

American Patients First: Understanding the President's Blueprint & the Implications to Managed Care Pharmacy

May 21, 2018



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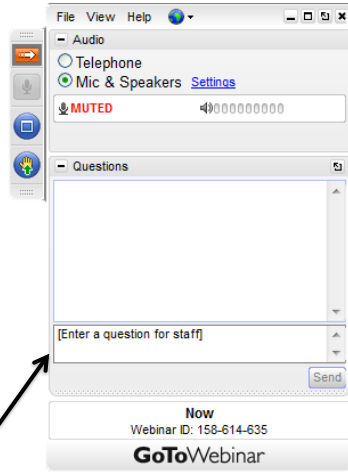
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Today's Speakers



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Agenda

- Background
- AMCP's Role
- Immediate Actions
- Further Opportunities
- Reactions & The Path Forward
- Question & Answer

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Background

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Background

- A major policy position for President Trump's 2016 campaign
- [American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs](#)
 - Released May 11, 2018
 - Comments due July 16, 2018

“

*One of my greatest priorities is to reduce the price of prescription drugs. In many other countries, these drugs cost far less than what we pay in the United States. That is why I have directed my Administration to make fixing the injustice of high drug prices one of our top priorities. Prices **will** come down.”*

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— PRESIDENT DONALD J. TRUMP

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Background

Four Major Challenges Faced by American Patients

High list prices for drugs

Seniors & government programs overpaying for drugs due to lack of the latest negotiation tools

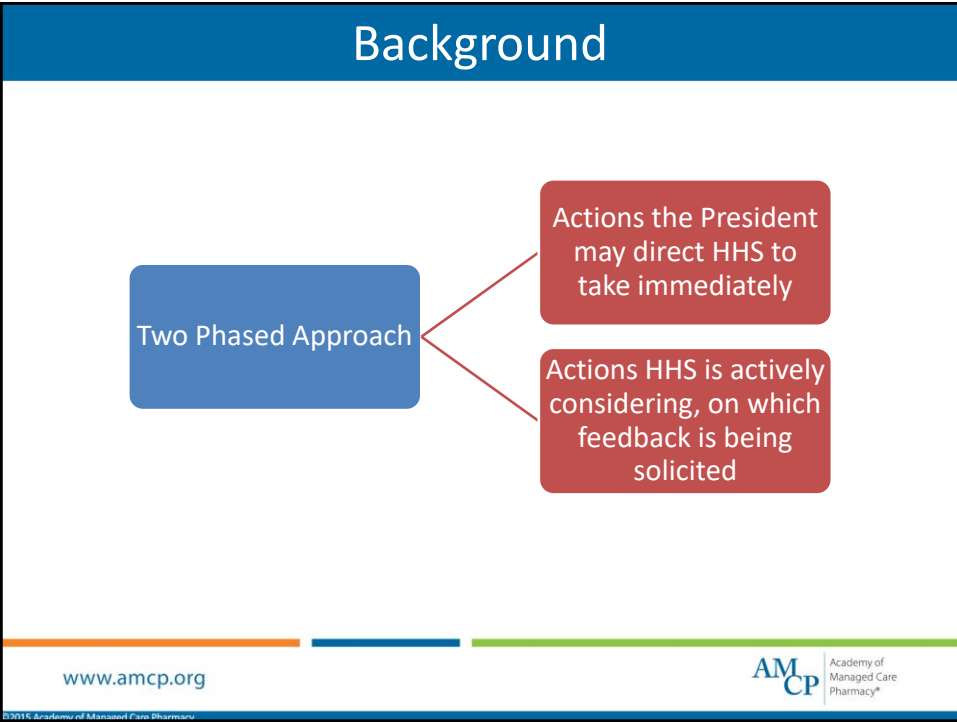
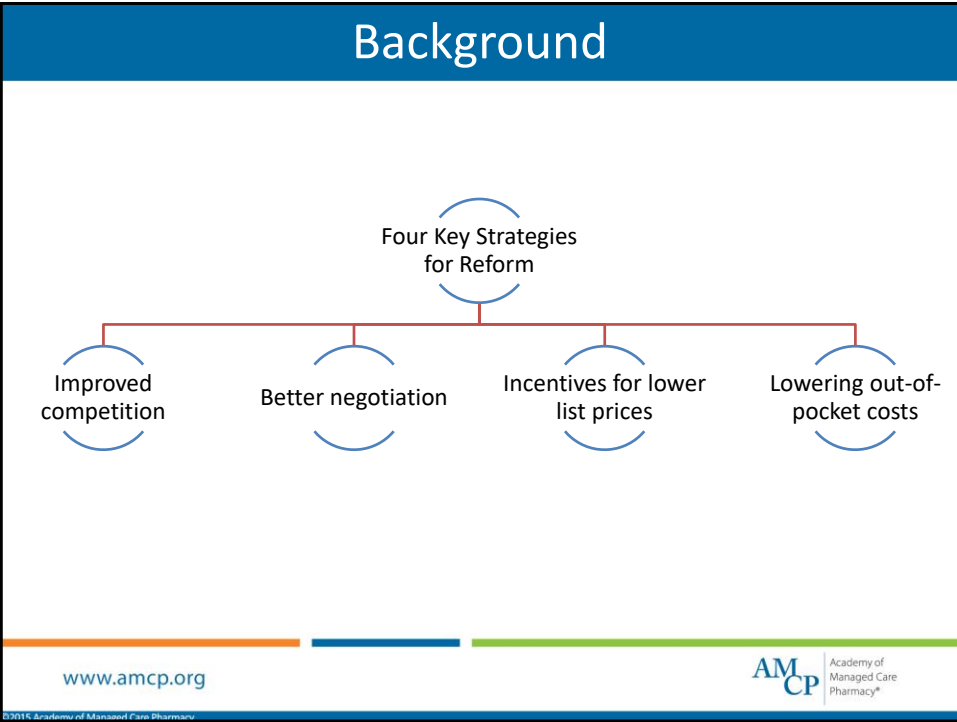
High and rising out-of-pocket costs for consumers

