

AMCP 2018

Policy & Advocacy Focus Areas

January 30, 2018



Presenters:

Brian Lehman, MHA, MBA, RPh

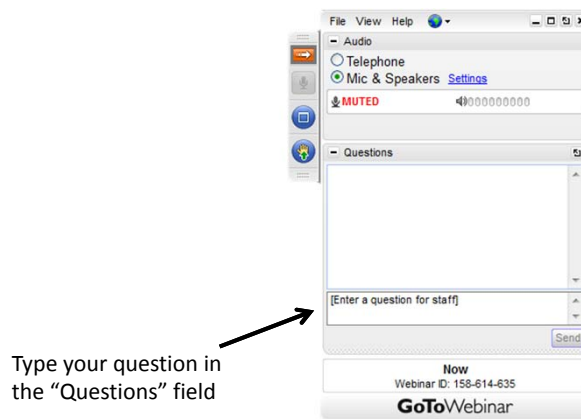
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Abigail Stoddard, PharmD, MBA

Vice Chair, AMCP Legislative & Regulatory
Action Committee (LRAC)



How to Ask a Question



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AMCP 2018 Policy & Advocacy Focus Areas

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Overview

- AMCP process for developing policy and advocacy focus areas
- AMCP Policy & Advocacy Focus Areas for 2018
- Discussion of 2018 Focus Areas
- AMCP Resources
- How can you get more involved?

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AMCP Process for Developing Policy and Advocacy Areas

- AMCP surveyed all members in August 2017 for input on 2018 priorities
 - Included a list of 2017 categories of priority issues
 - Participants ranked each priority on a scale of 1-5 and were also able to select an “other” category
- During AMCP’s October 2017 NEXUS, the Public Policy and Legislative & Regulatory Action Committees (LRAC) met jointly to consider and develop focus areas for consideration by AMCP’s Board
- AMCP’s Board reviewed, discussed and approved the focus areas for 2018

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AMCP2020 – STRATEGIC PLAN (2018-2020)

- The Plan has 4 strategic initiatives:

- ❖ Thought Leadership
- ❖ Member Engagement
- ❖ Build the Brand
- ❖ Operational Excellence

- AMCP2020 Promise

AMCP promises its members and stakeholders that it will help managed care pharmacy practitioners improve patient outcomes and control rising health care costs through enhancing knowledge, improving collaboration and intensifying advocacy.

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Policy and Advocacy Focus Areas for 2018



The rising cost of medications



Shift from fee for service to value based contracts



Opioid Management

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Rising Cost of Medications

- Federal Legislation
 - Advocate for passage: H.R. 2026 the Pharmaceutical Information Exchange Act of 2018
 - Advocate for passage H.R. 2212/S. 974 (CREATES)
 - Oppose H.R. 242/S. 41 – Medicare Prescription Drug Price Negotiation Act

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Rising Cost of Medications

- State Legislation
- Support legislation that will allow biosimilars to be marketed without additional restrictions
 - Oppose MAC pricing restrictions
 - Oppose unnecessary restrictions on step therapy, prior authorization
 - Oppose limits on mail service delivery
 - Oppose “transparency” that is not meaningful

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Messaging: Rising Cost of Medications

Value for Outcomes

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

- Support utilization management such as prior authorization, formulary tiers, step therapy and other tools to promote selection of medications that work and are cost effective
- Support application of these tools in Medicare Part B

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Messaging: Rising Cost of Medications

Enhanced Approaches to Coverage Determinations

Expand 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.

- Support care delivery models that reward use of medications and treatments that define value as better outcomes for patients
- Support 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

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Messaging: Rising Cost of Medications

Competition to Lower Costs

Advocate for policies that encourage innovation and competition among new, cutting edge medicines, biosimilars other established therapies to provide options that improve patient health and reduce unnecessary costs

- When appropriate, branded medicines should be exchanged for generics and biosimilars

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Shift from Fee for Service to Value-Based Contracts

- AMCP convened a partnership forum in June 2017 of diverse stakeholders to develop strategies to enable expansion of “value-based contracting” (VBC)
- Consensus definition: A VBC is a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes or measures.

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Shift from Fee for Service to Value-Based Contracts

Federal Anti-Kickback Statute

•Issue: The Anti-kickback Statute (42 U.S.C §1320a-7b) prevents parties from giving something of value with intent to influence a purchase under a federal program.

•Solution: A new safe harbor for VBCs or clarification on existing federal rules is needed.

