Prescription Drug Price Gouging

Joint Commission on Health Care
September 4, 2019 Meeting

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The impact of rapid price increases of prescription drugs

- ✓**Drugs don't work if you can't afford to buy them.**
- ✓**In 2016, 28% of Americans aged 16 – 64 stopped taking medication as prescribed due to cost.[1]**
- ✓**The drug pipeline is complex and lacks transparency.**
- ✓**There has been increasing outcry from consumers.**
- ✓**Between 2012 and 2017 the price of these brand name drugs increased:[2]**

1. State Health Access Data Assistance Center (SHADAC) analysis of National Health Interview Survey Data.
2. Stephan W. Schondehmeyer and Leigh Purvus. Rx Price Watch Reports. Washington, DC: AARP Public Policy Institute, June 2019.

2

SB 1308 (Edwards) was introduced in 2019 session to prohibit unconscionable price increases of essential off-patent or generic drugs.

- The DMAS Director must report to Secretary of HHR if price gouging suspected.
- When prices increases meet gouging criteria the Secretary would notify the Attorney General who is then authorized to issue a a civil investigative demand.
- SB 1308 was modeled after a Maryland bill that was later struck down as unconstitutional.
  - The court determined that the bill violated the dormant commerce clause by regulating the price of transactions outside of Maryland.[1]
- SB 1308 was passed by indefinitely in Education & Health Committee with letter of request to JCHC chair to study the issue.
- Patron request: research alternative solutions for state- and private-funded drugs.[2]
- See Appendix I for bill language.

[1] United States Court of Appeals for the Fourth Circuit, No. 17-2166.
[2] Communication with Senator Edwards April 18, 2019.

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Drug Spending Increases

- Drug unit price increases, not increased utilization, are driving drug costs.
  - From 2012 - 2016, the **price** of drugs rose approximately 25% while **utilization** increased by approximately 2%.[1]
- A common perception - the high price of drugs is justified by the cost of research and development, including the cost of drugs that never make it to market.
  - But a Thomson Reuters study found that drug companies spend far more on marketing and advertising then they do on research and development.[2]
- There are many players in the drug distribution chain – fingers are being pointed in all directions.

[1] The Real Price of Medications - A Survey of Variations in Prescription Drug Prices. Reuben Mathew, Lance Kilpatrick & Adam Garber. U.S. PIRG Education Fund, March 2019.
[2] https://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf

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To influence the system there needs to be an understanding of how it works.

Drug Pipeline Participants - Each can add to the price of a drug[1]

1. **Manufacturers** start the process by setting a price. Price factors include research and development costs, marketplace competition, number of patients that would use the drug and impact on their lives, and advertising and marketing costs.
2. **Wholesalers** purchase drugs in bulk directly from manufacturers. They in turn sell to pharmacies and other purchasers.
3. **Pharmacy benefit managers** (PBMs) handle the prescription drug benefit of most insurance plans. They negotiate prices from the manufacturer or wholesaler, set retail prices, pay pharmacies and determine what they will charge insurers or employers. PBM actions can have a direct impact on demand for specific drugs.
4. **Insurers** hire PBMs to negotiate with pharmacies and reimburse prescription drug costs.
5. **Pharmacies** pay for the drugs patients actually receive at a price the PBM negotiates.
6. **Consumers** may pay for the drug directly, if uninsured, or partially through their insurance. They will either pay a percentage determined by their insurer and PBM, a flat rate based on type of prescription, or the retail price if uninsured.

[1]https://masspirg.org/sites/pirg/files/reports/MAP%20Rx%20Price%20Report%20March%205.2019.pdf

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The drug delivery and payment pipeline involves multiple players and relationships that influence the cost of drugs.

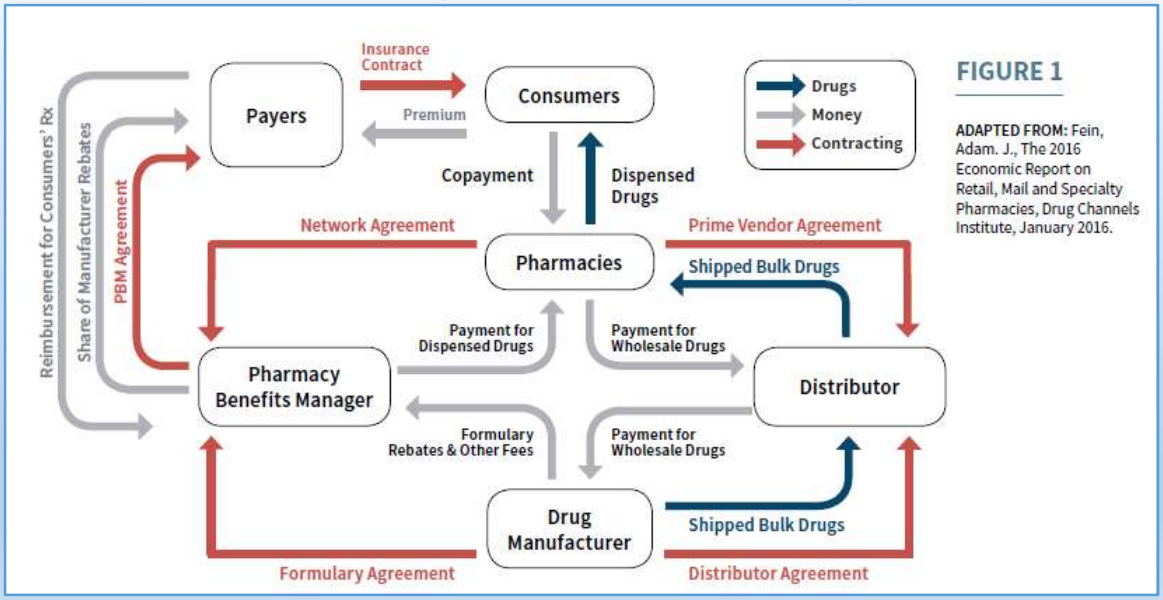

FIGURE 1

ADAPTED FROM: Fein, Adam. J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2016.

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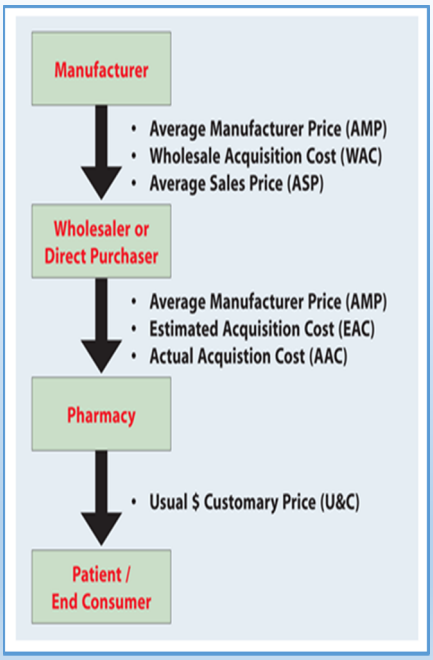
Drug Pricing Terms

- **The Average Manufacturer Price** (AMP) is a measurement of the price wholesalers pay for products from the manufacturer after *rebates* or discounts.
- **The Average Wholesale Price** (AWP) is a measurement of the price paid by pharmacies to wholesalers. This is an **estimate** based on reporting to data vendors.
- **The Wholesale Acquisition Cost** (WAC) is an estimate of the manufacturer's list price to wholesalers, it does not include discounts/rebates.
- **The Average Actual Cost** (AAC) is considered the *final* cost paid by pharmacies to their wholesalers *after all discounts have been deducted* and is derived from actual audits of pharmacy invoices. Currently, two states are using the AAC for pharmacy reimbursement.
- **The Average Sales Price** (ASP) is derived from the sales from manufacturers to all purchasers and includes most discounts, but is limited in that it *is only available for Medicare Part B covered drugs.*[3]



https://www.uspharmacist.com/article/understanding-drug-pricing.

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Drug Pricing Terms, Cont'd.

- **The federal upper payment limit** is the price ceiling used by Medicaid at the federal level.
- **The maximum allowable cost** (MAC) is the ceiling established by the states.
- **The Estimated Acquisition Cost** (EAC) is an estimated price that state Medicaid programs use to reimburse pharmacies for the cost of the drug plus a "reasonable" dispensing fee. The EAC is meant to reflect the cost of the drug to the pharmacy from the wholesaler, but is not a published figure.
- **The Usual and Customary Price**, or cash price is the amount charged at a retail pharmacy. It reflects the cost to the consumer without insurance.
- **The Best Price** is the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, (Medicaid, 340B covered entities, Medicare Part D plans, and certain other purchasers)

https://www.uspharmacist.com/article/understanding-drug-pricing

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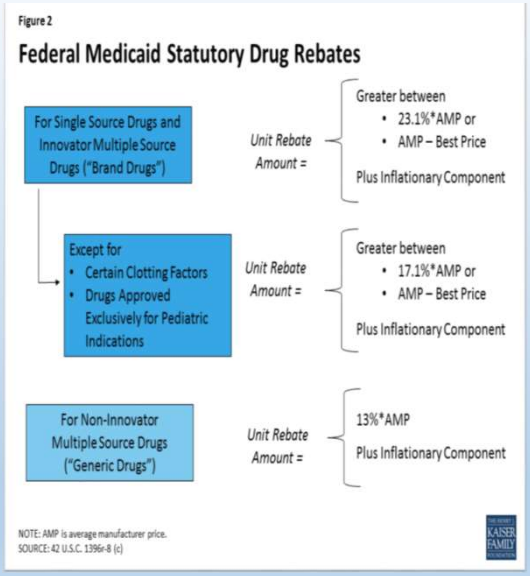
Federally mandated and supplemental rebates



- ***Federal rebates*** - Manufacturers must provide rebates to states in order to sell brand name drugs to Medicaid patients, or they are excluded from selling to other federal programs.
- Rebates are not reflected in list prices and have been cited as a barrier to lowering drug costs.
- ***Supplemental rebates*** (in addition to federal rebates) are paid in exchange for placement on a Preferred Drug List (PDL) and result in market share shifts to the preferred drug[1], *even if the list price is greater than an available alternative.*
- ***Price spread*** is the difference between the PBM cost and the price the PBM charges the insurer. The price spread would be narrowed if a manufacturer lowered the list price (versus paying rebates) but could result in a drug being removed from the formulary or placed in a higher price tier.

