State Solutions to Lower Prescription Drug Prices

Utah Health Reform Task Force

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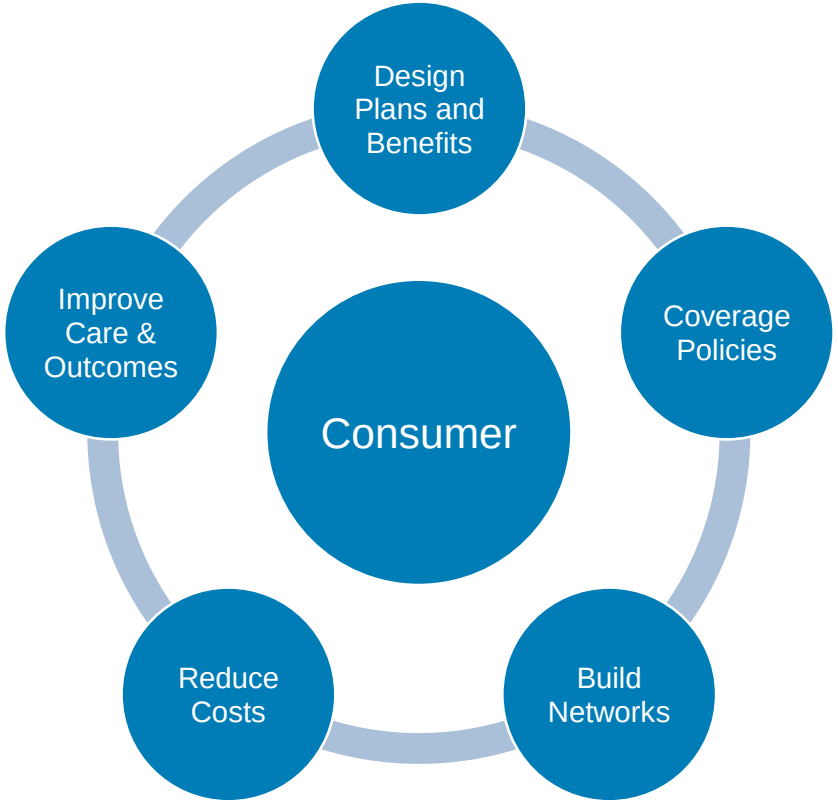
October 3, 2019
Salt Lake City, UT

Who is AHIP?

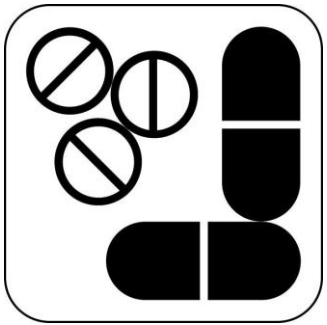
America's Health Insurance Plans (AHIP) is the national association whose members provide coverage and health-related services that **improve and protect the health and financial security of consumers, families, businesses, communities and the nation**.

Health Insurance Providers = 360º View

MEDICAL



PHARMACY



Out-of-Control Drug Prices:

Four themes

Broken and Distorted Pharmaceutical Market

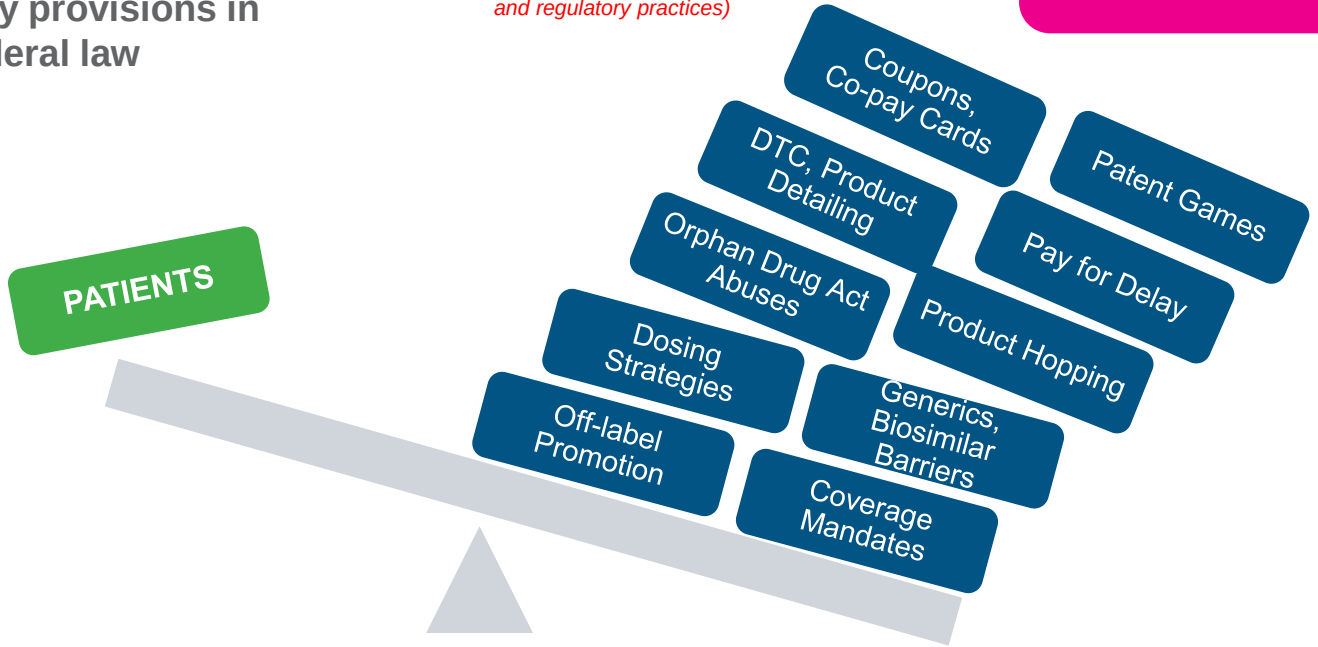
Government-granted monopolies via patent system and market exclusivity provisions in federal law

