

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

May 21, 2018



Disclaimer

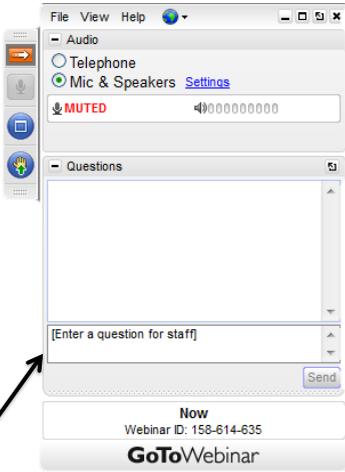
Organizations may not re-use material presented at this AMCP webinar for commercial purposes without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. Commercial purposes include but are not limited to symposia, educational programs, and other forms of presentation, whether developed or offered by for-profit or not-for-profit entities, and that involve funding from for-profit firms or a registration fee that is other than nominal. In addition, organizations may not widely redistribute or re-use this webinar material without the written consent of the presenter, the person or organization holding copyright to the material (if applicable), and AMCP. This includes large quantity redistribution of the material or storage of the material on electronic systems for other than personal use.

www.amcp.org



©2018 Academy of Managed Care Pharmacy

How to Ask A Question



Type your question in the 'Questions' area

www.amcp.org



©2018 Academy of Managed Care Pharmacy

Today's Speakers



Mary Jo Carden, RPh, JD
 VP, Government & Pharmacy Affairs
 Academy of Managed Care Pharmacy



Stephen Northrup, MPA
 Principal
 Rampy Northrup LLC



Soumi Saha, PharmD, JD
 Director, Pharmacy & Regulatory Affairs
 Academy of Managed Care Pharmacy

www.amcp.org



©2018 Academy of Managed Care Pharmacy

Agenda

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

www.amcp.org

 Academy of Managed Care Pharmacy®

©2015 Academy of Managed Care Pharmacy

Background

 Academy of Managed Care Pharmacy®

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.”*

www.amcp.org

— PRESIDENT DONALD J. TRUMP

AMCP Academy of Managed Care Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

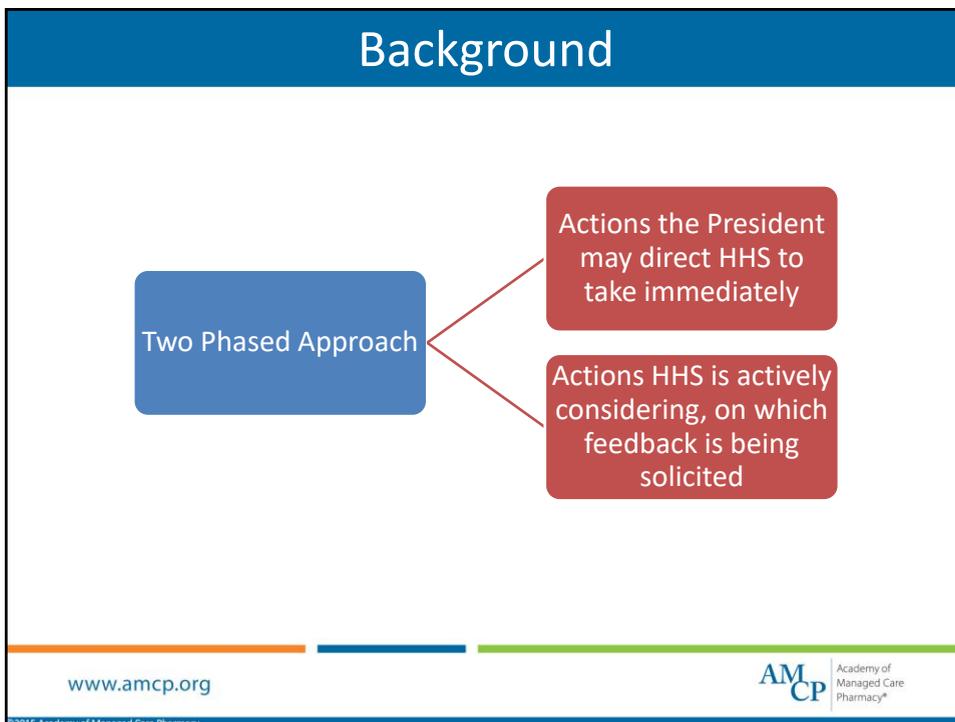
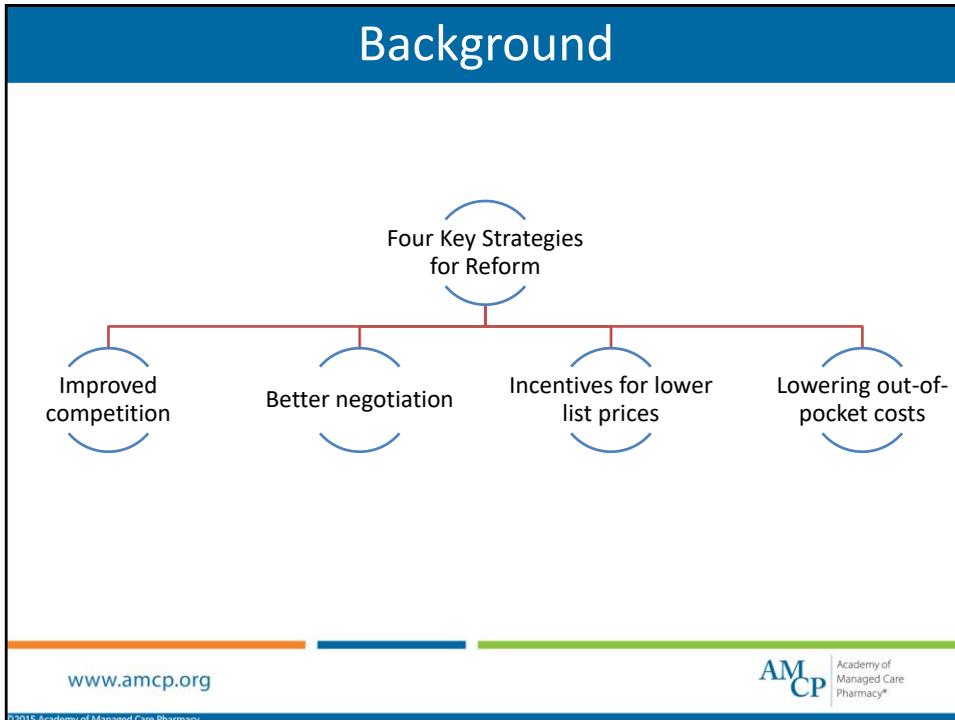
High and rising out-of-pocket costs for consumers