[1]https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf

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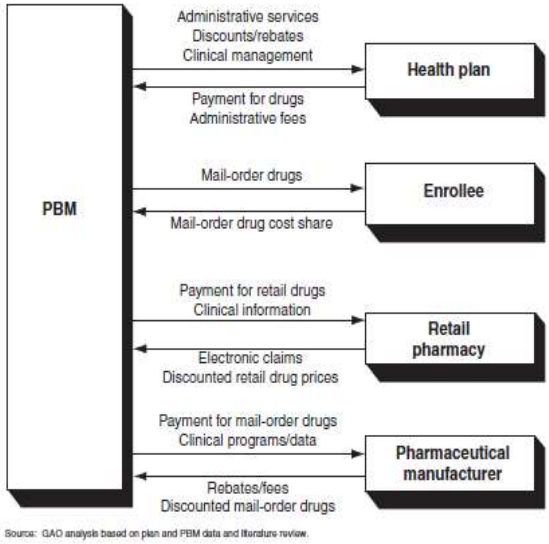
PBMs' Relationships with Market Participants. PBMs' primary customers are *health plans and employers*, not patients.



PBMs receive payment from multiple entities:

- MCOs provide payments for administering pharmacy services.
- Beneficiaries pay a copay at the time of dispensing.
- PBMs receive proprietary negotiated supplemental rebates from manufacturers and other fees based on their contract for services, (e.g., efforts to increase a manufacturers share of products, favorable formulary tier placement, encouraging physicians to change prescribing patterns, patient education on compliance regimens, and data reporting).

In turn, PBMs pay:

- Pharmacies a negotiated payment for drugs based on ingredient costs and dispensing fee.
- MCOs may receive a negotiated portion of supplemental rebates from manufacturers and other fees.
- Direct and indirect remuneration (DIR) fees from pharmacies after the point-of-sale.

Payment rate agreements between PBMs and pharmacies, and pharmacies and wholesalers, are complex and generally not known to plan sponsors (payers).

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Ninety-five percent of insured individuals have drug coverage managed by a PBM.
The three largest PBMs control 80% of the market.

- PBM market power is directly related to their ability to provide exclusive formulary coverage to manufacturers.
- PBMs sell logistical infrastructure and bargaining power to insurers, and may provide clinical services (formulary development/management, prior authorization, drug utilization reviews, and generic substitution).
- PBMs choose which drugs are covered by insurers and receive rebates from manufacturers, based on a percentage of list price.
- This can result in perverse incentives where PBMs profit on brand-name drugs more than they profit on generics (e.g., 5% of $10 versus $100).
- Agreements are **kept secret** to encourage manufacturers to provide discounts, so it is unknown if savings ever reach patients.

Information Sources: Pharmacy Benefit Management, 2015: Are Reporting Requirements Pro- or Anti Competitive? Danzon; Int. J. of the Economics of Business Is More Information Always Better? CO Health Institute, August 2018.
Pharmacy Benefits Managers – As Drug Prices Soar, Policymakers Take Aim.
Mandatory Disclosure Regulations in the Prescription Drug Market. J. Shepherd, Cornell Law Review Online Vol. 99:1.
In Depth Analysis of Pharmaceutical Pricing. UNC Chapel Hill Gillings School of Public Health, March 3, 2017.

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PBM Pricing Models

- *Spread-pricing*:
  - There is an agreed-upon price paid by the PBM to the manufacturer or wholesaler for a drug which is different from the price the PBM pays the pharmacy; the PBM keeps the difference.
- *Pass-through pricing*:
  - The PBM charges the insurance company the amount they reimburse the pharmacy (for ingredient cost and dispensing fees) and charge separate fees for administrative and clinical tasks.

Pass-through models are more transparent than spread-pricing.

- **A number of states have banned spread-pricing contracts. The JCHC may consider proposing legislation to ban spread-pricing contracts in Virginia.**

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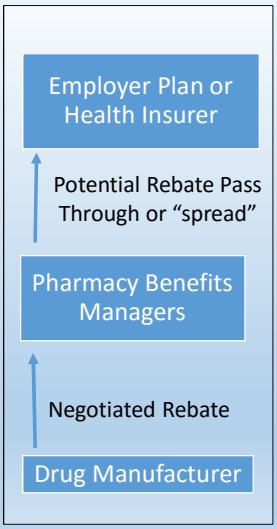
Rebates paid by manufacturers to PBMs are the primary cause for over-utilization of brand name drugs when more affordable generic versions are available.



- Proponents of rebates paid to PBMs argue that rebates lower overall drug costs; critics argue they perversely increase patient out-of-pocket costs and costs for payers as a whole.
- A PBM may decide to cover only one drug with multiple competitors in exchange for a better rebate. This can drive "drug pumping" where a PBM favors a higher-priced drug because they make more on the rebate (which is based on percentage of the WAC).
- Rebates are not reflected in the WAC or list price amounts. Patients are charged the list price, despite the PBM rebates.
- Most health plans do not have access to the PBM's payment amounts paid to a pharmacy; they can't compare what the PBM charges the plan to what it pays the pharmacy.[1]
- The PBM Association claims that the lack of transparency is a myth and increasing transparency would result in higher prices, as it would make tacit collusion more feasible and distort market dynamics.

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/

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Several states have audited PBM spread pricing in their Medicaid Managed Care programs.

State	Finding
Ohio	• From 4/1/17 – 3/31/18 the spread on drugs in the Medicaid MCO program ranged from 0.8% for branded drugs, 31.4% for generics, and 1.1% for specialty drugs with a total average spread of 8.9%.[1] • The average price spread represented **$224.8M** on 39.4 million drug claims. • In 2018 Ohio announced that its Medicaid MCO programs would switch to a pass-through model.
KY	• PBMs that contracted with Kentucky Medicaid MCOs reported being paid **$957.7M** for spread pricing contracts, $123.5M of which was kept by the PBMs in CYs 2018 and 2019.[2]
Mass	• Drug spending in 2012 grew twice as fast as other MassHealth spending. The state noted its concern of the use of spread pricing for generic drugs by PBMs.[3] • In 2014, spread pricing covered 22% of all PBM compensation, but in 2016 that number rose to 54%. • For SFY 2020, Massachusetts officials have proposed a requirement for PBMs to be transparent about pricing and to limit PBM margins under MCO and accountable care organization contracts. • The government projects savings of $10 million.

1. Ohio's Medicaid Managed Care Pharmacy Services Auditor of State Report, August 16, 2018.
2. Medicaid Pharmacy Pricing. Kentucky Cabinet for Health and Family Services Office of Health Data Analytics, 2/19/2019.
3. https://www.fiercehealthcare.com/payer/massachusetts-puts-transparency-demands-pbms-as-drug-spend-jumps-41

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Virginia Medicaid Medallion 4.0 Contract Requirements - HB 1700 Item 307 #1h.

- The MCO Contractor shall report the following to DMAS for all pharmacy claims:
  - The amount paid to the pharmacy provider per claim, including costs of drug reimbursement, dispensing fees, and copays.
  - The amount charged to the plan sponsor for each claim by its PBM.
- In the event of a difference per claim between the amount paid to the pharmacy and that charged to the plan sponsor by its PBM, the plan shall report all administrative fees, rebates, and processing charges.
- DMAS shall annually report to the Chairmen of the House Appropriations and Senate Finance Committees on this initiative and its impact on expenditures by 10/01 each year. Nothing in the report shall contain confidential or proprietary information.
- The 2017 findings; 7.3% of claims had an MCO payment greater than the amount paid to the pharmacy, resulting in estimated **MCO payments to PBMs $13.8M above PBM payments to pharmacies.**
- Limitations of the report include that one quarter of data is not sufficient to make accurate conclusions about the relative impact of various pricing models. The next report will be published in October 2019.

https://www.dmas.virginia.gov/files/links/1566/Medallion%204.0%20Contract%20(07.26.2018).pdf

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PBMs are not regulated in Virginia other than needing a business license. The JCHC may wish to provide authority to the state to regulate PBMs.