+

Market Dysfunction
(via problematic marketing, legal, and regulatory practices)

=

HIGH PRICES HIGHER COSTS



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Market Distortion:

Copay Cards

Coupon usage is 18% of all branded prescriptions in 2017

Usage is 42% of all specialty prescriptions

Specialty medications for autoimmune diseases, HepC, and MS have coupon usage rates above 50%

Very little transparency in the system when they are used

Source: Medicine Use and Spending in the U.S. - A Review of 2017 and Outlook to 2022, IQVIA Institute, April 2018

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Copay Coupons

Coupons increased brand drug makers' revenue by **$700 million to $2.7 billion**, an average windfall of $30 to $120 million per drug

- Coupons reduce the use of generic drug competitors and **increase brand drug sales by more than 60%**
- Coupons are prohibited in federal health care programs like Medicare and Medicaid (*Considered a "kickback", as they induce a patient to take a certain drug*)

When Discount Raise Costs: The Effect of Copay Coupons on Generic Utilization.

Massachusetts vs. New Hampshire

In a 2017 study on copay coupons, the researchers took neighboring states that had differing approaches to copay coupons to analyze the impact coupons have on generic utilization and drug spending.†

	Massachusetts	New Hampshire
Coupons Allowed?	**NO** - Massachusetts banned the use of coupons statewide	**YES** - New Hampshire allows coupon use in non-federal programs
Drugs Not Offering Coupons	When branded drugs did not offer coupons, **use of generic alternatives was equivalent** in both states	
Drugs Offering Coupons to All Patients		• When branded drugs offered coupons, use of generic alternatives was **3.4% LOWER** • This amounted to **$700 million more in drug spending – $2.9 billion over five years**
Drugs That Offer Coupons Among Patients <65 yrs		• When branded drugs offered coupons for this age group, use of generic alternatives was **6.3% LOWER** • Increased spending could reach close to **$6 billion**

† *When Discount Raise Costs: The Effect of Copay Coupons on Generic Utilization.*

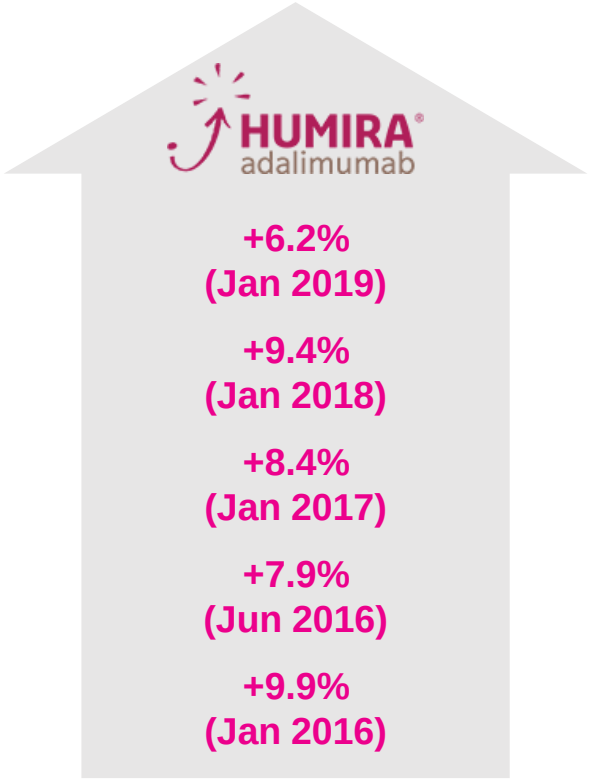
Large Price Increases on New & Older Therapies

Multiple Sclerosis Drugs Cost Much More Today than When Introduced

FDA Approval			2017
(1993)	BETASERON® (interferon beta-1b) 0.3 mg for SC injection	**$8,300 - $11,000** Average cost in 1990s	**$91K**
(2004)	EVERY 4 WEEKS 300mg IV TYSABRI® (natalizumab)	**30% per year** Average price increase for some drugs over two decades	**$82K**
(2016)	ONCE MONTHLY Zinbryta® (daclizumab) 150 mg Subcutaneous Injection	**$83,000+** Average cost in 2017 for all MS therapies	**$88K**

Source: Huff, Charlottte; "MS Drugs: Expensive, Often Lifelong, and Not Cost-Effective," Managed Care Magazine, Sept 30, 2018.

