

Massachusetts health policy commission

2018 HEALTH CARE COST TRENDS HEARING Wednesday, OCTOBER 17, 2018

"spotlight on state solutions to health care spending"

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National Academy for State Health Policy

- Private, non-profit, bipartisan forum of and for state leaders
- Serving States for 31 years
- Cross disciplinary- Legislative and executive branches
 - AG's
 - Insurance departments
 - Exchanges
 - Cost Commissions
 - Medicaid
 - Public Health
 - State employee health plans
 - Governor's office
 - Legislators and staff
- Guided by cross disciplinary Steering Committees and work groups

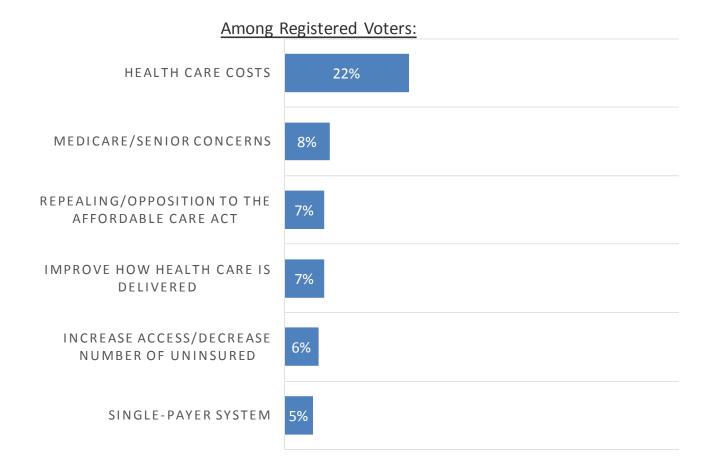
Louis Gutierrez David Seltz Daniel Tsai

What Motivates States to Act?

- +/- 40% of healthcare in states paid by public dollars
- Balanced budget requirements
- Medicaid
- Market dynamics
 - Individual and small group
 - Increasing out of pocket exposure
- States as "Laboratories of Innovation"
 - ACA
 - Children's health
 - Medical health parity
 - "Gag clauses"
- Public outcry

Health care costs is the top health care issue voters want 2018 candidates to talk about

While this year's election is still a long way off, what health care issue do you most want to hear candidates talk about during their upcoming campaigns? (*open-end*)



NOTE: Only top six responses listed.

SOURCE: Kaiser Family Foundation Health Tracking Poll (conducted February 15-20, 2018)

State of the State – Health Cost Reduction Strategies

• Payment and delivery system reforms

- » Medicaid
- » ACO's / Integrated Delivery (VT all payer ACO)
- » WA Technology Assessment Program.
- Global budgets/ Sustainable growth rate
 - » MA, VT, OR
- Ratesetting
 - » MD
- Market oversight
 - » DON/CON/COPA- MA, CT, ME, VA, TN
 - » Insurance review and oversight e.g. 23 States "Surprise Billing" laws
- Transparency cost compare websites
 - » APCD's WA, NH, ME

Cont.- State of the State – Health Cost Reduction Strategies

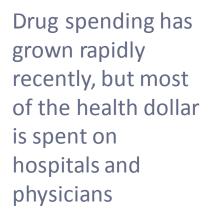
Reference pricing

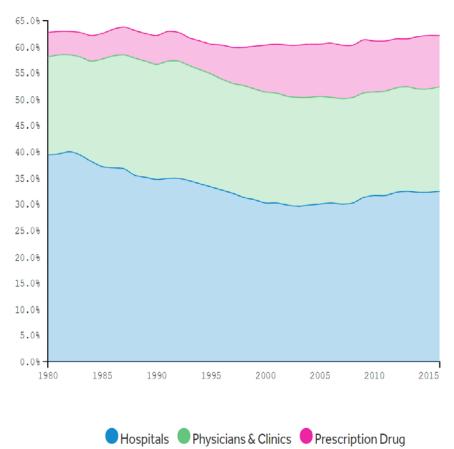
- » MT hospital rates
- » CA "shoppable services"

• Consolidate state purchasing

- » WA Health Care Authority
- » Oregon Health Authority Purchases for 1:3; Medicaid, public employees, educators; 3. 4% SGR
- » TN episode based payment across state employees, retirees, and Medicaid
- » WI Dept. of Employee Trust Funds allows local government and public universities opt in

Why Focus on Rx?





Source: Kaiser Family Foundation analysis of National Health Expenditure (NHE) data from Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group

Why States Take on Rx?