- The absence of PBM transparency, and lack of a legal obligation for the PBM to act in the best interest of the insurer and its members, create opportunities for arbitrage.
- Remedies include:
  - ✓ Legislation requiring PBMs to work in the best interest of the insurers and their members,
  - ✓ pass-through versus spread contracting, and
  - ✓ increased transparency and reporting requirements.
- Twenty-seven states require PBMs to obtain licensure from their states' departments of insurance.
- Current Virginia Bureau of Insurance (BOI) regulations specify that the BOI has authority over *insurance companies*. BOI representatives have expressed the concern that PBMs are not insurance companies (although many, if not most, are owned by insurance companies).
- Other states have had success by regulating PBMs through their insurance partners.
- The JCHC may consider providing the BOI with authority to regulate PBMs through insurers.

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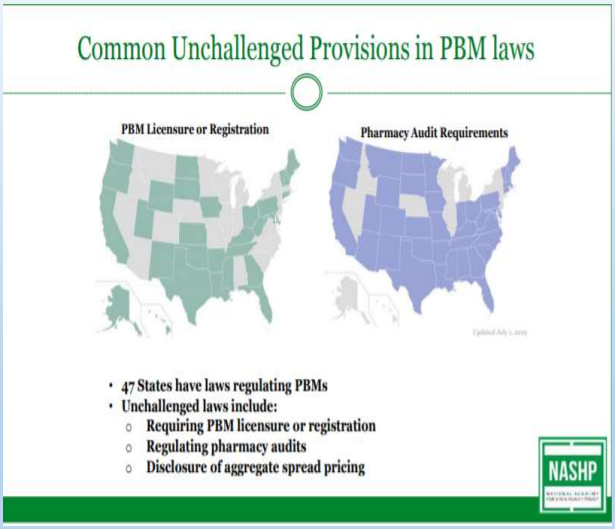
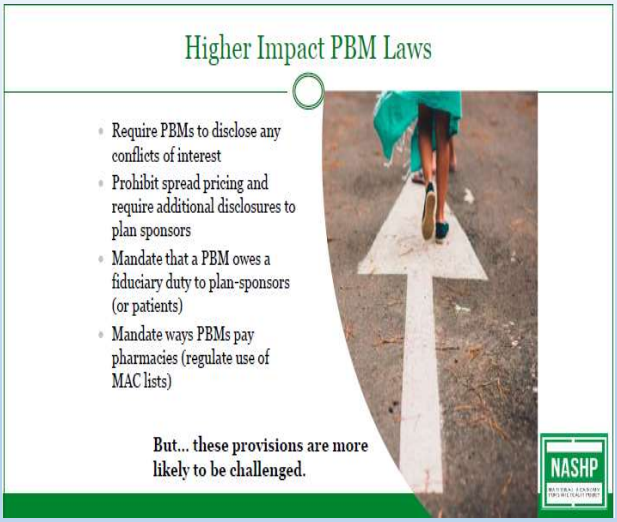
In order to craft bills that will withstand legal challenge, Virginia lawmakers would work closely with the State Attorney General Office and Legislative Services staff, as well as consult with other states that have been successful in this respect.





State laws are vulnerable to challenge based on: the dormant Commerce Clause, void-for-vagueness challenges, ERISA, free speech, trade secrets, and *takings*.

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California, Connecticut and Louisiana passed Laws in 2018 to mandate disclosures from PBMs on in addition to existing laws that require PBMs to be licensed.

State	Requirements
California	• PBMs must register with the Department of Managed Health Care and disclose aggregate rebates. • The law creates a task force and pilot project to assess if the state should require PBMs to disclose more information, and requires that manufacturers notify the state of raises in the price of a drug by greater than 16% over a 2-year period. • The law is being challenged by PhARMA.
Connecticut	• PBMs must report to the state Insurance Commissioner aggregate rebates for drugs. The law also requires insurers to give lawmakers information about the cost of drugs and whether insurance carriers are using the rebates from PBMs to reduce premiums or cost-sharing.
Louisiana	• PBMs must publish a report on the state's Department of Insurance website with information about the typical size of drug rebates and if rebates are passed on to insurers.

http://sourceonhealthcare.org/spotlight-on-2018-state-drug-legislation-part-6-pharmacy-benefit-manager-regulation/

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Require PBMs to act in the best interests of insurers and members.

- Nevada and Maine implemented the requirement that PBMs **work in the best interest of insurers and their members**, and at least four other states are considering similar laws.
- Maine's law requires PBMs to be licensed by the state starting 1/1/20**.** The law:
  - Requires PBMs to use a **single maximum allowable cost list** for each pharmacy provider and disclose the sources used to establish the maximum allowable costs (It is standard practice for PBMs to use a **lower-priced** MAC list to pay a pharmacy and then use a **higher-priced** MAC list to bill the carrier, and keep the difference).
  - **Disallows retroactive payment reductions to pharmacies**, unless fraudulent or paid in error. It requires any reductions at the point of sale benefit the covered person.
  - Requires that insurer payments to PBMs for administrative services **be classified as an administrative cost when calculating the medical loss ratio**.

http://www.ncsl.org/research/health/pbm-state-legislation.aspx

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Pharmacy Services Administrative Organizations (PSAOs) are cooperative networks for independent pharmacies to help them compete against large, national chains.

- When an independent pharmacy signs a ***network aggregate reimbursement guarantee agreement*** with a PSAO, it joins a network of independent pharmacies, aggregating bargaining power.
- Most PSAOs are owned by drug wholesalers or pharmacy cooperatives; they collect receivables for the independent pharmacies and send payments to them.
- Under these agreements, PSAOs reconcile pharmacy claims (for up to a year after payment) from every contracted pharmacy *together* and compares the actual total aggregate reimbursement to the network aggregate reimbursement guarantee amount.
- **The PBM can reimburse the pharmacy at any rate it deems appropriate as long as overall reimbursement for all combined claims for all contracted pharmacies during the contract period equals the rates in the agreement.**
- Overpayments are deducted from future claims payments. The deductions can be dramatic and result **in cash-flow problems for the pharmacy**.

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Authorized generic drugs are approved brand name drugs that are marketed without the brand name on the label.

- The marketing and production of authorized generic drugs are **exclusively controlled and directed by brand-drug manufacturers.**
- There are approximately 1,2000 authorized generics approved in the U.S. according to the Food and Drug Administration**.**
- Even though an authorized generic drug is the same as the brand name product, a company may **choose to sell the authorized generic drug at a lower price than the brand name drug**.
  - Authorized generic drug are usually **not subject to rebates** and may therefore be more profitable for the manufacturer, even at a lower price.
  - Authorized generic drugs **do not promote competition.**[1]
- Proposed federal regulation would require that authorized generic drugs be excluded from the Average Manufacturer's Price (AMP) calculation under the Medicaid rebate program, which would have the effect of increasing rebates, as only brand-name drugs are eligible for federal rebates.

[2] https://khn.org/news/drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/

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Pay-to-Delay

- New drug patents give manufacturers a period of exclusivity to recoup costs. As soon as patents expire, generic versions of the drug can be manufactured and sold.
- Generic drugmakers can try **to shorten the period of exclusivity** by challenging patents. When they do, brand-name makers often **sue them for patent infringement**.
- Because litigation is costly, the generic drug companies often settle and agree to delay release of their version of the drug.
- The Federal Trade Commission has estimated that pay-to-delay deals cost consumers and taxpayers $3.5B every year.[1]
- **Introduced in California - AB 824: Preserving access to affordable drugs.** The bill would classify agreements in which "anything of value" is exchanged between brand-name and generic drugmakers that delay release of generic versions as anticompetitive and therefore illegal. This would help the state Department of Justice bring cases against drugmakers by shifting the burden of proof: It would be up to the companies to prove their deals are legitimate. Violations can result in civil action and penalties up to $20M.[2]
- The JCHC may wish to propose legislation to prohibit pay-to-delay using California legislation as a model.

[1] https://californiahealthline.org/news/california-bill-would-fight-deals-that-delay-generic-drugs/
[2] https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB824

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Manufacturer Coupons

- Coupons lower consumer out-of-pocket costs at the point of purchase and can improve adherence to medication regimes; they are used by manufacturers to increase sales.
- Coupons are generally focused on higher cost drugs.[1]
- When there is a generic competitor, coupons for the brand-name drug are intended to shift consumers away from the generic competitor, (often one that paid rebates in exchange for a more favorable formulary placement.)[1] The coupon price is not reflected in list price calculations.
- A study published in *Health Affairs* found that in 2015 that **only 12% of couponed brand name drugs had *no* generic substitute or equivalent** and virtually all coupons were for brand name drugs.[2]
- Coupons are banned by Medicare and Medicaid where they are characterized as kickbacks.
- The JCHC may wish to consider proposing legislation to ban the use of coupons in Virginia.