Large Price Increases: Humira Case Study



#1 selling drug in the world with $19.9 billion in sales in 2018*

*Abbvie Financial Results 2018, reported Jan 25, 2019

>$50,000 in annual drug expenses per patient

15+ years with no biosimilar competition (FDA approved in 2002)

Patent settlement blocks biosimilar (until at least 2022)

Source: Bloomberg, EvaluatePharma, US Bureau of Labor Statistics; Statista.com; Medicare/Medicaid Drug Dashboard; Barron's

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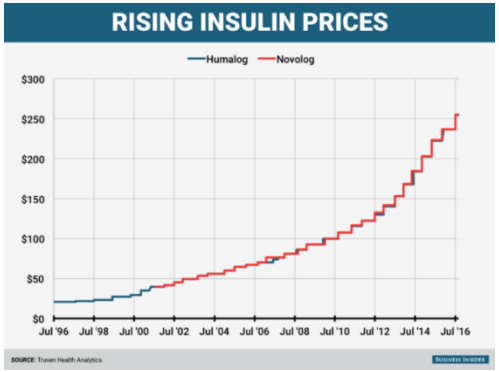
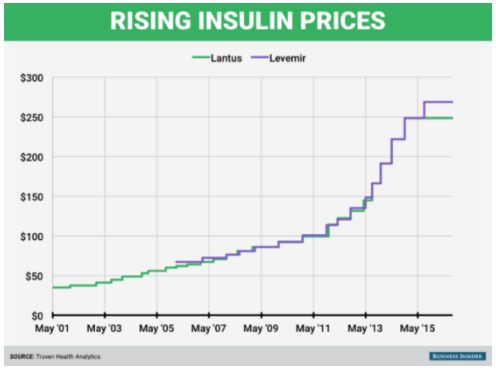
Diabetes Drug Prices are Increasing





These graphs depict the lock-step price increases for short-acting insulin (Humalog and Novolog) and long-acting insulin (Lantus and Levemir).
SOURCE: Business Insider

Based on reporting from the Nevada Department of Health and Human Services, the rising cost of diabetes drugs has strained the health and finances of the state and Nevadans.
155 essential diabetes drugs in the report showed significant price increases, more than the threshold established by law.

- **60% of those drugs experienced both a one- and two-year significant price increase.**
- The report found that drugmakers' **average profit for EDDs was $51.9 million**, almost 48 times higher than the median profit.
- Of the drugs analyzed in the report, **76% earned profits greater than the combined cost of production and administrative expense.**
- Drugmakers **earned an average $1.52 in profit for every $1 spent** on production and administrative costs.
- **55% of the reports indicated NO rebates were provided** by manufacturers to pharmacy benefit managers.

Rx Spending Growing at Unsustainable Rates

U.S. spending on prescription medicines is projected to reach **over $600 billion by 2022**

$600 billion (2022)

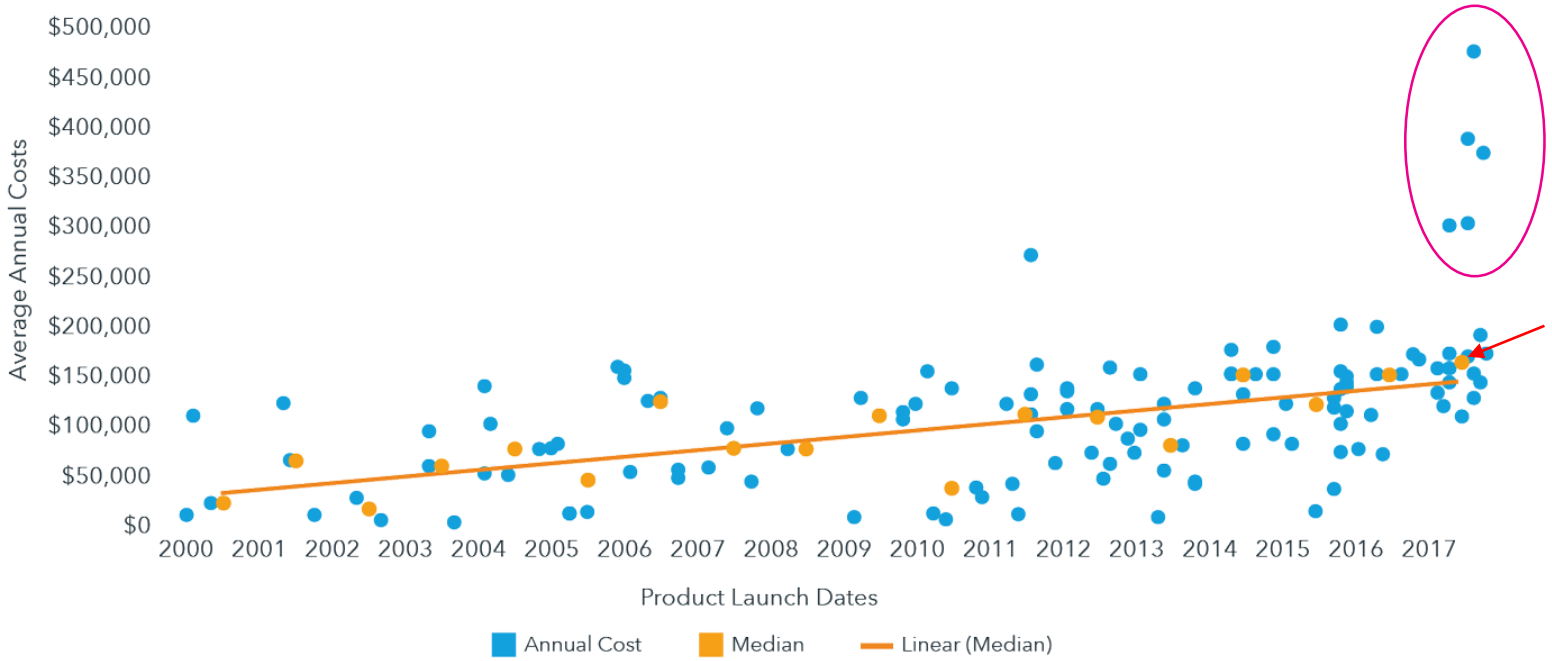
$453 billion (2017)