Medicaid Best Price Rule

•Issue: Unrealistic for manufacturers to write contracts in which they could receive dramatically reduced payments, because they may be required to offer their product to federal programs for free

•Solution: An exemption for VBCs that include 100% price discount from Medicaid Best Price Rule

The 21st Century Cures Act

•Issue: Became law in December 2016 (Public Law 114-255), included a provision for improved communication of real-world data between manufacturers and formulary committees/payers

•Solutions Payers and manufacturers allowed to have limited but necessary pre-approval communication via H.R. 2026 The Pharmaceutical Information Exchange (PIE) Act of 2017

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Shift from Fee for Service to Value-Based Contracts

Advancing Value-Based Contracting – Proceedings from the AMCP Partnership Forum

(webinar recorded on October 11, 2017)

<http://amcp.org/Newsletter.aspx?id=22690>

AMCP Partnership Forum: Advancing Value-Based Contracting – Journal of Managed Care and Specialty Pharmacy -November 2017

<https://www.jmcp.org/doi/full/10.18553/jmcp.2017.17342>

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Shift from Fee for Service to Value-Based Contracts

- During AMCP September 2017 Lobby Days members discussed VBC during their Hill visits
- Later in 2017, House Diabetes Caucus released a request for information on VBC and AMCP provided comments
- Public Policy members working with staff to develop AMCP policy statement on VBC

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Opioid Management

- Support H.R. 3545 Overdose Prevention and Patient Safety Act and S. 1850 the Protecting Jessica Grubb's Legacy Act
- Updating AMCP's policy digest statement and where we stand on opioid management
- Building on the work of the AMCP Addiction Treatment Advisory Group, AMCP is in the process of establishing an Addiction Advisory Group (AAG)

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Opioid Management Key Areas for 2018

- Ensure that CMS implements the proposed drug management program for Part D after consideration of AMCP's and stakeholder comments - Full comments available here: <http://bit.ly/2FTXvcz>
- Reduce the potential for fraudulent Part D claims by promoting legislation allowing for suspension of claims based on a credible allegation of fraud
- Continuing to engage on state legislative and federal regulatory fronts
- Allow health plans, pharmacy benefit managers, and other payers to have access to PDMP data
- Ensure that payers have flexibility to make determinations on opioid management and addiction treatment based on clinical evidence

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2018 Federal Landscape

- ❖ Second year of new administration
- ❖ 115th Congress in the second year
- ❖ Secretary of HHS – Alex Azar (January 2018)
- ❖ FDA Commissioner - Scott Gottlieb, M.D. (May 2017)
- ❖ Administrator of CMS - Seema Verma (March 2017)

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2018 State Landscape

- 39 States and the District of Columbia have started sessions: AR, CT, KS, LA, MN, OK, OR, and WY left to convene.
 - MT, NV, ND, and TX do not convene in 2018
- Key Issues:
 - Rising Cost of Medications
 - Maximum Allowable Cost (MAC) reporting and “Price Gouging”
 - Opioid Management
 - Rx limits and Prescription Drug Monitoring Program use
 - Many Governors establishing Opioid Commissions

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AMCP RESOURCES

- AMCP Legislative Tracking Vendor:
www.stateside.com
- AMCP Policy Digest
- Managed Care Pharmacy (best practices)
- Monthly Legislative and Regulatory Briefing
- Policy Statements, Tool Kits and Volunteers
- AMCP Grassroots Advocacy Vendor:
www.votervoice.net

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STATESIDE

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The Leader in State and Local Government Affairs

We empower our clients' state and local advocacy efforts, by enabling their access to a wealth of public and private sector relationships, informing their advocacy decisions with intelligence and perspective and providing them with a deep bench of government affairs expertise and experienced professional bandwidth.

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AMCP Policy Digest

POLICY Digest

1999-PRESENT

A collection of AMCP's position statements on professional and practice issues

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CERTIFIED EASY TO USE CERTIFIED

www.amcp.org/policydigest

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Best practices that offer quality care and cost-effective coverage to patients, payers, employers, and government



- Pharmacists are Medication Experts
- Electronic Prior Authorization (ePA)
- Step Therapy
- Medication Therapy Management
- Mail Service Pharmacy



<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22111>



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Biosimilars Resource Center



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Learn more.



LEGISLATIVE MAP
View legislation in your state.



NEWS AND PERSPECTIVES
FDA Approves Erelzi, First Biosimilar Etanercept



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AMCP Members Advocate!



AMCP members participating in 2017 Lobby Days

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AMCP AFFILIATES

<http://www.amcp.org/affiliates/>



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State Advocacy Coordinators (S.A.C.)

Grassroots advocacy at the state level

Volunteer Now!