[1]Roehrig, C. PhD. The Impact of Prescription Drug Rebates on Health Plans and Consumers. ALTARUM, April 2018.
[2]https://www.healthaffairs.org/do/10.1377/hblog20180215.988517/full/

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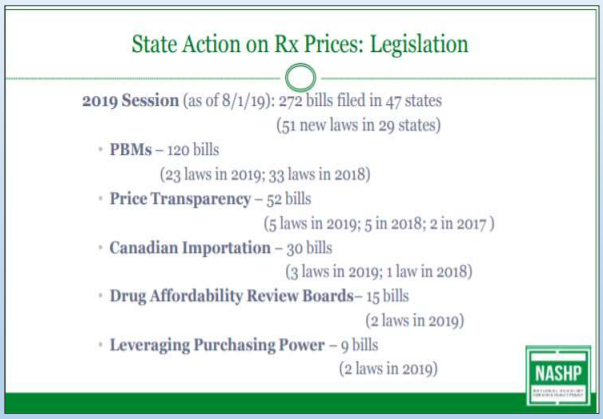
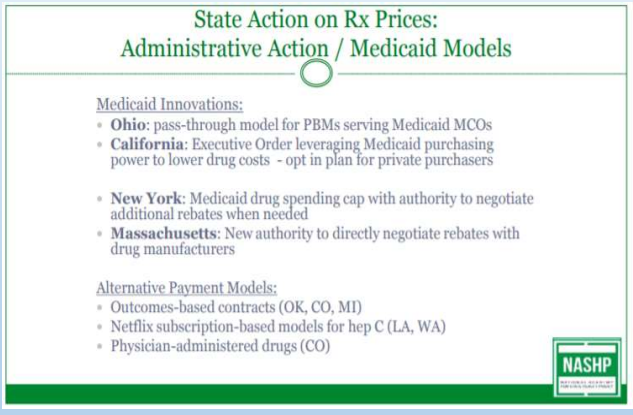
Many states have introduced and/or passed legislation to tackle high drug prices.

Virginia can learn from their experience.





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State Actions: Lawsuit Against Anti-Competitive Actions of Drug Makers

- Attorneys General from 44 states (including Virginia) are alleging that the nation's largest generic drug manufacturers conspired to artificially inflate and manipulate prices for more than 100 generic drugs.
- The lawsuit filed in federal court in Connecticut on 5/10/19, names 15 senior executives responsible for sales, marketing and pricing. (The Associated Press 5/11/19).
- The allegations show the lengths manufacturers went to hide price fixing plans, mislead Congress and destroy evidence.[1]

[1] "60 Minutes" Episode: "The Price of Generics" (5/12/2019) https://www.cbs.com/shows/60_minutes/video/_SPbK7pa0HqLvYkr65pLG0cjLDGbZOoJ/t he-price-of-generics-the-most-unlikely-meeting-mark-bradford/.

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State Actions: Drug Price Transparency

States	Requirement
Vermont	• Authorized a board to identify 15 drugs for which the state spends a significant amount, including drugs with a WAC increase of 50%.
Connecticut & Nevada	• PBMs and manufacturers must disclose the amount all rebates. • Manufacturers that raise the price of diabetes therapies must disclose costs associated with marketing and production.
Texas	• Drug companies must provide information when a drug price increases more than 15% in a year, or more than 40% over 3 years. • PBMs would have to report rebates, fees, price protection payments and other payments from drug companies and how much they retained.
Maine	• Regulates PBMs through the insurance companies. • PBMs must provide an annual report on the 25 most frequently prescribed drugs, 25 most costly, and 25 drugs with the highest year-over-year cost increase.
Kentucky	• PBMs contracting with Medicaid MCOs must report financial and business relationship information regarding their interactions with MCOs and Kentucky-enrolled pharmacies.
South Carolina	• PBMs must be licensed and audited by the state.

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State Actions: Transparency report requirements for manufacturers

State	Manufacturers must report
Connecticut	• Total company-level research and development costs for the most recent year.
Nevada	• Total administrative expenditures. • Profit earned and percentages of total profit attributable to a drug. • Total amount of financial assistance provided as patient assistance. • Cost associated with coupons. • WAC. • 5-year history of price increases. • Aggregate rebates provided to PBMs.
Texas	• Total company level research and development costs for the previous year.
Washington	• Annual manufacturing, marketing and advertising costs. • Total cost of clinical trials and regulation. • Total costs for drug acquisition. • Total financial assistance given via coupons, rebates, etc.

Sources: Connecticut HB 5384/Public Act 18-41(2018);
Nevada Department of Health and Human Services (2018a);
Texas HB 2536 (2019);
Washington HB 1224, Chapter 334 (2019).
In addition to the items indicated, each state requires manufacturers to report reasons for price increases.

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Transparency Report Elements – National Academy of State Health Policy and Mathematica

- What do you want to know?
  - What has changed in the base price,
  - the market size in the state,
  - profit per unit,
  - rebate amounts,
  - production costs,
  - R & D costs,
  - financial assistance to consumers,
  - rebates to PBMs and others
  - price before rebates,
  - marketing and advertising costs,
  - other administrative expenses,
  - company-level capital expenses.
- Drugs of interest: Top 25 in 4 categories:
  - high total spend,
  - year over year change in total spend,
  - high total spend per user,
  - high year over year change in total spend per user.
- Which entities must report:
  - insurance companies,
  - manufacturers,
  - PBMs, and
  - wholesalers.
- Penalties for reporting non-compliance.
- Provisions for data protection.
- Manufacturers must notify 60 days prior to:
  - 20% in WAC of a brand name drug over 12 months,
  - 200% increase in WAC of a generic drug priced $100 or more per WAC unit over 12 months,
  - New drug priced $670 or more per WAC unit.

Must use consistent reporting concepts, requirements, measurement units for all reporters.

https://nashp.org/drug-price-transparency/

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State Actions: Importation from Canada - Canada has expressed concern about in-country drug shortages.

State	Program Details
Florida	The Governor signed legislation on 6/11/19 allowing the state to develop programs to import drugs from countries such as Canada. • The legislation establishes an international export permit for participation in the Drug Importation Program. • The program does not allow importation of a controlled substance, biological product, infused drug, IV injected drug, drugs inhaled during surgery or parenteral drugs. • Canadian suppliers would export drugs to the State Department of Central Pharmacy to then distribute to health departments, free clinics, Medicaid pharmacy, Department of Corrections, and developmental disabilities centers. • The program must include an operation plan, safety and tracing plans, estimate cost savings and cost of implementation. • The program will be administered by a third party that will compile drug lists, ensure safety, meet financing requirements, obtain a bond against the financial consequences of acts of malfeasance or fraud, and provide detailed reporting.
Maine	The governor signed a law on 6/24/19 to set up a wholesale prescription drug importation program with approval from the U.S. Department of Health and Human Services. • HHS Secretary Alex Azar said he and President Trump "are committed to making importation work".

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State Actions: In- and Cross-State Purchasing Coalitions

- The California Governor and Los Angeles County said they would sit at the same bargaining table when negotiating prescription drug prices with manufacturers.[1]
- The Department of General Services was tasked with creating a list of high-cost drugs on which to focus and to develop a plan for bulk purchases.
- Governors in Rhode Island, Colorado and Illinois have expressed interest in a similar model.
- Delaware's state Legislature has established an Interagency Pharmaceuticals Purchasing Study Group.[2]

1. https://www.latimes.com/politics/la-pol-ca-california-gavin-newsom-prescription-drugs-costs-20190417-story.html
2. https://nashp.org/delaware-takes-on-high-prescription-drug-costs-by-leveraging-public-purchasers/

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State Actions: Colorado Caps the Payment of Insulin[1]

- Insulin has been around for nearly a century, but the price that patients pay has doubled since 2012.[1]
- The average U.S. list price of the 4 insulin categories increased by 15% - 17% per year from 2012 to 2016, despite the fact that patents for many formulations have expired.
- There has been a widening gap between the net and list price of insulin, which appears to result from increasing rebates and discounts. The rate of increase in rebates has accelerated to approach approximately half of the list price.
- Under a bill signed by the Colorado governor, diabetics will pay no more than $100 a month for insulin starting 1/1/20.
- The law requires the Colorado AG to investigate why drug manufacturers started rapidly raising the price of insulin in recent years and report the findings by 11/20.
- Insulin manufacturer Novo Nordisk reported $2.02 billion in profit in its 2019 second-quarter earnings report, up from $1.83 billion in the same quarter of last year, with sales rising 9.6 percent to $4.5 billion. The company attributed the growth to sales in its diabetes-and-obesity business. (MarketWatch).[2]

1. https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf
2. https://mail.google.com/mail/u/0/#inbox/FMfcgxwDqfFTGxftlZqgRQzwNCKRhZdM

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State Actions: Louisiana Subscription-Based Payment Model For Hepatitis C Drugs

- Louisiana entered into a 5-year contract with Gilead to pay a fixed annual cost for unlimited access to drugs for Medicaid members and prisoners.
- Louisiana is paying an amount based on their previous year's spend; no other charges occur.
- The state used supplemental rebates and 340b providers to get around the best price problem (so the amount the state pays is not included in the best price calculation, which would apply to all purchases and inhibit a deal).
- The state is rolling out an outreach program and adding Hepatitis C testing and treatment as a Statewide Protocol (Hepatitis C antibody tests can be preformed without a M.D. order).
- Advantages to the model:
  - Predictable spending regardless of an increase in utilization from the base year.
  - All beneficiaries/prisoners with the condition can be treated, based on a positive screening test (versus liver damage criteria).
  - Could be expanded to include other drugs for which access and risk of overuse are limited (e.g., diabetes drugs).
- Disadvantages:
  - There must be unmet need in the target populations.
  - Need a strong commitment from the state, and implementation may take a year or more to conclude.
  - Based on the success of the outreach efforts, Hepatitis C testing will increase (positive for public health but will increase testing costs).
- See Appendix IV for information on disease prevalence in the country and in Virginia corrections systems.

https://www.fiercepharma.com/pharma/louisiana-seeking-comments-netflix-model-for-hep-c-drugs

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State Actions: Value-Based Pricing – Paying for Drugs that Work

States	Program Details

Michigan	• The state received federal approval of an 1115 Demonstration Waiver to negotiate Medicaid drug prices based on how well medications work.
	• Several drugs have been included:
	  • long-acting antipsychotics,
	  • Orbactiv, a one-time injectible antibiotic for skin infections, and
	  • the epilepsy drug Fycompa.