$380 billion (2014)

Source: Medicine Use and Spending in the U.S. - A Review of 2017 and Outlook to 2022, IQVIA Institute, April 2018

New Drug Launch Prices Continue to Skyrocket

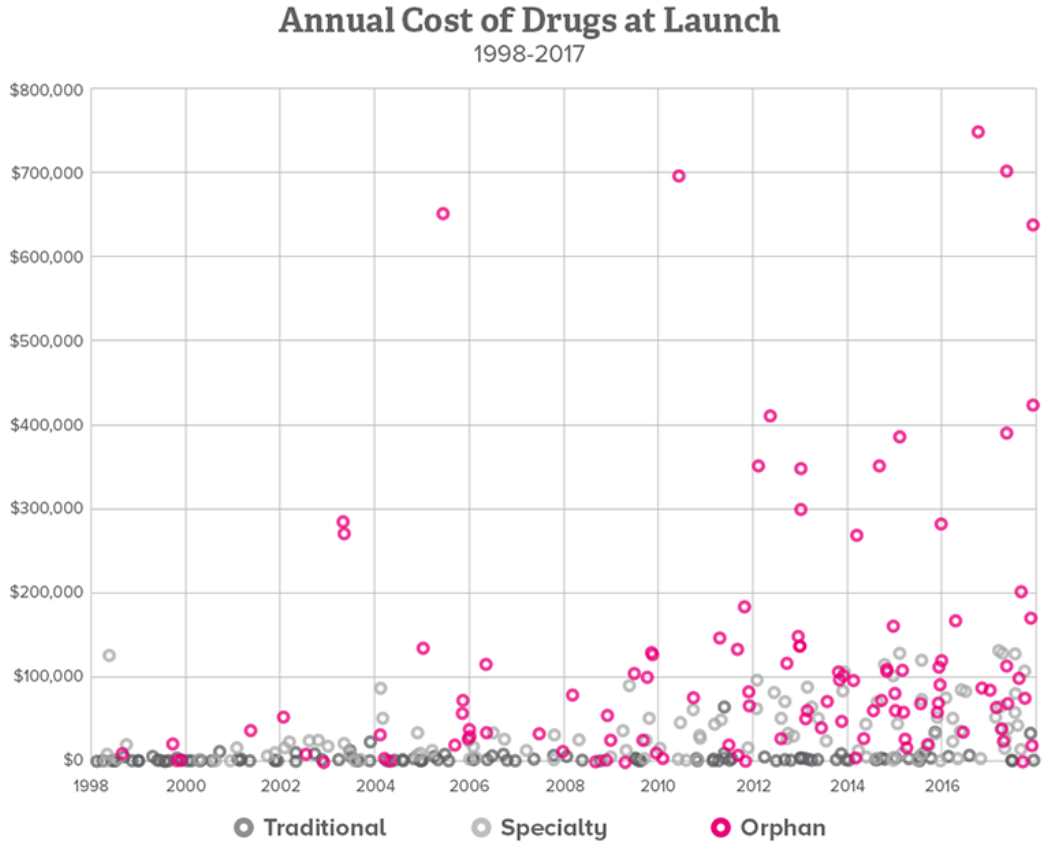
Average Annual Costs For Oncology Products by Launch Year in the United States



Source: IQVIA Institute, Apr 2018

Notes: If published annual costs are available they have been included, and if not, annual costs were estimated based on IQVIA Institute interpretation of the most-common dosing in the approved label and available product unit pricing information.