Foreign governments free-riding off of American investment in innovation

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AMCP's Role in Addressing the Rising Cost of Pharmaceuticals



AMCP's Role

Health care costs in the United States are becoming unsustainable, largely due to high costs of some medicines and specialty drugs

To preserve budget in our economy to cover costs of new and innovative medicines, we must create room in the health care system

Health care spending increased by 4.6% to reach nearly **\$3.5 trillion** in 2017¹

Annual patient premiums reached **\$18,764** in 2017²




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AMCP's Role




Managed care pharmacists and other professionals have a key role in containing costs

Our prescription for reducing costs and lightening the system's load

- Evaluate safe and effective medicine** when there are multiple available options for a patient's disease
- Support use of biosimilars and the ability to substitute for branded biologics**
- Confirm** whether a patient needs the most expensive medicines when a lower cost alternative produces the result

- Use strategies such as preferred drug lists to **make effective medicines affordable**
- Pursue payment systems that reward value by demonstrating good patient outcomes
- And we support availability of treatment options and competition, including generics and biosimilars, so that providers have more options that serve patient's health and reduce costs**





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AMCP's Role

END RESULT

-  **Patient receives right medicine** at right time
-  **Patient out of pocket costs are lower**
-  **Health care system saves money** by using most appropriate medicine
-  **More room in the system for emerging, game changing treatments**




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AMCP's Role




**H.R. 2026
The Pharmaceutical
Information Exchange
(PIE) Act of 2018**

Three Main Imperatives Driving the Need for PIE


| | |
|--|--|
| Value-Based Payment Models | <ul style="list-style-type: none"> The inability to communicate proactively about emerging therapies has been identified as a major barrier to the uptake of value-based payment models and contracts. Therefore, to increase the utilization of value-based payment models, PIE is needed to implement these models in a timely and effective manner upon FDA approval. |
| Patient Access to Breakthrough Therapies | <ul style="list-style-type: none"> Under its expedited approval pathway, the FDA may approve therapies before clinical trial data is published. PIE is critical to ensuring population health decision makers are aware of information on these products, and thus are able to make coverage decisions immediately upon FDA approval. |
| Planning, Budgeting, and Forecasting for Benefit Design | <ul style="list-style-type: none"> Insurance benefit design, formularies, and rates must be submitted to federal and state regulators as early as 12-18 months before the beginning of the intended plan year with little flexibility for adjustments once submitted. PIE is needed for proper planning, budgeting, and forecasting to account accurately for the impact of new therapies that will enter the market. |

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Actions the President May Direct HHS to Take Immediately



Immediate Actions

Increased Competition

- Steps to prevent manufacturer gaming of regulatory processes
REMS
- Measures to promote innovation and competition for biologics
- Developing proposals to stop Medicaid and Affordable Care Act programs from raising prices in the private market