Oklahoma & Colorado	The states received CMS approval for value-based payment programs.
Washington	• On 6/12/19 CMS approved a request to pursue supplemental rebate agreements involving value-based purchasing primarily focused on Hepatitis C drugs using the subscription model. • A contract between Amgen and Harvard Pilgrim on Repatha cholesterol drug - Harvard gets a rebate based on the patients' cholesterol levels.

- CMS welcomes proposals from other states for amendments to allow the negotiation of supplemental rebates involving value-based purchasing in Medicaid.
- Challenges include defining and measuring outcomes and the need to take into account factors such as oversight of the physician, lack of medication adherence by the patients, etc.

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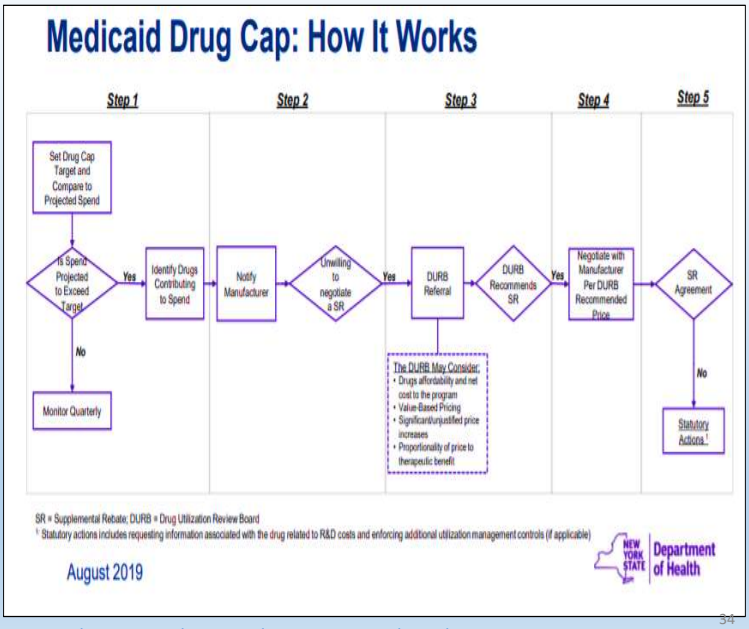
State Actions: New York Medicaid Drug Spending Growth Cap

- New York imposed a Medicaid drug spending growth cap limiting growth to the 10-year rolling average of the medical component of the CPI plus 4%.
- When it appears the cap will be breached, the Commissioner of Health may refer a drug to the state Drug Utilization Review Board (DURB).
- The DURB has authority to recommend a target supplemental rebate amount.
- If the Commissioner cannot negotiate a supplemental rebate of at least 75% of the target, the Commissioner is authorized to place the drug on the prior authorization list.
- In the first year, the Drug Cap successfully achieved $55M in savings. The provision is estimated to save $85M in SFY 2018-2019.[1]



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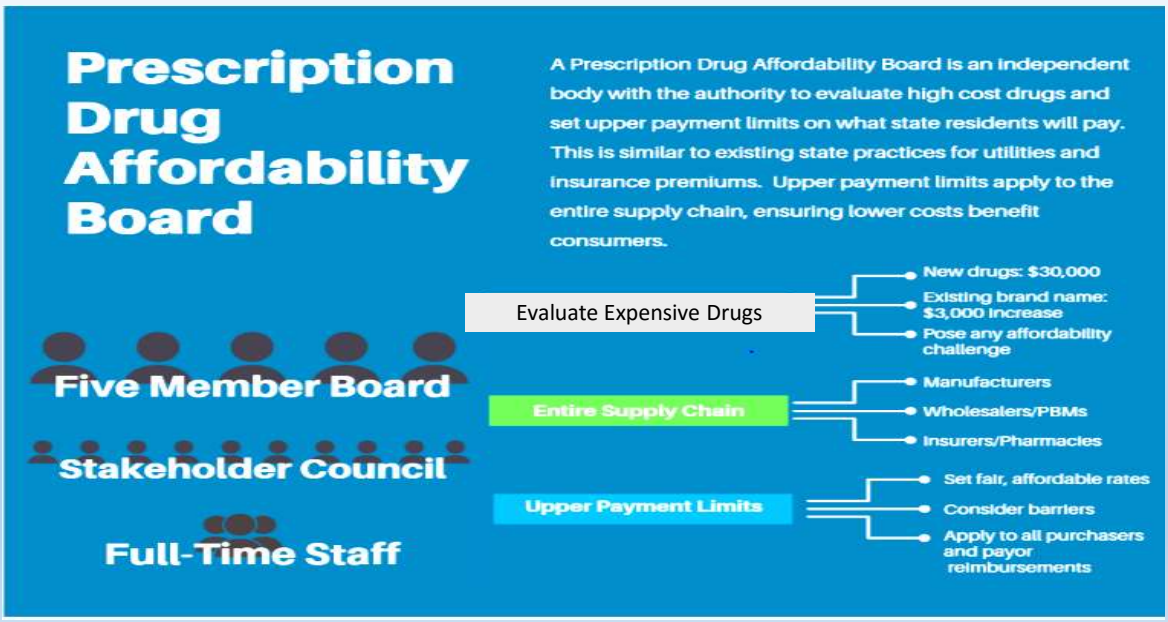
[1] https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/monthly/sfy_2018-2019/docs/mar_2019_report.pdf

State Acton: Maryland's Prescription Drug Affordability Board (PDAB)



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Maryland Prescription Drug Affordability Board – Upper Payment Limits (UPL)

- H.B. 11942/S.B. 10233 established a PDAB to set upper payment *reimbursement* limits (UPL) (versus price limits) for certain drugs purchased for state, municipal, state university, and community college employees and teachers. The law went into effect 7/1/19.
- The Board will look at drugs with costs that greatly impact Marylanders, including dugs that impact the budgets of state, county & local government programs and facilities.
- Beginning in 2022, in consultation with the Legislative Policy Committee, the Board may begin to set UPLs for drugs purchased by state/county/local governments and may expand to all purchasers in 2024.
- Strategies to meet expenditure goals can include: collaborating with other states, consortia to purchase in bulk, restructuring formularies, procuring common expert services for public payers, and securing deeper rebates.
- The law requires PBMs to obtain a license from the Bureau of Insurance.
- The law imposes transparent, clearly defined fiduciary relationships with enforcement and oversight performed through the health insurance carriers with whom PBMs contract.
- Maryland estimated $750,000 of new state general funds would be needed in the first year, which must be refunded to the state. It estimated that a 0.5 FTE OAG position would be needed, which would cost $81,945 in the first year. Sources of repayment could include assessments on manufacturers, PBMs, insurance companies, wholesale distributers, using rebates that the state receives.

A survey sponsored by the Maryland Citizen's Health Initiative in 2019 asked voters if they were in favor of, or in opposition to, a Drug Affordability Board. The majority of respondents favored a Board.

https://familiesusa.org/sites/default/files/product_documents/SILC_2019-RX-Agenda-Report.pdf
https://nashp.org/Maryland-passes-nations-first-prescription-drug-affordability-board-legislation/
https://states.aarp.org/maryland/may-2019-rx-drug-survey

