

Federal efforts to address high prescription drug prices: What's in play in 2019?

Leigh Purvis, Director, Health Services Research
AARP Public Policy Institute

OVERVIEW

- **Why is this issue so important to AARP?**
- Administration is very engaged
- What else is being discussed at the federal level?
- What about the states?
- What is AARP doing?
- What does the future hold?

Older adults are particularly vulnerable to high drug prices

- High utilization
 - Part D enrollees take an average of 4.5 prescriptions/month
 - 68% of Medicare beneficiaries are being treated for 2+ concurrent chronic illnesses
- Most Medicare beneficiaries live on modest incomes
 - Median income is ~\$26,000
 - 1/4 have incomes below ~\$15,000
- Many Medicare beneficiaries have limited financial resources
 - 1/4 have less than ~\$15,000 in savings



Taxpayer-funded programs are under increasing pressure

- Medicare Part B prescription drug spending more than doubled from \$13 billion to \$32 billion between 2005 and 2017
 - Beneficiaries are responsible for 20 percent of their costs
- Total Medicare Part D spending is approaching \$150 billion
 - Enrollees have out-of-pocket limit but...
- Medicaid program is also under considerable stress, which isn't helping state budgets

High drug prices affect everyone



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“The Blueprint”



- Does a great job of describing the problem...
- Touches on large number of potential solutions but unclear how they would be implemented or when.
 - Some would require legislation.
- Does not address manufacturer pricing behavior.

International Pricing Index Model for Medicare Part B Drugs

- Demonstration program that would:
 1. Replace ASP + 6% with a flat fee.
 2. Allow private sector vendors to negotiate with drug makers.
 3. *Phase down Medicare payment for selected Medicare Part B drugs to more closely align with international prices.*
 - Fits with larger narratives of “free-riding” and “fairness.”



Strong interest in rebates

Meet the Rebate, the New Villain of High Drug Prices

A growing chorus, including the Trump administration, is calling for a rethinking of after-the-fact drug discounts that some say contribute to rising prices.

- Administration concerns:
 - Creates incentive for manufacturers to raise list prices to maintain their profits and offer even bigger rebates.
 - Health plans and PBMs could be less inclined to negotiate effectively if they profit from rebates.
- “Rebate rule” would have required Part D plans to share rebates with beneficiaries at the point-of-sale.
 - CBO concluded that it would increase costs for beneficiaries and taxpayers and have no impact on drug prices.

But change can still be elusive...

- Rebate rule was ultimately dropped.
- DTC rule that would have required drug manufacturers to provide their prices in TV ads was struck down in court.
- Proposed changes to Part D protected classes were pulled back.
- Recent talk about executive orders (e.g., “favored nations” policy) but details remain vague.

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Strong signs of life in Congress

- LOTS of hearings
- LOTS of proposals under discussion
 - Pay-for-delay/REMS abuses
 - Medicare Part D changes
 - Importation
 - Out-of-pocket caps
 - Value-based purchasing
 - Price transparency
 - Patent/exclusivity reforms



Focus on the indefensible

- Pay-for-delay agreements where a brand name drug company compensates a generic drug company for delaying the launch of its competing product.
- Increasing number of brand name drug companies are using REMS to prevent generic and biosimilar companies from purchasing samples of their products.
 - Delays or even blocks competition since samples are needed to obtain FDA approval.

Medicare is getting a lot of attention

- 92% of the public supports allowing Medicare to negotiate lower drug prices BUT...
- Lots of talk about changing benefit to include a hard out-of-pocket cap.
 - Important to get this right to ensure that beneficiaries and the Medicare program are protected.
- Also considering an inflation-based rebate similar to what's under Medicaid.



A sample Medicare Health Insurance card for Jane Doe. The card features the Medicare logo and the text "MEDICARE HEALTH INSURANCE" at the top. Below this, it lists the phone number "1-800-MEDICARE (1-800-633-4227)". The beneficiary's name is "JANE DOE". The Medicare claim number is "000-00-0000-A" and the sex is "FEMALE". The card indicates entitlement to "HOSPITAL (PART A)" and "MEDICAL (PART B)", both with an effective date of "07-01-1986". At the bottom, there is a line for the beneficiary to sign, labeled "SIGN HERE". A large, diagonal "SAMPLE" watermark is overlaid on the card.

