmacy services for a prescription drug or selling more affordable alternative to insured if one is available.
- PBM contracts cannot prohibit, restrict or limit disclosure of information to Department of Insurance, law enforcement, or government officials investigating complaint or PBM compliance with this law.