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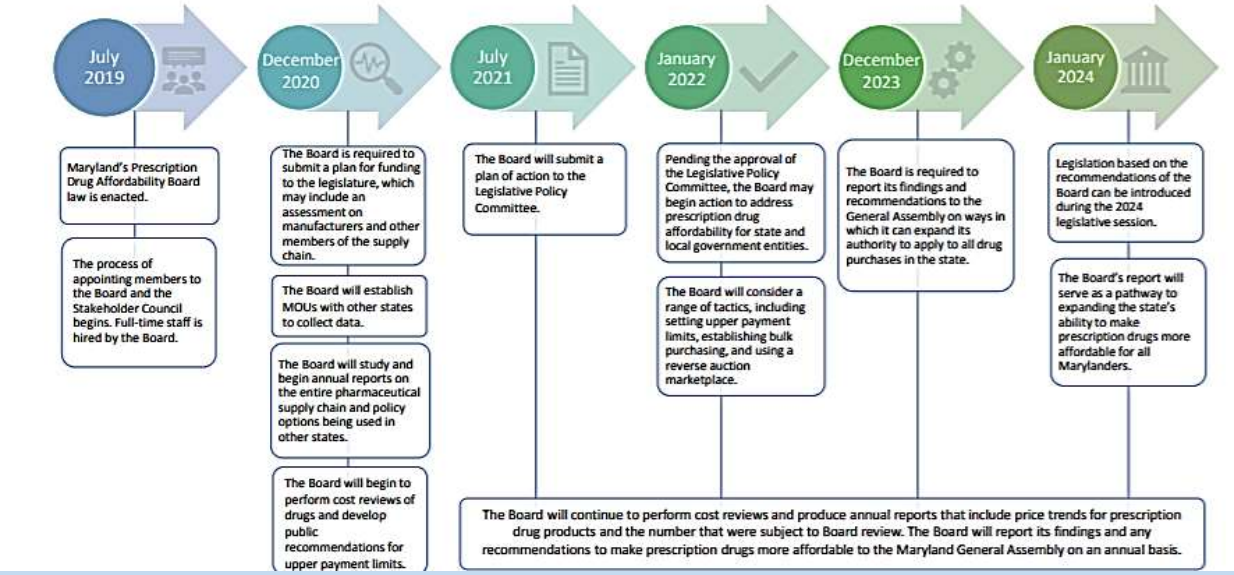
Maryland's Prescription Drug Affordability Board Timeline



NASHP%20Rx%20Preconference%20Ebook%208.15.19.pdf

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Policy Options

No.	Option	Pros	Cons
1.	Maintain the current status.	• Implementing new programs would require significant work and budget allocations to pay for this work. • State programs could take a year or more to implement. • New Federal laws may make state action unnecessary.	• It is uncertain if any of the proposed Federal legislation will become law, or if they do, what the final language will be.
2.	Propose new regulation to authorize the BOI to license and regulate PBMs through insurance companies.	• Would allow the state to mandate elements of PBM activities (e.g., requiring pass-through contracts, transparency reports, no clawbacks, conflict of interest, etc.). • Regulating PBMs through their insurance partners avoids ERISA challenges. • Depending on the spread retained by a PBM, this may reduce overall costs, and savings may flow through to lower out-of-pocket costs and insurance premiums.	• The BOI has expressed concern that PBMs are not insurance products. • May require additional staff and a budget appropriation to fund new positions and administrative functions.

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Policy Options, Cont'd.

No.	Option	Pros	Cons
3.	Require pass-through contracts between PBMs and insurance companies with audit rights. (with Option 2).	• Pass-through contracts require that PBMs charge insurers the net price of a drug. • Increases transparency and eliminates spread pricing. • Discourages the use of brand name drugs when cheaper generics are available.	• The administrative portion of insurer's payments to PBMs may increase to compensate for lost income from supplemental rebates and lower revenue, related to the reduction of the use of higher priced brand-name drugs. • May result in a decrease of insurer's medical loss ratio if previous contracts classified all PBM payments as medical costs.[1] • If cost-plus reimbursement is used, it may incent manufacturers to set higher prices.[2]

[1] CMS guidance dated May 15, 2019 requires that rebates and administrative costs be removed from MCO MLR calculations, including those performed under contracts with third-party vendors and requires vendors to report underlying claims data to MCOs. This also applies to vendors who are paid by the MCO on a capitated basis; administrative costs included imbedded in capitation payments must be classified as such, in order to calculate the MLR.

[2] Pharmacy Benefit Management, 2015: Are Reporting Requirements Pro- or Anti Competitive? Danzon; Int. J. of the Economics of Business.

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Policy Options, Cont'd.

No.	Option	Pros	Cons
4.	Require PBMs to submit transparency reports. (with Option 2).	• Would increase transparency, reporting could include: • Administrative expenses – require PBMs to categorize as admin versus medical costs, more accurate MLR. • Profits earned • Financial assistance provided • Rebates • Cost associated with coupons • WAC • 5-year history of increases • Advertising & marketing costs • R & D costs	• May add to administrative costs to PBMs that get passed on to employers. • If information is not confidential could enable tacit collusion. • May give unfair insights into competitors. • May require audits. • May reduce margins on generics undermining incentives to encourage generic utilization.[1]

1. These considerations were articulated in the Cornell Law Review Online Vol.99:1, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*. Joanna Shepherd, Associate Professor of Law, Emory University School of Law which relies on findings from the GAO-03-196 published January 2003; Federal Employees' Health Benefits Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies.

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Policy Options, Cont'd.

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No.	Option	Pros	Cons
5.	Require PBMs to act in the best interest of insurers and members. (with Option 2).	• Would provide transparency and discourage hidden arbitrage. • Increased bargaining power of health plans and pharmacies to level the playing field. • Discourage the use of brand name and authorized generics and increase the use of lower cost generic drugs. • Disallow PBMs using lower cost MAC lists to pay pharmacies, higher cost MAC lists to bill insurance companies, and keeping the difference.	• Could require increased monitoring.
6.	Prohibit the use of manufactures' coupons.	• May increase price transparency. • The use of coupons can drive shifting from generics to brand name drugs and result in higher insurance premiums.	• Coupons may be used by uninsured individuals or when the coupon lowers the price paid by the consumer to below the insurance copay amount. • Patients may perceive this as a price increase, as the use of coupons lowers the cost to the patient at the point of sale.
7.	Introduce legislation modeled after California to ban pay-to-delay agreements.	• Would accelerate the pipeline for generic drugs.	• Would require resources of the Office of the Attorney General and possible budget appropriation to pay for the increased resource need.

Policy Options, Cont'd.

No.	Option	Pros	Cons
8.	Develop a program to import drugs from Canada.	• Could lower costs for imported drugs. • Supported by the Trump Administration and CMS. • Imported drugs would be safe. • The drug market is already a global market.	• Canada has released statements of opposition, citing concern about drug shortages in their country. • Would take significant state resources and time to craft/pass legislation and implement a program. • A Budget appropriation may be needed for administrative costs.
9.	Develop a subscription model for purchasing Hepatitis C and other drugs for Medicaid members and incarcerated individuals.	• Could expand access to treatment and lower the price of Hepatitis C drugs. • Could help prevent the spread of Hepatitis C. • Could be expanded to include diabetes and other appropriate drugs.	• The model only works if there is unmet need. • The lack of providers trained in treating Hepatitis C would need to be addressed (Project Echo may be a solution). • Hepatitis C testing costs would increase. • Would take significant state resources and time to craft/pass legislation and implement a program. • A Budget appropriation to pay administrative costs may be needed.
10.	Implement a Drug Affordability Board and Upper Payment Limits, such as Maryland, Maine, New York and Vermont.	• Imposes transparency. • Would help set fair, affordable prices.	• Would take significant state resources and time to craft/pass legislation and implement a program. • A Budget appropriation to pay administrative costs would be needed.

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Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on September 25, 2019.

- Comments may be submitted via:
  - email: jchcpubliccomments@jchc.virginia.gov
  - fax: 804-786-5538
  - mail: Joint Commission on Health Care
    P.O. Box 1322
    Richmond, Virginia 23218

Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 14th decision matrix meeting.

(All public comments are subject to FOIA release of records)

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Appendix I: Virginia Senate Bill 1308 Offered January 9, 2019 (Edwards)

- A BILL to amend the Code of Virginia by adding a section numbered 32.1-330.6 and by adding in Title 5 32.1 a chapter numbered 20, consisting of sections numbered 32.1-373 through 32.1-376, relating to 6 prohibition on prescription drug price gouging.
- Be it enacted by the General Assembly of Virginia: 12 1. That the Code of Virginia is amended by adding a section numbered 32.1-330.6 and by adding 13 in Title 32.1 a chapter numbered 20, consisting of sections numbered 32.1-373 through 32.1-376, as follows:
- 15 § 32.1-330.6. Prescription drug price gouging; notification to Attorney General.
- A. As used in this section, "wholesale acquisition cost" has the same meaning as in 42 U.S.C. 17 § 1395w-3a. B. The Director shall notify the Attorney General of an increase in the price of an essential off-patent or generic drug, as defined in § 32.1-373, if
  - (i) the increased price, alone or in combination with other price increases, would result in a price increase of 50 percent or more in the wholesale acquisition cost of the drug as compared with the wholesale acquisition price for the same drug prior to the increase or the price paid by the Department for the drug prior to the price increase, (ii) the cost of a 30-day supply of the maximum recommended dosage of the drug for any indication approved by the U.S. Food and Drug Administration would cost more than $80 at the wholesale acquisition cost, or (iii) in cases in which the drug is made available to consumers only in quantities that do not correspond to a 30-day supply, a full course of treatment of the drug would exceed $80.