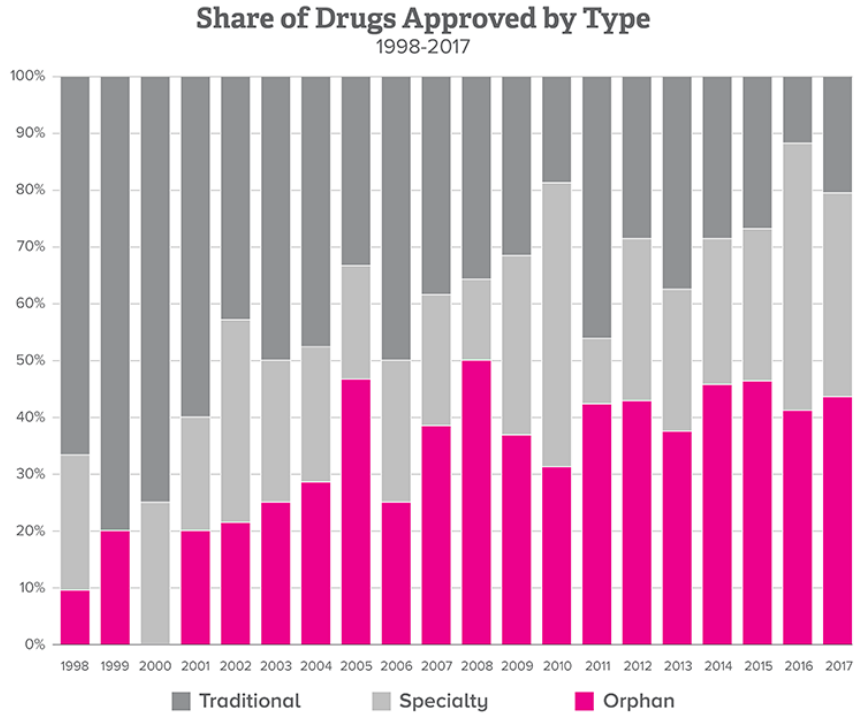
Report: Global Oncology Trends 2018: Innovation, Expansion and Disruption. IQVIA Institute for Human Data Science, May 2018



The average annual drug cost for orphan drugs was $123,543,

25 times more expensive than traditional drugs.

AHIP Research Reveals Impact of Specialty Drugs



Orphan drug approvals have increased 4-fold, soaring from 10% of all drug approvals in 1998 to 44% in 2017.

Most Prescribed Medications Are Not Rebated By Drug Makers

	Drugs without Significant Rebates				Drugs with Significant Rebates	Total
	No Rebates		Some Rebates			
	Brand	Generic	Brand	Generic	Brand	
% of Scripts	2%	87%	1%	0%	10%	100%
% of Drug Count	34%	46%	5%	0%	15%	100%

- ***89% of prescriptions*** written in 2016 had no rebates
- ***81% of all Part D drugs analyzed*** did not have rebates from drug makers in 2016, and ***64% of brand drugs analyzed*** did not have rebates

https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf

Brand Drugs, Rebates, and Competition

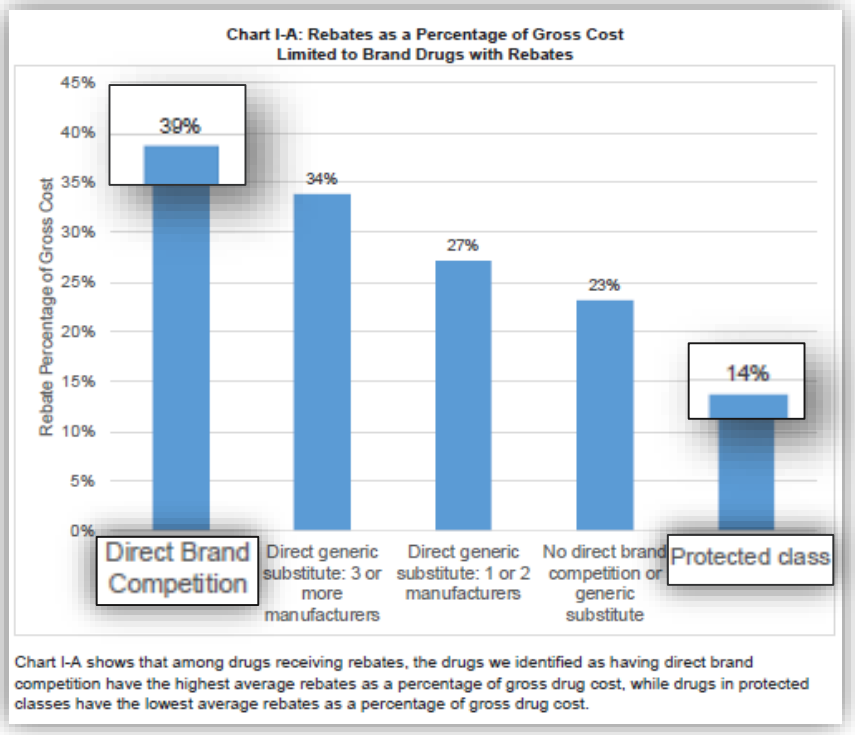


Chart I-A shows that among drugs receiving rebates, the drugs we identified as having direct brand competition have the highest average rebates as a percentage of gross drug cost, while drugs in protected classes have the lowest average rebates as a percentage of gross drug cost.

