



**WEBINAR**

RUTLEDGE v. PCMA

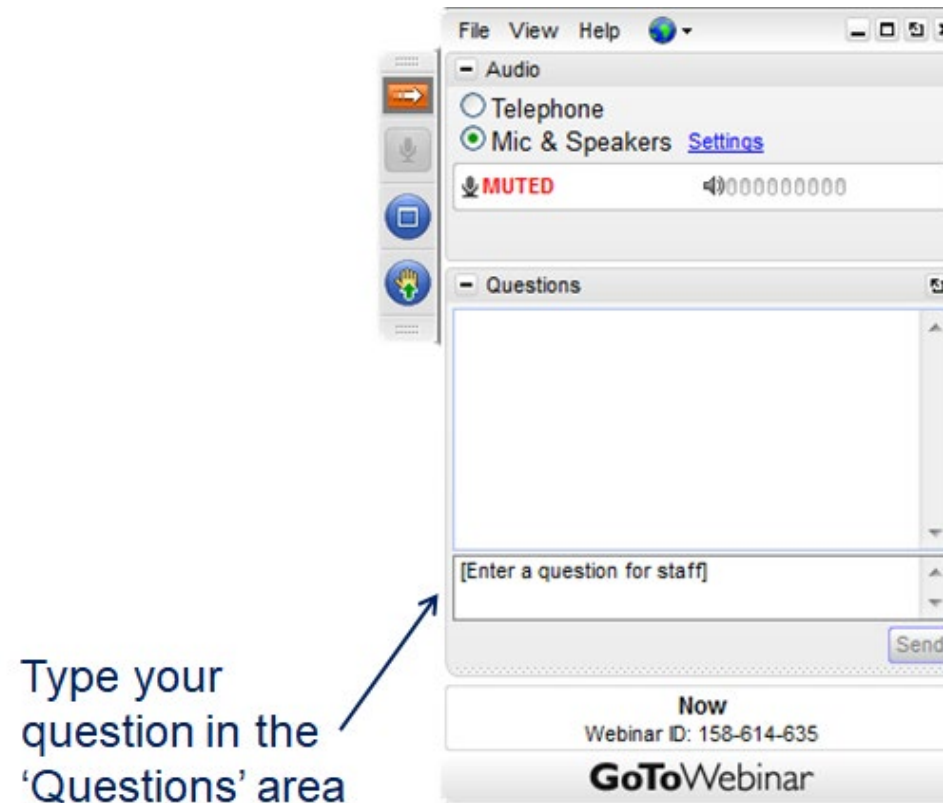
# **Impact on Managed Care Pharmacy**

APRIL 1, 2020

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# How to Ask a Question





# Presenters

**James T. Kenney, RPh, MBA**  
President, AMCP

**Tacy F. Flint, JD**  
Partner, Sidley Austin LLP

**Susan A. Cantrell, RPh, CAE**  
CEO, AMCP



## Mission

To improve patient health by ensuring access to high-quality, cost-effective medications and other therapies.



# Managed Care Pharmacy

Managed care pharmacy is the practice of developing and applying evidence-based medication use strategies that enhance patient and population health outcomes while optimizing health care resources.

# Platform to Stem Rising Costs

## MAIN MESSAGE

### VALUE FOR OUTCOMES

We support strategies to evaluate the effectiveness and the costs of prescription medicines for coverage determinations. These approaches optimize patient outcomes, avoid expensive prescriptions that are not needed, help reduce costs to our health care system, and promote use of the right medicine at the right time.

- Utilization techniques, such as prior authorization, formulary tiers, step therapy and other tools, promote the selection of medicines that work and are worth the cost.
- We support the application of these tools to Medicare Part B to achieve optimal outcomes for patients and reduce government and taxpayer costs.

### ENHANCED APPROACHES TO COVERAGE DECISIONS

Expanding the application of real-world evidence and outcomes, while advancing methods for evaluating and rewarding therapeutic value, will help providers make clinically appropriate and cost-effective patient treatment decisions.