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Appendix I: Virginia Senate Bill 1308 Offered January 9, 2019 (Edwards)

- Definitions. As used in this chapter, unless the context requires a different meaning: "Essential off-patent or generic drug" means any prescription drug
  - (i) for which all exclusive marketing rights granted under the federal Food, Drug, and Cosmetic Act, § 351 of the federal Public Health Service Act, and federal patent law have expired;
  - (ii) that appears on the Model List of Essential 34 Medicines most recently adopted by the World Health Organization or that has been designated by the Secretary as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities or daily living;
  - (iii) that is actively manufactured and marketed for sale in the United States by three or fewer 38 manufacturers; and
  - (iv) that is made available for sale in the Commonwealth.
- "Essential off-patent or generic drug" includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights granted under the federal Food, Drug, and Cosmetic Act, § 351 of the 41 federal Public Health Act, and federal patent law have expired.
- "Manufacturer" has the same meaning as set forth in § 54.1-3401.
- "Price gouging" means an unconscionable increase in the price of a prescription drug.
- "Unconscionable increase" means an increase in the price of a prescription drug that

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Appendix I: Virginia Senate Bill 1308 Offered January 9, 2019 (Edwards)

  - (i) is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health and
  - (ii) results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of the importance of the drug to their health and insufficient competition in the market for the drug.
- "Wholesale distributor" has the same meaning as set forth in § 54.1-3401. § 32.1-374. Price gouging prohibited.
- A. No manufacturer or wholesale distributor shall engage in price gouging in the sale of an essential off-patent or generic drug
- B. An increase in the price of an essential off-patent or generic drug charged by a wholesale distributor shall not constitute price gouging if the increase is directly attributable to additional costs for the drug imposed on the wholesale distributor by the manufacturer. § 32.1-375. Designation of essential drugs. The Secretary may designate a drug as an essential drug for the purposes of this chapter. Such designation shall be based on a finding of the drug's unique efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities or daily living. A list of all drugs identified as essential drugs for the purposes of this chapter shall be posted on a website maintained by the Department. § 32.1-376. Enforcement. Upon receipt of notification of suspected price gouging pursuant to § 32.1-330.6 or in any other case in which the Attorney General has reasonable cause to believe that any person has engaged in, is engaging in, or is about to engage in any violation of this chapter, the Attorney General is empowered to issue a civil investigative demand. The provisions of § 59.1-9.10 shall apply mutatis mutandis to civil investigative demands issued pursuant to this section.

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Appendix II: Federal Bills Working Through Congress.

Bill	Purpose
116TH CONGRESS 1ST SESSION H. R. 965	Promotes market competition for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of drugs and biological products.
116TH CONGRESS 1ST SESSION H. R. ___	Prohibits prescription drug companies from compensating other drug companies to delay the entry of a generic drug, biosimilar biological product, or interchangeable biological product into the market.
Affordable Prescriptions for Patients Act	U.S. Senators John Cornyn (R-TX) and Richard Blumenthal (D-CT) introduced a bill to curb major drug companies' anti-competitive use of patents to protect their prescription drugs and prevent generic and biosimilar competition from coming to market.
116TH CONGRESS 1ST SESSION H. R.___	Enables the Federal Trade Commission to deter filing of sham citizen petitions to cover an attempt to interfere with approval of a competing generic drug or biosimilar, to foster competition and facilitate the efficient review of petitions filed in good faith to raise legitimate public heath concerns, and for other purposes.
116TH CONGRESS 1ST SESSION H. R. ___	Requires the Federal Trade Commission to study the role of intermediaries in the pharmaceutical supply chain and provide Congress with appropriate policy recommendations, and for other purposes.
H.R. 275 Medicare Pres. Drug Price Negotiation Act of 2019	Requires CMS to negotiate with drug companies on prices for drugs covered under the Medicare drug benefit. Current law prohibits the CMS from doing so.

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Appendix II Federal Bills Working Through Congress

Bill	Purpose
S. 1664 – Prescription Drug Price Reporting Act	Requires manufacturers to report annually; • Each drug marketed in the U.S., current wholesale acquisition cost, average wholesale acquisition cost per 30-day supply, average net price per 30-day supply, total rebates and other payments to health plans or PBMs. • Financial and non-financial factors the manufacturer took into consideration when making the price change, including any changes or improvements to the drug. • Changes in the WAC within 30 days of the effective date and establish an internet-based system to post price change reports.
S. 1895, Lower Health Care Costs Act	Allows some generic or biosimilar drugs to enter the market earlier, on average. • Imposes new rules for insurers' contracts with PBMs and health care providers, (e.g., banning anti-tiering and -steering clauses). • Prohibits spread pricing. • Increases access to cost and quality information. • CBO estimates a deficit decrease of $7.6B.
S. 102 Pres. Drug Price Relief Act of 2019	Establishes oversight and disclosure requirements relating to the prices of brand-name drugs. Requires the HHS to review at least annually all brand-name drugs for excessive pricing and upon petition. If drugs are found to be excessively priced, HHS must: (1) void any government-granted exclusivity; (2) issue open, nonexclusive licenses for the drugs; and (3) expedite the review of corresponding applications for generic drugs and biosimilar biological products. HHS must also create a public database with its determinations for each drug.

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Appendix II: Federal Bills Working Through Congress - The Prescription Drug Pricing Reduction Act of 2019

- Creates a Medicaid state plan option to enter into risk-sharing, value-based purchasing arrangements with gene therapy manufacturers.
- Prohibits PBM spread pricing in Medicaid.
- Allows states to consider a drug, biological, or insulin provided on an outpatient basis under a bundled payment a "covered outpatient drug" and therefore subject to rebates.
- Enhances CMS's authority to audit manufacturers' pricing and product information reported to the Medicaid Drug Rebate Program.
- Excludes authorized generics from AMP calculations, which will increase mandatory rebates for states.
- Increases the maximum Medicaid rebate ceiling in the from 100% to 125% of AMP.
- Adds conflict of interest requirements for state Drug Utilization Review (DUR) Boards and Pharmacy and Therapeutics (P&T) Committees and a General Accounting Office report on conflicts of interest in current DUR Boards and P&T Committees.
- Adds a SSA Section that would require the HHS Secretary to audit the price and drug product information for manufacturers that participate in the Medicaid rebate program.
- Amends SSA §1927(k)(1) so that authorized generic drugs are excluded from the AMP calculation under the Medicaid rebate program, which will have the effect of increasing rebates.
- **The Congressional Budget Office projects that the PDPRA would save more than $100 billion in Medicare and Medicaid spending over 10 years, lower Medicare beneficiaries' out-of-pocket costs by $27 billion and lower beneficiaries' premiums by $5 billion; Medicaid provisions would save a net $3.1 billion over five years; $16.5 billion over ten years.**
- Passed by the Senate Finance Committee 7/25/19.

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Appendix II: Federal Bills Working Through Congress

- A current proposed plan would authorize the HHS secretary to negotiate the prices of the 250 most expensive drugs and would apply not only to the government but to all payers, including employers and insurers. The bill will be introduced in the House after the August recess.[1]

[1] https://khn.org/news/pelosi-aims-for-feds-to-negotiate-drug-prices-even-for-private-insurers/

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Appendix II: Federal Bills Working Through Congress
HHS and FDA Release Drug Importation Plan to Lower Prices

The Department of HHS and the FDA released a plan on 7/31/19 for the safe importation of certain drugs intended for foreign markets, the plan includes:

- A demonstration project for states, wholesalers and pharmacists to import drugs from Canada. States, wholesalers and pharmacists submit applications to HHS demonstrating how they will comply with safety and cost conditions.
- Applications from states must propose an arrangement with a wholesaler/pharmacist and submit attestations regarding the authenticity and eligibility of the drug.
- Excluded drugs: Controlled substances, biological products, infused and IV drugs, those inhaled during surgery, and some parenteral drugs.
- Importation from Canada into the U.S. with a new NDC number that identifies the drug as originally meant for a foreign market.

https://www.fiercehealthcare.com/payer/hhs-and-fda-release-importation-plan-to-lower-prices?

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Appendix III: Stakeholder Input

The Health Care Distribution Alliance (represents wholesalers)	Vector Corp. (represents generic drug makers)
The Association for Accessible Medicines	The Virginia Association of Health Plans
Health Care for All-Maryland Citizens' Health Initiative	The Virginia Bureau of Insurance
Kemper Consulting, Inc. (represents PhRMA)	Virginia Commonwealth University School of Pharmacy
Kerr Government Strategies	The Virginia Department of Corrections
Phizer Inc. Representative	The Virginia Department of Health
Troutman–Sanders (represents PBMs and McKessen)	The Virginia Department of Health Professions Boards of Pharmacy and Medicine
Virginia Department of Medical Assistance Services	

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Appendix IV: Centers for Disease Control and Prevention Estimates of Reported and Unreported New Cases of Hepatitis C, 2006 - 2016

Hepatitis C

Reported Acute (New) Cases of Hepatitis C Virus (HCV)

2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
802	849	878	781	853	1,230	1,778	2,138	2,194	2,436	2,967

Estimated Actual New Cases of HCV (range)

2011 (estimated)*	2012 (estimated)*	2013 (estimated)*	2014 (estimated)*	2015 (estimated)*	2016 (estimated)*
16,500 (7,200-43,400)	24,700 (19,600-84,400)	29,700 (23,500-101,400)	30,500 (24,200-104,200)	33,900 (26,800-115,500)	41,200 (32,600– 140,600)

* Actual acute cases estimated to be 13.9 times the number of reported cases in any year

Est. No. of Chronic Cases In the United States

3.5 million

https://www.cdc.gov/hepatitis/statistics/DiseaseBurden.htm

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Appendix IV: Hepatitis C Incidence in Virginia Corrections System

- More than 5,000 of approximately 30,000 Virginia offenders could have Hepatitis C, according to a VCU Health study published in the Journal of Correctional Health Care. But according to the Department of Corrections (DOC), only 452 were treated between 3/2015 and 7/2018, meaning thousands are living with the disease while a cure is now available.[1]
- The Virginia DOC recently implemented an *opt out* testing procedure to determine a more accurate measure of Hepatitis C Virus (HCV) among incarcerated individuals in the Commonwealth.
- According to Virginia DOC officials, there are approximately 2,800 incarcerated individuals in Virginia who are known to be HCV positive at this time (8/1/19), and close to 1,000 have been treated.[2]
- According to DOC officials, it is assumed that **the true percentage of positive offenders is closer to 15-30% of 30,000 individuals (4,500 to 9,000 individuals), which is the known percentage in other states.**
- There is a **lack of provider capacity** to treat patients who test positive. Offenders are referred to the VCU clinic but they lack the capacity to meet the demand. If the provider shortage is addressed, drug use will increase. [2]
- Project ECHO training through VCU and UVA could help address provider training needs.

