

July 12, 2018

# American Patients First:

The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

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**Colorado Consumer  
Health Initiative**

# The Problem

News > Medscape Medical News

## Brand-Name Prescription Drug Prices Skyrocketing for Seniors

Megan Brook  
March 29, 20

Axios Video Jun 21

SAVE 

The drug pricing war that leaves patients caught in the middle

Regulat

Expe  
choic

by Paige Minemyer | Jun 18, 2018 8:27am

 **the CT mirror**




Politics Health Care Budget/Economy Schools/Child Welfare Envii

### Drug prices keep rising despite efforts to address problem

By: ANA RADELAT | July 9, 2018

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## Drug Manufacturers Continue to Significantly Increase Prescription Drug Prices

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[Pharmaceutical Care Management Association](#) →

Jul 05, 2018, 14:34 ET



# Overview

# Challenges

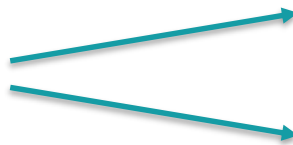
- High **list prices** for drugs
- **Lack of negotiation** tools for public programs (Medicaid & Medicare)
- High and rising **out-of-pocket costs** for consumers
- Foreign government “free-riding”

# Strategies for Reform



- Improved competition
- Better negotiation
- Incentives for lower list prices
- Lowering out-of-pocket costs

## Two Phases



1. HHS can take **action now**
2. HHS is soliciting feedback for **future action**

# Strategies to Increase Competition

Strategies to Increase Competition			
Issue	Action	Can be Done Today	Feedback Requested
Generics	Take steps to prevent manufacturer gaming of regulatory processes such as the Risk Evaluation and Mitigation Strategies (REMS) program. FDA will issue guidance	X	
Generics	Encourage sharing of samples needed for generic drug development (REMS, samples for biosimilars and <u>interchangeables</u> )		X
Biosimilars	Establish measures to promote innovation and competition for biologics. FDA will issue new policies to improve availability, competitiveness, and adoption. Increase awareness of biosimilars through education	X	
Biosimilars	Employ additional efforts to promote the use of biosimilars (e.g., Purple Book, interchangeability, provider education)		X
Prices	Review, assess and understand the impact, if any, of the Medicaid Drug Rebate Program, ACA taxes and other rebates on rising prices and cost-shifting to the private sector		X

**Source** Anne Winter & Aimee Lashbrook, *Health Management Associates* (May 24, 2018)

# Strategies for Better Negotiation

Strategies for Better Negotiations			
Issue	Action	Can be Done Today	Feedback Requested
Value	Experiment with value-based purchasing (VBP) in Medicare and Medicaid through demonstration authority	X	
Value	Further use of VBP, such as indication-based pricing and long-term financing in Medicare and Medicaid		X
Value	Remove government-created impediments to VBP by private payers		X
Medicare	Allow more substitution in Part D to address price increases for single-source generics	X	
Medicare	Give Part D plan sponsors significantly more power when negotiating with manufacturers, including the protected classes	X	
Medicare	Update Part D star ratings methodology to support plans appropriately managing utilization of high-cost drugs by addressing Independent Review Entity appeals issues	X	

Medicare	Evaluate opportunities to allow high-cost drugs to be priced or covered differently based on health indication	X	
Medicare	Report to President on potential for savings by moving some Part B drugs to Part D plans	X	
Medicare	Leverage Competitive Acquisition Program for Part B	X	
Medicare	Require site neutrality for Part B drug administration		X
Foreign Governments	Assess the problem of foreign "free-riding"		X
Foreign Governments	Address foreign government threats of compulsory licensing or intellectual property theft		X
Transparency	Evaluate accuracy and usefulness of current national drug spending data		X

Source Anne Winter & Aimee Lashbrook, *Health Management Associates* (May 24, 2018)

# Strategies to Develop Incentives for Lower List Prices

Strategies to Develop Incentives for Lower List Prices			
Issue	Action	Can be Done Today	Feedback Requested
Transparency	Ask FDA to evaluate requiring manufacturers to include list prices in direct-to-consumer advertising	X	
Medicare	Update Medicare's drug pricing dashboard to make price increases and generic competition more transparent	X	
Medicare	Provide incentives to discourage manufacturer price increases for Part B and Part D drugs		X
Medicaid	Develop proposals related to ACA Maximum Rebate Amount, which limits rebates in Medicaid to 100% of the average manufacturer price (AMP)	X	
Medicaid	Implement reforms to the Medicaid Drug Rebate Program		X

Rebates	Restrict use of rebates, including revisiting the safe harbor under the Anti-kickback statute		X
Rebates	Implement additional reforms to rebating processes		X
Rebates	Consider creating fiduciary status for PBMs		X
340B	Implement reforms to the 340B Drug Discount Program		X
Drug Coupons	Consider changes to how they factor in pharmacy reimbursement (for example, do they lower consumer costs or increase list prices?)		X

**Source** Anne Winter & Aimee Lashbrook, *Health Management Associates* (May 24, 2018)



# Strategies to Lower Out-of-Pocket Expense

Strategies to Lower Out-of-Pocket Expense			
Issue	Action	Can be Done Today	Feedback Requested
Medicare	Prohibit “pharmacy gag clauses” in Part D contracts	X	
Medicare	Improve Part D explanation of benefits by including information about drug price increases and lower cost alternatives	X	
Medicare	Inform Medicare Part B and D beneficiaries about lower-cost alternatives		X
Medicare	Provide better information on Part D costs to beneficiaries, annually or more frequently		X

**Source** Anne Winter & Aimee Lashbrook, *Health Management Associates* (May 24, 2018)



# What do we think?

# What do we think?

## Overview

- Opportunity for positive change
- Modest reforms
- Unanswered questions
- Some missed opportunities

# What do we think?

## Specifics

There's potential...

- for significant impact on Medicare beneficiaries out-of-pocket costs
- for savings to be passed through to consumers through additional PBM regulation
- to limit rebates and discounts that contribute to an opaque supply chain and high list prices
- to require list prices be disclosed in direct-to-consumer advertising
- to control Medicare Part B price increases

# What do we think?

## Specifics

Room for improvement...

- to more directly impact prices
- to discourage patent abuses
- to require meaningful transparency

# What do we think?

## Specifics

We're concerned about...

- Medicaid and Medicare programs not covering certain drugs
- price gouging & bad actors
- encouraging increased prices outside the U.S.

# Thank you!

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