- Rx price increases rapid and unpredictable
- Specialty drugs, biologics, immunotherapy = costs will continue to rise
- 21st Century Cures -> Fast Tracking
- State Medicaid Spending
 - » 25% 2016; 14% in 2015
 - » CMS predicts 6% growth 2016-2025
 - » PT. D "claw back"
- No federal consensus on action despite President's "Blueprint"
 - States can't wait on Feds
 - E.g. 28 states enacted "gag clauses" before Congress did
- Disrupt business model
- Rx issues cross the partisan divide

NASHP's Center for State Rx Pricing

- Laura and John Arnold Support
- Pharmacy Cost Work Group
- Model legislation, legal resources, track emerging activity, other technical assistance

https://nashp.org/center-for-state-rx-drug-pricing/

• Diverse state engagement

How Are States Approaching Rx Costs?

- 2018 Session: 171 Bills
- <u>28 States Passed 45 New Laws:</u>
 - PBMs 92 Bills (31 laws in 20 states eg: AR, AZ, FL, KS, KY, MO, SC, CA, CT etc
 - Transparency 26 Bills (7 laws: OR, VT, ME, NH, CT, CA*, NV*)
 - Importation 9 Bills (1 law: VT; Utah Proposal due to Legislature Oct 1)
 - Price Gouging 13 Bills (1 law: MD*)
 - Rate Setting 3 Bills: MD, NJ, MN
 - Volume Purchasing 4 Bills

(*= enacted in 2017)

State Transparency Law	Requires reporting from				
	Health Plans	PBMs	Manufacturer Price Increases	Manufacturer Launch Price	Other
California (SB 17)	Х		Х	Х	
Connecticut (HB 5384)	Х	X	X	Х	
Maine (LD 1406) *Study only			Х		
Nevada (SB 539) *Only relates to diabetes drugs		x	Х		Pharmaceutical sales reps. & manufacturer donations to non-profit organizations
New Hampshire (HB 1418) *Study only		Х	Х		
Oregon (HB 4005)	Х		Х	Х	
Vermont (S 92)	Х		Х	Х	
Maryland's Price Gouging Law (MD 631) *law's main focus is not on transparency			х		
Louisiana's PBM Laws (SB 283 & HB 436) *law's main focus is not on transparency		х			

Vermont: Transparency (S. 92)

- Vermont was the first state to enact transparency laws in 2016. S. 92 adds reporting from health plans and public disclosure of manufacturer reports.
- Requires Reporting from:
 - Health Plans on most costly drugs, the impact of drugs costs on premium rates, and information on PBM use
 - Manufacturers on price increases and high launch prices.
 - Price Increases: reporting occurs on 15 drugs with WAC increases of 50% or more in past 5 years or 15% or more in previous year (must explain each factor that caused net cost increase)
 - Launch Prices: sponsors of new drugs with a WAC that exceeds the threshold for a specialty drug under Medicare Part D must report expected utilization, FDA approval designation, acquisition cost, and drug pricing plan

California: Transparency (SB 17 Chapter 603, Statutes of 2017)

Manufacturer Reporting

1) Chap. 603 requires manufacturers to give <u>60 days advance notice of price increases</u> when certain thresholds are met:

- The wholesale acquisition cost (WAC) for a drug is more than \$40 for a course of treatment
- The manufacture will increase the WAC more than 16% (including the proposed and cumulative increases that occurred within the previous two calendar years)

2) If a pending price increase triggers reporting requirements for advance notice, manufacturers must also report specified financial and non-financial factors that contributed to the price increase

3) When launching new drugs that exceed \$670, manufacturers must report expected utilization, acquisition cost if applicable, FDA approval designation, pricing plans, and launch price.

<u>Health plans</u> must report 1) the 25 most frequently used drugs; 2) the 25 most costly drugs by total spend; 3) the 25 drugs that contribute the most to year-over-year plan spending

PhRMA Files Suit Against CA SB 17

- In response to SB 17, PhRMA filed suit challenging the law. PhRMA claimed the law would cause market distortions, such as drug stockpiling and reduced competition. PhRMA also argued that SB 17 violates:
 - The Commerce Clause, which prohibits CA from regulating drug pricing beyond the state's borders;
 - The First Amendment, by compelling speech through manufacturers justifying price changes; and
 - The Fourteenth Amendment's due process clause because the law is unconstitutionally vague.

PhRMA Files Suit Against CA SB 17

- U.S. District Judge Morrison England dismissed the case on August 28, 2018. He argued PhRMA failed to show that the court has jurisdiction to hear the case
- The judge gave PhRMA 30 days to amend the complaint after finding its initial claim – that CA's law attempted to "dictate national health policy"without merit
- On September 28, PhRMA refiled.