- We support care delivery models that reward use of medications and treatments that define value as delivering better outcomes for patients.
- We support the development and refinement of real-world evidence tools, including comparative effectiveness research and value assessment models, to enhance decision-making on questions about the right therapies for patients at an appropriate cost.
- Information gathered from real-world evidence – meaning how people respond to medicines outside of clinical trials – should always be implemented into prescribing practice.
- The use of data to demonstrate outcomes and comparative effectiveness relative to other medicines should be encouraged in prescribing practices.

### COMPETITION TO LOWER COSTS

We advocate for policies that encourage innovation and competition among new, cutting-edge medicines, biosimilars and other established therapies – so providers have options to serve patient health and prevent unnecessary costs.

- When appropriate, branded medicines should be exchanged for generics and biosimilars to reduce costs while delivering consistent therapeutic outcomes.

## PROOF POINTS

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**Tacy F. Flint, JD**  
**Partner, Sidley Austin LLP**



# Rutledge v. PCMA

- Question presented: Whether ERISA preempts an Arkansas statute (Act 900) that regulates the use of maximum allowable cost (MAC) pricing by pharmacy benefit plans and pharmacy benefit managers (PBMs)?
- In June 2018, the U.S. Court of Appeals for the Eighth Circuit held that Act 900 was preempted.
- The Supreme Court agreed to hear the case after the U.S. Solicitor General weighed in to say the case should be taken.
- Argument is scheduled for April 27, 2020.

# Employee Retirement Income Security Act of 1974 (ERISA)

- ERISA preempts all state laws that have an impermissible “connection with” ERISA governed health plans, including state laws that “interfere[] with national uniform plan administration.”
- The purpose of ERISA’s preemption clause is to promote uniformity and allow employee health benefit plans to maximize value for plan beneficiaries without needing to negotiate disparate state and local requirements.
- Congress recognized that if plan administrators needed to comply with a patchwork of state regulations, they’d face large administrative and financial burdens, which would ultimately be borne by beneficiaries.

# PCMA's Argument: ERISA Preempts Act 900

- Act 900 impermissibly connects with pharmacy benefit plans in several respects:
  - Requires disclosures of detailed plan information.
  - Sets specific criteria and timelines by which plans (and the PBMs acting as their agents) must update MAC lists.
  - Dictates appeal procedures that plans must establish for pharmacies to challenge MAC list prices and particular claim reimbursements.
  - Requires plans to permit reversal or rebilling of claims if the MAC list rate is less than the pharmacy's acquisition cost.
  - Permits a pharmacy to refuse to serve a plan participant if the MAC list rate is below a pharmacy's acquisition cost.
- These requirements regulate the conduct of PBMs, the plans PBMs serve, and the administration of pharmacy benefit plans. They therefore are preempted by ERISA.

# AMCP's Brief

- AMCP's goal: Explain the many tools that can be used in managed care pharmacy to promote health and reduce costs – and advocate for broad ERISA preemption so that state regulations will not foreclose the use of these tools in ERISA-governed plans.
  - Evidence-based tools, such as prior authorization and step therapy, help patients get appropriate medicines at an affordable cost, improving population-wide health.
  - State regulations could foreclose ERISA-governed pharmacy benefit plans from implementing these and other medication-use management strategies in their plan designs.
  - Increased compliance costs will offset the cost-saving benefits of these managed care pharmacy tools and undermine development and deployment of these tools.

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**Susan A. Cantrell, RPh, CAE**  
**CEO, AMCP**

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RUTLEDGE v. PCMA

# Impact on Managed Care Pharmacy



POLICY & ADVOCACY

GRASSROOTS ADVOCACY

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POLICY & ADVOCACY FOCUS  
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AMCP Policy Digest



5/20/19

# Maximum Allowable Cost (MAC) Pricing

## Where We Stand:

Maximum Allowable Cost (MAC) pricing is a payment model contractually agreed to in the marketplace by all participants. It includes payers and pharmacies and ensures employers and consumers – those purchasing health insurance benefits – get the lowest possible price on generic drugs. MAC price reimbursement is a more

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# Questions?

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