Among brand drugs with manufacturer rebates, rebates as a percentage of total drug spending were on average:

- ***Highest*** for drugs with direct brand and generic ***competition***
- ***Lowest*** for ***protected classes drugs***

https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf

State-Based Solutions

What can states do to address high drug prices?

Our Industry's Market-Oriented Solutions

Our Industry's Market-Oriented Solutions

Real Competition

- Create a robust biosimilars market
- CREATES, BLOCKING, Reduce red tape and abuses to limit generic and biosimilar entry
- Revisit orphan drug incentives
- Revisit guaranteed periods of market exclusivity

Open & Honest Price Setting

- Publish Rx prices, true R&D costs, and price increases
- Limit third-party schemes
- Evaluate DTC impact
- Extend manufacturer liability into Part D catastrophic benefit

Paying for Value

- Inform patients on effectiveness and value
- Expand value-based formulary programs
- Reduce regulatory barriers to value-based pricing

State Solutions Encouraged

Drug Transparency to Consumers

- Drug companies to report when, how much and why their drug costs are increasing

Drug Transparency to Providers

- Pharma drug reps should include the cost of the drug when marketing to providers

State Enforcement

- State AGs should continue to investigate price anomalies like shadow pricing and price gouging

Solutions that Save Patient & Taxpayer Dollars

- Manufacturers could lower drug prices so that patients can afford their medications.
- Policymakers could prohibit copay coupons when there is a less expensive and equally effective alternative medication.
- Policymakers could require drug makers to be transparent in their use of coupons, third-party payments, or patient assistance programs that steer patients toward certain types of coverage.
- Protect and expand tools that foster competition and lower drug costs (e.g., formulary management to incent price negotiation).
- Increase transparency in how drug companies set, and why they raise, prices.
- Develop an infrastructure for independent reporting of value/comparative effectiveness.

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Utah Action - 2019

PBM Regulation and Disclosures: **HB 370** (Ray)

- Transfers prior PBM registration under DOPL to require PBMs be licensed under the Utah Department of Insurance (UID)
- Requires PBMs to annually report the following:
  - insurers, pharmacies, and pharmacists with which the PBM contracts;
  - the total value, in aggregate, of all rebates and administrative fees attributable to enrollees of a contracting insurer; and
  - the percentage of aggregate rebates that the PBM retained under the agreement with a contracting insurer
- Requires UID to publish the reported information in its annual evaluation of the health insurance market without identifying a specific submission or disclosing trade secrets
- Prohibits PBM from requiring an enrollee to pay more than the lesser of the applicable allowable claim amount and the applicable pharmacy reimbursement
- Requires PBMs to permit a pharmacy to collect a consumer's cost share from any source
- Limits a post-claim denial or reduction of reimbursement to a pharmacy/pharmacist to several defined scenarios

Utah Action - 2019

Prior Authorization: SB 264 (Vickers)

- Requires health plans to provide all enrollees with each authorization requirement for each drug, device, and covered service that is subject to a preauthorization requirement (or all devices or covered services in a particular category with the same preauthorization requirement, if they are too numerous to list separately). Also requires health plans to provide sufficient information to allow a network provider or enrollee to submit all of the information necessary to meet each authorization requirement.
- Requires 30 day notice before an insurer may modify an existing authorization requirement, unless the waiting period would create a danger to the enrollee's health or safety or the modification is for a newly covered drug or device.
- Requires an insurer that receives a request for authorization to treat the request as a pre-service claim under ERISA regulations and process the request in accordance with those regulations and existing state requirements.
  - Prohibits preauthorization requirements for emergency health care.
  - Requires an insurer to specify how long an authorization is valid.
- Requires an insurer to allow a provider to resubmit and correct a claim that was originally submitted with an unintentional error that results in a denial of the claim.
- Requires an adverse preauthorization determination regarding clinical or medical necessity to be made by an individual who has knowledge of the enrollee's medical condition or disease or consults with a specialist who has knowledge of the enrollee's medical condition or disease before making the determination.
- Limits the circumstances in which an insurer can revoke an authorization for a drug, device, or covered service.
- Requires an insurer that removes a drug from the formulary to permit an enrollee to request an exemption from the change for the purpose of continuity of care and have a process to review and make a decision regarding a requested exemption
  - Prohibits an insurer that makes a mid-plan year change to the formulary from implementing the changes for enrollees on an active course of treatment for the drug unless the insurer provides at least 30 days' notice before the change is implemented.
- Requires insurers to annually report to the DOI the percentage of authorizations (not including a claim involving urgent care) for which the insurer notified a provider regarding an authorization or adverse preauthorization determination more than 1 week after the insurer received the request for authorization.
  - Requires UID to include in its annual evaluation of the health insurance market information regarding each insurer's preauthorization determinations and adverse benefit determinations.