[1] https://www.virginiamercury.com/2018/09/17/thousands-of-virginia-inmates-are-believed-to-have-hepatitis-c-and-cant-access-the-cure/

[2] Communications August 1 and 15, 2019 with Trey Fuller, Pharm, D Assistant Director of Health Services, Chief Pharmacist, Health Services Unit Virginia Department of Corrections

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Appendix V: The American Medical Association Supports State Regulation of Pharmacy Benefit Managers

Supports the regulation of PBMs by state departments of insurance which would require:

- The application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to prices at the point of sale.
- Increased transparency in how DIR fees are determined and calculated.
- Improved transparency on PBM operations; disclosure of utilization, rebates, discounts, and financial incentives.
- P&T committee information, including records on why a medication is chosen for or removed from a formulary, whether committee members have a conflict of interest, and decisions related to tiering, prior authorization and step therapy.
- Information on why certain drugs are preferred over others.
- Information on cost-sharing responsibilities made available to patients at the point-of-care and to prescribers in electronic health records.
- Methodology and sources utilized to determine drug classification and multiple source generic pricing.
- The percentage of sole source contracts awarded annually.

The AMA also will develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.

https://www.ama-assn.org/delivering-care/public-health/time-scrutinize-pbms-outsized-role-rx-decision-making

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Appendix V: The National Council of Insurance Legislators Pharmacy Benefit Manager's License and Regulation: A Model Act

- The model establishes standards and criteria for regulation and licensure of PBMs to promote, preserve and protect public health, safety and welfare.
- The model act provides for oversite powers and duties of the Insurance Commissioner and the State Insurance Department, and it prescribes penalties for violations.
- Sections include:
  - Authorizes the commissioner to prescribe the requirements for license application and application and renewal fees;
  - PBM Network Adequacy;
  - Compensation and Prohibited Practices;
  - PBM information is not subject to FOIA; all information considered proprietary;
  - Prohibits gag clauses; and,
  - PBMs must notify pharmacies subject to the Maximum Allowable Cost List within 7 days of an increase of 10% or more.

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Appendix VI: Model Legislation to Regulate Pharmacy Benefit Managers

Center for State Rx Drug Pricing

HOME / PHARMACY BENEFIT MANAGER MODEL LEGISLATION AND RESOURCES

Pharmacy Benefit Manager Model Legislation and Resources

NASHP's Center for State Rx Drug Pricing has developed model legislation that allows states to define new standards for pharmacy benefit manager (PBM) business practices. This model bill addresses PBMs' fiduciary responsibilities and bans PBM gag clauses that prevent pharmacists from sharing lower cost drug options with consumers.

Pharmacy Benefit Manager Model Legislation A: This model legislation enables states to directly regulate PBMs, and gives states flexibility to identify which agency should oversee PBMs.

Pharmacy Benefit Manager Model Legislation B: This PBM model legislation allows states to regulate PBMs through their state insurance departments. It is modeled after Maine's Bill 1504, approved in 2019.

Montana Explores a New Approach to Regulating Pharmacy Benefit Managers: This blog highlights Montana's approach to address PBM business practices by leveraging i insurance department's regulatory authority over insurance carriers.

Pharmacy Benefit Manager Questions and Answers: Commonly asked questions and answers about PBMs' role in the drug supply chain and NASHP's model legislation.

How Legislation Helps States Shed Light on Pharmacy Benefit Manager Operations: This blog explores how states can use this model legislation to license PBMs, ban gag clauses that prevent pharmacists from sharing lower-price drug options with consumers, and require more transparency into exactly who profits from rebates.

Chart Comparing Pharmacy Benefit Manager laws in 21 states. States took varied approaches to regulating PBMs in 2018. This chart details each state's approach and how their laws compare with NASHP's PBM Model Legislation A.

NASHP's Center for State Rx Drug Pricing develops model legislation to help states control rising prescription drug costs, and features the bills on its website. State officials interested in these model bills should contact Jennifer Reck for more information.

NASHP is continuing to research state legislative and administrative actions to control pharmaceutical costs. Check the resources listed below for updated information.

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Appendix VI: Model Regulation for Drug Price Transparency

Center for State Rx Drug Pricing

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Drug Price Transparency Model Legislation and Resources

NASHP developed two versions of a model drug cost transparency bill to enable states to take a comprehensive approach to unlock the black box of pharmacy pricing and increase consumer awareness.

Comprehensive Transparency Model Legislation: This bill includes language detailing the data components. Download the following reporting templates to capture the data required:

- Manufacturer Report for New Drugs
- Pharmacy Benefit Managers Report
- Wholesale Drug Distributor Report
- Insurance Issuer Report

Enabling Transparency Model Legislation: This version of the transparency model legislation does not have the provisions that detail the data components.

Transparency Model Legislation Q&As

NASHP and its work group are working to support states as they advance transparency legislation and will track those efforts at its Center for State Rx Drug Pricing. State officials interested in this model legislation can have access to a legislator's guide and additional background materials as they become available. Contact Jennifer Reck for more information.

NASHP continues to research state actions on pharmaceutical pricing. Check out the resources below for the latest on prescription drug transparency.

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Appendix VI: Model Regulation for Drug Affordability Review Boards

Center for State Rx Drug Pricing

HOME / DRUG AFFORDABILITY REVIEW BOARD LEGISLATION

Drug Affordability Review Board Legislation

NASHP's prescription drug affordability review board legislation enables states to set allowable rates for certain high-cost drugs, similar to the process states use to regulate utilities or insurance premiums. Under this law, a state drug affordability review board would establish the maximum amount that payers would pay for individual drugs. While transparency laws expose the true cost of drugs, this approach takes the next step to protect consumers and payers from over-priced drugs.

- Model Affordability Review Board (Rate-Setting) Legislation
- Model Legislation Explanation
- Drug Affordability Review Board Legislation Q&A
- Drug Affordability Review Boards (Rate Setting) Explained – Blog
- Comparison Chart of States' Affordability Review Board Bills

NASHP works with states to advance drug affordability review board legislation and will continue to track and report on those efforts at its Center for State Rx Drug Pricing. Contact Jennifer Reck for more information.

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Appendix VI: Model Legislation and Toolkits for Drug Importation

Center for State Rx Drug Pricing

HOME / DRUG IMPORTATION MODEL LEGISLATION AND TOOLKITS

Drug Importation Model Legislation and Toolkits

NASHP's drug importation model legislation creates a state wholesale importation program to purchase lower-cost drugs from Canada and make them available to state residents through an existing supply chain that includes local pharmacies.

Model Prescription Drug Importation Legislation – "An Act to Permit the Wholesale Importation of Prescription Drugs into (State)"

Wholesale Drug Importation Legislation Q&A

Easy-to-understand Infographics explaining how drug importation works

An overview explaining of NASHP's Model Importation Legislation

Other resources:

- *Vermont's Wholesale Importation Program for Prescription Drugs Legislative Report*, December 2018. NASHP and a team of consultants, including FDAImports.com, LLC, provided staff support to Vermont's effort, which concluded that significant savings would result from importation. Based on just 17 high-volume, high-cost drugs identified for two of the state's three major carriers the savings from Canadian importation would be between $1 and $5 million annually.
- *NASHP Worksheet for Payers #1: Determining Top 35 Prescription Drugs by Payer "Spend,"* January 2019. This worksheet helps states prioritize which prescriptions drugs are candidates for wholesale importation from Canada by prompting payers to identify their top-spend drugs based on cost times utilization.
- *NASHP Worksheet for Payers #2: Savings for Payers from Canadian Importation*, January 2019. This worksheet builds on the top-spend drug list and allows payers to determine potential savings from wholesale importation from Canada.
- *Press Release: NASHP Applauds Vermont for Taking Next Step in Prescription Drug Importation*, January 2019. NASHP released a press release after Vermont published its report on wholesale importation in December 2018.

NASHP and its work group helps states advance legislation to contain prescription drug prices and tracks states efforts on its website. State officials who are interested in this model legislation have access to a legislator's guide and additional background materials. Contact Jennifer Reck to receive this material for state officials-only.

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