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Immediate Actions

Better Negotiation

- Experimenting with value-based purchasing in federal programs
- Allowing more substitution in Medicare Part D to address price increases for single-source generics
- Reforming Medicare Part D to give plan sponsors significantly more power when negotiating with manufacturers
- Sending a report to the President on whether lower prices on some Medicare Part B drugs could be negotiated for by Part D plans
- Leveraging the Competitive Acquisition Program in Part B
- Working across the Administration to assess the problem of foreign free-riding

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Immediate Actions

Incentives for Lower List Prices

- FDA evaluation of requiring manufacturers to include list prices in advertising
- Updating Medicare's drug-pricing dashboard to make price increases and generic competition more transparent

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Immediate Actions

Lowering Out-of-Pocket Costs

- Prohibiting Part D contracts from preventing pharmacists' telling patients when they could pay less out-of-pocket by not using insurance
- Improving the usefulness of the Part D Explanation of Benefits statement by including information about drug price increases and lower cost alternatives

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Actions HHS is Actively Considering, on Which Feedback is Being Solicited

Further Opportunities

Increased Competition

- Considering how to encourage sharing of samples needed for generic drug development
- Additional efforts to promote the use of biosimilars

Further Opportunities

Better Negotiation

- Considering further use of value-based purchasing in federal programs, including indication-based pricing and long-term financing
- Removing government impediments to value-based purchasing by private payers
- Requiring site neutrality in payment
- Evaluating the accuracy and usefulness of current national drug spending data

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Further Opportunities

Incentives for Lower List Prices

- Measures to restrict the use of rebates, including revisiting the safe harbor under the Anti-Kickback statute for drug rebates
- Additional reforms to the rebating system
- Using incentives to discourage manufacturer price increases for drugs used in Part B and Part D
- Considering fiduciary status for Pharmacy Benefit Managers (PBMs)
- Reforms to the Medicaid Drug Rebate Program
- Reforms to the 340B Drug Discount Program
- Considering changes to HHS regulations regarding drug copay discount cards

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Further Opportunities

Lowering Out-Of-Pocket Costs

- More measures to inform Medicare Part B and D beneficiaries about lower cost alternatives
- Providing better annual, or more frequent, information on costs to Part D beneficiaries

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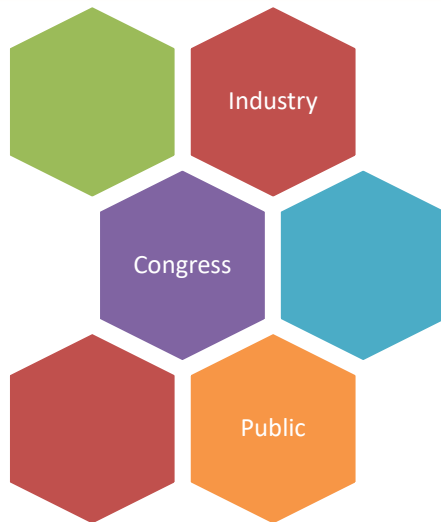
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Reactions and the Path Forward

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Reactions



“AMCP has long supported several of the recommendations contained in the President’s blueprint, including the need to foster a competitive generic and biosimilars marketplace, and greater flexibility in benefit design for the Medicare program. However, AMCP also believes some of the elements outlined in the President’s blueprint require further consideration and broad stakeholder input to ensure that they are sustainable solutions to decreasing medication costs without resulting in unintended consequences that may disrupt patient care.”

Susan A. Cantrell, RPh, CAE
CEO, AMCP

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The Path Forward

- Projected timeline for change?
- Timeline and likelihood for Congressional action?

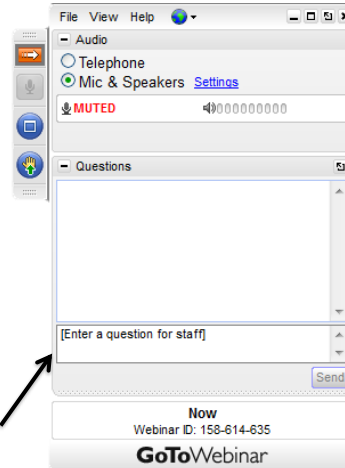
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Question & Answer

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AMCP Comments on Proposed Rule

Comments on this proposal must be submitted to HHS by July 16, 2018

You may provide feedback via email to Mary Jo Carden at mcarden@amcp.org by Friday, July 6, 2018 to inform AMCP's comments to HHS

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