SB 223 (2019) - Pharmaceutical Entity Transparency Act

Section 1, 2, 5 and 14. *Unneeded now (2019 HB 370 and SB 264 addressed these issues)*

Section 3. Pharmaceutical Supply Chain Transparency

- Sec 4. Definitions
- Sec 6. Prescription Drug Reports to Department (Health Insurer, PBM, Wholesaler/Distributer, PSAO, and Pharmacy)
- Sec 7. Pharmaceutical Manufacturer Reports to Department
- Sec 8. PBM Reports to Plan Sponsor/Health Plan
- Sec 9. Pharmaceutical Manufacturer Advance Notice to Purchasers (plan sponsors, PBMs, and health plans)
- Sec 10. Pharmaceutical Manufacturer Report of Price Increases to Department
- Sec 11. Pharmaceutical Manufacturer Report on New Prescription Drugs Costs
- Sec 12. Transparency on Patient Assistance Programs
- Sec 13. Report to Legislature (From Department re Price Reporting Trends)

Section 15. Violations for Inducements by Providers and Pharmaceutical Manufacturers

Section 16 and 17. Promoting Mandatory Generic Substitution and Interchangeable Biologics

Section 18. Pharmaceutical Supply Entities

- Sec 19/20. Transparency on Pharmaceutical Sales Representatives
- Sec 21. Transparency on Drug Prices to Physicians

Section 22. Brand Manufacturer Compliance with Federal Law/Generic Samples (State CREATES Act)

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Drug Supply Chain

= supply flow
= money flow
= negotiation

Drug Makers

Set Drug List Prices

Drug Makers negotiate with PSAOs to distribute their drugs to Pharmacies

Drug Makers pay Rebates to PBMs per Negotiated Agreements

PBMs

Negotiate Discounts with Drug Makers on Behalf of their Health Plan Clients or Large Employer Clients

PSAO / Wholesaler

PSAOs sell/distribute drugs to their Pharmacy Clients

PSAOs Negotiate Drug Reimbursement on Behalf of their Pharmacy Clients with PBMs

PBMs/Health Insurance Providers pay pharmacy for drugs dispensed

Health Insurance Providers

Health Insurance Providers Cover Enrollee Drug Costs

Pharmacy

Pharmacy Dispenses Drugs To Patients

Patient pays copays for Drugs

Patient

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3. Pharmaceutical Supply Chain Transparency

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Supply Chain Transparency

“Top 25” Reporting

- Requires health insurers, PBMs, wholesalers or distributors, PSAOs, and pharmacies to report:
  - the 25 costliest drugs by total net annual plan spending;
  - the 25 drugs with the highest year-over-year increase in total annual plan spending; and
  - the impact of the costs of drugs on premium rates (insurers only).
- ~~Requires PBMs to annually report, for all clients in aggregate, the combined amount of rebates, discounts, and price concessions negotiated that are attributable to patient utilization and the combined amount that are passed through to the plan sponsor~~.
  - *Unneeded with the passage of HB 370 (2019)*
- Requires the insurance department to create an annual report using the above reports that demonstrates the overall impact of drug costs on premiums.
- Clarifies that information reported under this subsection is a protected record and does not allow Insurance Department report to include any information that can reasonably identifies in relationship to a specific reporting party.

Supply Chain Transparency

PBM/PSAO Reports on Drug Utilization Payments

- Upon request, requires a PBM to annually report to an insurer or plan sponsor the aggregate of all drug utilization payments received by the PBM due to the insurer's or plan sponsor's utilization; and the aggregate of those payments passed on to the insurer or the plan sponsor.
- Upon request, requires a PSAO to annually report to an insurer or plan sponsor the aggregate of all drug utilization payments received by the PBM due to the insurer's or plan sponsor's utilization; and the aggregate of those payments passed on to the insurer or the plan sponsor.

Supply Chain Transparency

Pharmaceutical manufacturer Reporting

- Annual reporting to the Department on the 25 drugs (including generics) of which the state spends significant health care dollars or for which the WAC has increased by 10% or more over the prior calendar year.
- Advance notice of price increase to purchasers (plan sponsors, PBMs and health insurers) 10% or more increase in a year for WAC of $150-1000, 5% or more for WAC $1000+
  - Include description of any change/improvement to the drug that necessitates the price increase
- Advance notice of price increase to Department
  - Include specific factors used re increased price
- New Drug Reporting if WAC over CMS payment threshold (currently $670/month)
  - Include price, marketing plans, projected usage, FDA designation (“breakthrough”, “Orphan”, “priority review”)
- Confidentiality information provision

Transparency on Patient Assistance Programs

Patient Assistance Program Reporting

- Requires a patient assistance program that received a contribution from a PBM, manufacturer, third party (or trade group of those entities) to annually report all of those contributions.
- Requires the report to be posted on the patient assistance program's or the Insurance Department's website.