Online Application: amcp.org/sac-application

- Keep AMCP members informed on opportunities for advocacy and legislation
- Establish/maintain relationships with stakeholders in your state
- 33 states and D.C. need a S.A.C.: AL, AK, AR, CT, DC, HI, IA, ID, IN, KS, LA, MA, MD, ME, MO, MS, MT, ND, NE, NJ, NM, NV, OH, OR, RI, SC, SD, TN, UT, VA, VT, WI, WV, and WY

Who is Your S.A.C.? Get Involved!

www.amcp.org/sac

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Student Advocacy



Mission: The AMCP Chapter Challenge allows student pharmacists from across the country the opportunity to get involved with AMCP's strategic policy priorities. This keeps student members informed and knowledgeable about relevant managed care pharmacy issues that may impact the future of the managed care pharmacy profession. Through the Chapter Challenge, students members will become the changing agent on both federal and state managed care pharmacy matters that will improve healthcare for all.

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Policy Issues & Advocacy



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Affordable Care Act

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Monthly Updates

<http://amcp.org/publications/amcp-legreg/2017/>




In This Issue

- [White House Declares the Opioid Crisis a National Emergency](#)
- [Senate Goes on Summer Recess Leaving ACA Unchanged](#)
- [AMCP Supports Introduction of CREATES Act](#)
- [AMCP Supports Overseas Prevention and Patient Safety Act](#)
- [Senate Passes FDA Reauthorization Act of 2017 \(FPARA\)](#)
- [Upcoming Comment Periods](#)
- [Washington State Finalizes Substitution Requirements for Interchangeable Biological Products](#)

Spotlight Story: Opioid Epidemic

White House Declares Opioid Crisis a National Emergency

President Trump on Aug. 10 declared the opioid crisis a national emergency, the Administration's strongest action so far to address the epidemic. The declaration came days after the White House Opioid Commission, led by Gov. Chris Christie (R-NJ), recommended the action as a means to direct congressional efforts. While no specific steps have been outlined, the President stated that a lot of time and money will be spent on the crisis. The White House Opioid Commission did, however, make several recommendations including increasing access to treatment, requiring prescriber education and model language for state legislatures to create standing orders for naloxone.

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Position Statements



WHERE WE STAND

www.amcp.org/PositionStatements

- **Any Willing Provider**
- **Biosimilar Drug Therapies**
- **Formularies**
- **Management of Opioids**
- **Medication Synchronization**
- **Mail Service Pharmacies**
- **Population Medication Management Services**

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Issue Toolkits

<http://www.amcp.org/Toolkits/>

Toolkits generally include a brief background on an issue, sample legislation, AMCP policy, materials and studies from non-AMCP sources, and news articles from electronic and print media.

Toolkits:

- Biosimilars
- Medicaid Managed Care
- Specialty Tiers
- Uniform Prior Authorization
- Mandated Benefits
- Pharmacy Audits
- Opioid management
- Coverage Parity for Oral and IV Chemotherapy Drugs
- Exemptions to a State's Generic Substitution Laws
- Health Insurance Marketplaces
- Mail order
- MAC Pricing

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Action Alerts

AMCP Legislative Action Center



AMCP Needs Your Support - Contact Your Member of Congress Today!

AMCP needs your help - urge your Member of Congress to support H.R. 2026 - The Pharmaceutical Information Exchange (PIE) Act of 2018. The bill is based on consensus recommendations developed during two multi-stakeholder meetings convened by AMCP on the...

Take Action →

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Action Alerts 2017

Federal

Alert Topic	Bill Number	Recipient	Date
Support- Pharmaceutical Information Exchange Act - PIE	H.R. 2026 (subcommittee hearing and markup favorable)	House Energy and Commerce Committee	April 2017 August 2017
Oppose drug importation from foreign pharmacies and wholesale distributors	Proposed Amendments (amendments failed)	U.S. Senate HELP Committee	May 2017
Requesting members to become a cosponsor	HR 2051 - FAST Generics Act	House Energy and Commerce Committee	May 2017
Requesting members to become a cosponsor	H.R. 3545 – Overdose Prevention and Patient Safety Act	All House members	August 2017

State

Alert Topic	Bill Number	Recipient	Date
Tennessee – Ask Gov. to sign – bill implements a pilot MTM program for patients in TennCare	House Bill 628 Governor signed	Gov. Haslam	May 2017

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Policy Issue Groups

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

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

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2018 Annual Meeting



AMCP Annual Meeting 2018 - Boston, MA (April 23-26)

- Registration open at www.amcpmeetings.org
- Early bird rate through March 23
- Members get a substantial discount

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Your Feedback!!

Suggestions!!

Questions?

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