Connecticut: Transparency (HB 5384)

- Connecticut's transparency law is one of the most robust—it requires reporting from health plans, PBMs, and manufacturers on both price increases and launch prices.
- Requires Reporting from:
 - Health Plans on the most costly drugs and the impact of drugs costs on premium rates
 - Pharmacy Benefit Managers on aggregate amount of rebates collected from manufacturers and amount of rebates going to carriers
 - Manufacturers on price increases and high launch prices
 - Price Increases: reporting occurs on 10 outpatient drugs where 1)WAC increased by at least 20% during previous year or by 50% over past three years or 2)WAC was more than \$60/month or course of treatment
 - Must report each factor that caused net cost increase, company level research & development costs
 - Launch Prices: ALL sponsors of new drugs or biologics must report expected utilization, clinical trial comparators, FDA approval designation, and

estimated market entry date

New Hampshire & Maine: Transparency Studies

- New Hampshire and Maine enacted laws mandating further study of transparency
- New Hampshire created a commission to determine if increased transparency would lower drug costs. The commission will study:
 - PBMs' role in cost, administration, and distribution of prescription drugs.
 - Amount of rebates from manufacturers for certain high cost, high utilization drugs
- Maine requires the Maine Health Data Organization to develop a plan to collect data from manufacturers related to cost and pricing of drugs, including:

Maryland's Price Gouging Bill

- In 2017, lawmakers passed SB 631, which prohibited manufacturers and wholesale distributors from engaging in price gouging of generic drugs. This was the first price gouging legislation to become law.
- The Association for Accessible Medicines filed suit, claiming the law could hurt competition and drive up prices.
- The Fourth Circuit Court of Appeals found that the law regulates trade outside Maryland's borders and thus violates the Dormant Commerce Clause.

Maryland's Rate Setting Bill

- SB 1023/HB 1194, based on NASHP's rate setting model, would have created an all-payer drug rate setting program through a Drug Cost Review Commission.
 - Anticipate re-introduction in 2019
- Minnesota proposed a similar bill which failed to receive consideration, while New Jersey has a rate setting bill in the pipeline.

Wholesale Importation

- Section 804 of FDCA allows the HHS Secretary to approve a *program* of wholesale importation of prescription drugs that will:
 - Pose no additional risk to the public's health and safety; and
 - Result in a significant reduction in the cost of the covered products to the American consumer
- Vermont enacted S.175, which creates a wholesale importation program to purchase high-cost drugs in Canada and make them available to Vermonters through the existing supply chain
 - Vermont's Agency for Human Services is currently working to develop an application to HHS
- Utah's importation bill (HB 163) passed the House, but not the Senate
 - UT's Department of Health recently submitted a report on importation as requested state legislative leadership

Louisiana's Subscription Model

- In August, Louisiana issued an RFI on its plans to use a subscription-based model for Hep C medication.
- Under the subscription model, Louisiana would agree to pay a fixed amount of money over several years, and a manufacturer would provide the state with all the medication the state needs.
 - Payment to the manufacturer would be equal to or less than what the state currently spends to provide the medication.
 - In the first years, the state will get more drugs than they pay for; as fewer people need treatment, the manufacturer would get extra money.
 - Theoretically, a guaranteed fixed purchase price for a contracted period of time would allow the manufacturer to expand its product reach.

Medicaid Initiatives

Challenging – Medicaid law

- Rebates
- Best price
- Cannot limit Rx
- Tools inadequate (PDL, PA. limits etc.)

NEW YORK

- Budget cap on Rx spending
 - Target high cost Rx
 - Review value
 - Seek "supplemental/ supplemental"
 - Most cover all Rx but may:
 - Request more info on costs
 - Move rx to prior approval
 - Case study: Vertex's Orkambi

Medicaid Alternative Payment Models

<u>OKLAHOMA</u>

- OK Medicaid has entered into three separate APMs directly w/ drug manufacturers (first-in-nation)
- State and manufacturer agree upon outcome(s) to measure
- Additional rebates are based on performance against agreed-upon measure
- Example: As adherence targets are met- which result in greater usage, sales and outcomes- the price the state pays for the drug decreases

<u>COLORADO</u>

- Colorado is surveying physicians to determine their actual acquisition cost (AAC) for physician administered drugs (PADs)
- Results will be used to design a more transparent APM based on average acquisition cost (2019)

Next Steps

- States testing approaches to inform Federal debate
 - 28 Politically diverse states have enacted "gag clauses" before Congress acted eg: MS, TX, KY, IN, GA, CO, WVA, VT, NH
 - 23 States have enacted "surprise billing" laws Sen. Cassidy has proposed bipartisan draft legislation –no Congressional action yet
- New England states actively engaged on Rx issues
- NASHP eager to work with MA to push Rx pricing reforms