MEDICARE HEALTH INSURANCE	
1-800-MEDICARE (1-800-633-4227)	
NAME OF BENEFICIARY JANE DOE	
MEDICARE CLAIM NUMBER 000-00-0000-A	SEX FEMALE
IS ENTITLED TO HOSPITAL (PART A)	EFFECTIVE DATE 07-01-1986
MEDICAL (PART B)	07-01-1986
SIGN HERE _____	

Importation is back on the radar screen

- Fits with larger narratives of “free-riding” and “fairness.”
- Supported by 72% of the public.
- Can involve the product or just the price (i.e., international reference pricing).



Out-of-pocket or copay caps remain popular



- Understandably favored by patients facing high prescription drug costs.
- However, have to be mindful that remaining cost will come back in form of higher premiums and cost-sharing down the road.
- Way to preserve status quo for drug companies that could reduce incentive to change behavior.

New(-ish) kid on the block: value based purchasing

- Idea of paying for drugs based on how well they work rather than what the market will bear.
 - However, there is no universal definition of value and developing one will not be easy.
- Can be challenging to administer (e.g., non-adherence, drug-drug interactions)
- Limited to relatively few drugs at this point.



Transparency remains a hot topic

- Relatively easy to explain/justify.
- Response to drug industry argument that high drug prices are fair/necessary reflection of high costs incurred bringing drug to market.
- Also being expanded to include other parts of the supply chain (e.g., PBMs).
- Must be balanced with maintaining competition.



Nuclear options are increasingly on the table

- Revisiting when/how patents and exclusivity are granted.
- Revoking patents and/or exclusivity for bad behavior (e.g., compulsory licensing).



Drug companies have ideas, too

- Value-based purchasing.
- Expand use of biosimilars.
- Blame everyone else.



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States are extremely busy

- Price gouging
 - Importation
 - Bulk purchasing
 - Affordability review boards/price transparency
 - **LOTS** of PBM bills
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- Latest count: 30 bills passed in 18 states with work ongoing.
 - In the absence of federal legislation, states will likely continue the trend of going it alone.



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STOP GREED

CUT DRUG PRICES NOW

It's unfair that Americans pay the highest prescription drug prices in the world. We must crack down on price gouging and the greedy practices that keep prices artificially high. It's time our leaders stick up for people 50+ and their families.



States Join Fight to Lower Prescription Prices

43 legislatures consider measures ranging from transparency to drug importation



We Must Stop Rx Greed Now

Expensive prescription drugs are a problem for us all



The Barriers Blocking Cheaper Prescription Drugs

These practices reduce access to lower-cost medications

AARP's Solutions



Stop Price Gouging

Let Medicare negotiate prices



Increase Affordability

Cap out-of-pocket costs for seniors



Close Loopholes

Increase the availability of generics



Support Transparency

Make drug firms justify big price hikes

AARP priorities



Federal legislation

- Medicare Part D negotiation
- Create Medicare Part D out-of-pocket spending cap
- Improve access to lower-cost generic drugs
- Increase prescription drug price transparency
- Revisit exclusivity/patents
- Importation
- Part D donut hole improvements

State legislation

- Pharmacy benefit manager regulation
- Rate setting commissions
- Price negotiation/bulk purchasing
- Importation
- Price gouging
- Protecting state pharmacy assistance programs (SPAPs)
- Caps on out-of-pocket costs (with caveats)
- Limits on formulary changes
- State administrative actions

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What's next?

- Hearings will continue.
 - Really just a matter of waiting for the next egregious example—and there will always be a next one.
- Manufacturers do not seem to be responding to threats from the politicians.
- Issue will likely continue to get attention as more and more people become unable to afford their medications.

What's needed?

- Long-term, multi-pronged strategy.
- Multi-stakeholder agreement on proposed solutions.
 - Avoid “squeezing the balloon.”
- Avoid creating “strange bedfellows.”



What if nothing changes?

- The costs associated with prescription drugs are not sustainable for patients or payers.
- Efforts to reduce costs could save taxpayer-funded programs like Medicare and Medicaid billions of dollars.
- Many patients will be unable to afford their prescription drugs if they do not receive some level of price relief.

****Innovation is meaningless if no one can afford to use it****

Leigh Purvis
Director, Health Services Research
lpurvis@aarp.org

AARP Public Policy Institute
www.aarp.org/ppi

Twitter: @leighdrugwonk
www.Facebook.com/AARPpolicy
Blog: www.aarp.org/policyblog