15. Violations for Inducements by Providers and Pharmaceutical Manufacturers

- Prohibits a health care provider or manufacturer from waiving, providing a rebate for, or paying all or a portion of a covered individual's cost sharing if such conduct is intended to induce the individual to seek services from the provider or manufacturer.
- Declares that an entity engaging in a pattern of providing such assistance is presumed to be doing so with the intent to induce.

16/17. Promoting Mandatory Generic Substitution

Generic Substitution

- Amends existing (permissive) statute to require pharmacists to substitute a therapeutic equivalent or interchangeable biological product for a prescription drug.
- Repeals requirements that purchaser must specifically request or consent to substitution and that prescriber must authorize substitution.
- Repeals requirement that pharmacist report the dispensing of a biological product into an electronic medical records system.

19/20. Transparency on Pharmaceutical Sales Representatives

- Requires manufacturers to report monthly the names of all pharmaceutical sales representatives that it employs or contracts with.
- Requires representatives to annually report the health care entities to which the representative provided specified compensation, the name and manufacturer of each drug of which the representative provided a free sample, and the name of each entity to which the manufacturer provided a free sample of a drug.
- Requires the Division to develop an annual report, based on these reports, that includes an analysis of the activities of pharmaceutical sales representatives in the state.

21. Transparency on Drug Prices to Physicians

- Requires a person engaged in prescription drug marketing to a provider with intent that the provider prescribes the drug to provide the provider written materials that include the drug's manufacturer and the average wholesale price of the drug for each labeled indication.

22. Brand Manufacturer Compliance with Federal Law/Generic Samples (CREATES Act)

- Requires a manufacturer, wholesaler, or distributor to make available for sale a drug distributed in the state to a developer for the purpose of conducting testing required to support the application for a drug.
- Requires the drug to be sold at a price no higher than its WAC and without any restriction that would block or delay the application.
- Prohibits a developer that buys a drug made available for sale from charging a consumer a higher price for the drug than the price for which the developer bought the drug.

Additional Ideas to Lower Drug Costs

California - Drug Discounts: **AB 265** (2017)

- Prohibits drug manufacturers from offering discounts, repayments, vouchers, or other reductions ("discounts") on an individual's out-of-pocket expenses associated with his/her insurance coverage if there is a covered, lower cost, therapeutically equivalent generic drug available on a lower cost-sharing tier.
  - Does not apply to branded prescription drugs, until the first therapeutically equivalent branded drug has been nationally available for 3 calendar months.
- Prohibits manufacturers from offering discounts if the drug's active ingredients are available without prescription at a lower cost and are not otherwise contraindicated for treatment.
- Exempts discounts for:
  - Drugs required under FDA's Risk Evaluation and Mitigation Strategy for certain purposes;
  - Single-tablet drug regimens for treating or preventing HIV or AIDS that are as effective as a multi-tablet regimen unless multi-tablet is as/more effective and more likely to result in adherence;
  - Individuals who have completed required step therapy or prior authorization requirements for the branded drug;
  - Discounts not associated with patient's insurance coverage; and
  - Rebates received by a state agency.
- Does not prohibit any entity (including manufacturers and patient assistance programs) from offering products for free to patients and insurers. Does not affect a pharmacist's ability to substitute a drug. Does not prohibit or limit assistance from independent charity patient assistance programs.

Additional Ideas to Enhance Transparency

New York – Drug Retail Price List (Ch. 58/SB 2108 (2007))

- Requires every pharmacy to compile a drug retail price list, which shall contain the names of the drugs on the list provided by the board, the pharmacy's corresponding retail prices for each drug.
- Every pharmacy shall update its drug retail list at least weekly
- Every pharmacy shall provide the drug retail price list to any person upon request.
- The pharmacy's corresponding retail price means the actual price to be paid by a retail purchaser to the pharmacy for any listed drug at the listed dosage.
- Pharmacies shall have a sign notifying people of the availability of the drug retail price list and the availability of the department of health prescription drug retail price list database and the web address of that database, conspicuously posted at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing, in the waiting area for customers, or in the area where prescribed drugs are delivered.
- Nothing shall prevent a pharmacy from changing and charging the current retail price at any time, provided that the listed price is updated at least weekly to reflect the new retail price.

Additional Ideas to Stop Gaming of System

California – Prohibition on "Pay for Delay" Settlements (AB 824)

- Provides that an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, is to be presumed to have anticompetitive effects if a nonreference drug filer receives anything of value, as defined, from another company asserting patent infringement and if the nonreference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the nonreference drug filer's product for any period of time, as specified.
- Provides various exceptions to this prohibition, including, among others, if the agreement has directly generated procompetitive benefits and the procompetitive benefits of the agreement outweigh the anticompetitive effects of the agreement.
- A violation is punishable by a civil penalty that is recoverable only in a civil action brought by the Attorney General, as specified.
- Requires a cause of action to enforce those provisions be commenced within 4 years after the course of action accrued.

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