Foreign governments free-riding off of American investment in innovation

www.amcp.org

AMCP Academy of Managed Care Pharmacy®

©2018 Academy of Managed Care Pharmacy



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



www.amcp.org



©2018 Academy of Managed Care Pharmacy

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**

www.amcp.org



©2015 Academy of Managed Care Pharmacy

AMCP's Role

END RESULT

-  **Patient receives right medicine** at right time
-  Health care system **saves money** by using most appropriate medicine

-  Patient out of pocket **costs are lower**
-  More room in the system for emerging, **game changing treatments**



www.amcp.org



©2015 Academy of Managed Care Pharmacy

AMCP's Role



Three Main Imperatives Driving the Need for PIE

Value-Based Payment Models

- 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

- 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

- 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.

www.amcp.org



©2015 Academy of Managed Care Pharmacy

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

www.amcp.org

AMCP
Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

www.amcp.org

AMCP
Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

www.amcp.org

AMCP
Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

www.amcp.org

AMCP
Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

www.amcp.org

AMCP
Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

www.amcp.org

AMCP
Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

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

www.amcp.org

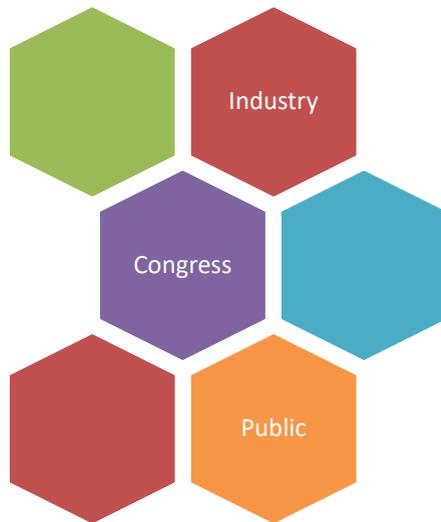
AMCP
Academy of
Managed Care
Pharmacy®

©2015 Academy of Managed Care Pharmacy

Reactions and the Path Forward

AMCP
Academy of
Managed Care
Pharmacy®

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

www.amcp.org

AMCP Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

The Path Forward

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

www.amcp.org

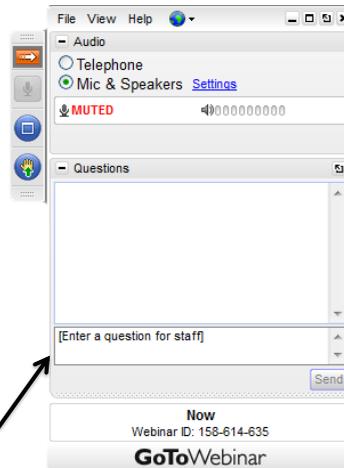
AMCP Academy of
Managed Care
Pharmacy®

©2018 Academy of Managed Care Pharmacy

Question & Answer

How to Ask A Question

Type your question in
the 'Questions' area



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

www.amcp.org



©2018 Academy of Managed Care Pharmacy

AMCP Staff Contacts



Mary Jo Carden, RPh, JD
Vice President, Government & Pharmacy Affairs
mcarden@amcp.org
703-684-2603



Soumi Saha, PharmD, JD
Director, Pharmacy & Regulatory Affairs
ssaha@amcp.org
732-266-5472

www.amcp.org



©2018 Academy of Managed Care Pharmacy

Policy Issue Groups

Sign up for
late-breaking info.
and the
opportunity to be in
the conversation:
www.amcp.org/list

- Specialty/Biosimilars
- Health Care Reform Implementation
- Medicare Part D
- MTM
- HIT
- Quality initiatives

www.amcp.org

AMCP Academy of
Managed Care
Pharmacy®

©2015 Academy of Managed Care Pharmacy

THANK YOU!

upcoming webinars
www.amcp.org/calendar

AMCP Academy of
Managed Care
Pharmacy®