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Spotlight Story: AMCP Legislative Days

AMCP Members, Staff Visit Capitol Hill to Support PIE Bill & Value-Based Contracting

AMCP members this month participated in a targeted legislative day event on Capitol Hill designed to garner additional support for H.R. 2026, “Pharmaceutical Information Exchange Act of 2017” (PIE Act) and to introduce AMCP’s activities on value-based contracting (VBC).

The visits on Sept. 12 targeted Members of Congress who expressed an interest in supporting the PIE legislation and hold key positions on the House Energy and Commerce Committee and Senate Health, Education, Labor and Pensions Committee. AMCP Board members and other members who live in key Congressional districts participated in nearly 30 meetings.

AMCP will follow-up with Members of Congress visited to encourage additional sponsorship of the PIE Act. The PIE Act was introduced in April 2017 by Rep. Brett Guthrie (R-KY). Even though the Food and Drug Administration (FDA) issued draft guidance in January 2017 that included an allowance for PIE, a more permanent solution is necessary to provide assurances that the correct procedure is incorporated into FDA laws.

Participants also introduced AMCP’s activities on VBC. As pharmacists and other health care providers who work in health plans and other managed care settings, many AMCP members administer these contracts and AMCP intends to be a leader in developing best practices and drive policy decisions in this area. Included in the message was a consensus definition of VBC created as a result of a multi-stakeholder

partnership forum called *Advancing Value-Based Contracting,* held in June 2017. It states: "A value-based contract 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."

AMCP also told lawmakers and legislative aides that it will be leading efforts to develop best practices for implementing VBC and supporting policy changes to the Anti-kickback Statute and certain federal pricing provisions to move VBC forward. AMCP will hold a webinar on the proceedings from the partnership forum on Oct. 11 from 2-3 pm EDT. This webinar is free to join and you can register here.

Photos: L-R, from upper left image clockwise: Larry Blandford, Jim Kenney, Brian Lehman; Michael Pazirandeh, Rep. Tony Cardenas (D-CA); Fahim Faruque, Marissa Schlaifer, Rep. Gene Green (D-TX), Elizabeth Sampsel; Tom Bizzaro, Susan A. Cantrell; Lauren Lyles, Sampsel, Schlaifer, Tim Antonelli, Reginia Benjamin, Faruque.

Federal Legislative Update

Advocacy Tip

Congress Returns From Recess for Fall Push

Congress returned from its summer recess on Tuesday, Sept. 5. The first session of the 115th Congress aims to adjourn on Friday, Dec. 15, with approximately 40 work days in the House and 45 work days in the Senate remaining in this session. The government is currently operating under a Continuing Resolution through Dec. 8.

Lawmakers Introduce New Bills to Address the Opioid Epidemic

On July 28, Rep. Tim Murphy (R-PA) introduced H.R. 3545, the Overdose Prevention and Patient Safety Act. The bill, which has bipartisan support, is designed to protect the confidentiality of substance use disorder patient records by including those records under the Health Insurance Portability Accountability (HIPAA) Act.

It allows appropriate access to patient information that is essential for providing whole-person coordinated care, and it strengthens protections for the disclosure of a patient's substance use disorder records. In these provisions, the bill addresses concerns with 42 CFR Part 2 limitations, which impede appropriate access to records and whole person coordinated care.

On Aug. 16, AMCP sent an action alert requesting members contact their representative in Congress and seek their support as a cosponsor of H.R. 3545. AMCP members responded to the alert by contacting 161 members of the House. The number of cosponsors on H.R. 3545 has increased since the alert.

Later this month, Sens. Joseph Manchin (D-WV) and Shelley Capito (R-WV) will introduce S _, the Protecting Jessica Grubb's Legacy (The Legacy Act). This bill is not an exact companion to H.R. 3545, but it would align Part 2 with HIPAA for the purposes of treatment, payment and operations. Read more.

ACA Faces Another Repeal Attempt in Senate

Before summer recess, the Senate failed to pass legislation that would repeal the Affordable Care Act (ACA). Since returning, GOP senators have worked to bring another repeal bill to the floor. Sens. Lindsey Graham (R-SC) and Bill Cassidy (R-LA) are leading this effort. Their proposal would include cuts to Medicaid, and generally maintain the current tax structure, but provide block grants to the states. At this time, the Congressional Budget Office (CBO) had not yet scored the proposal.

'Medicare for All' Legislation (S. 1804) Introduced in Senate

On Sept. 13, Sen. Bernie Sanders (I -VT) introduced S. 1804 (text is not available yet) to establish a government "single-payer" system for health care. The "Medicare for All" bill would be phased in over a four year period and include coverage for everyone. Year 1, Medicare eligibility age would be lowered to 55; Year 2 to 45; Year 3 to 35 and in Year 4 everyone would be covered. Coverage would go beyond

Your advocacy efforts are an important factor in helping to shape public policy. November elections will be here before you know it, so prepare yourself by attending town hall meetings, following candidates on social media and even reading "snail mail" from candidates.

current Medicare coverage by including dental and vision care. It would eliminate copays, deductibles and premiums. Some of Senator Sanders' ideas for potential payment options include a 7.5% income based premium paid by employers, 4% income based premium paid by households, savings from eliminating certain existing tax breaks, and making the personal income tax more progressive.

FDA Funding Measures Move Forward

The House passed fiscal year 2018 (FY18) funding for FDA last week, and the Senate passed its proposal out of committee. However, at this time, Senate leadership has not indicated when it will bring the matter to the floor for a vote. The House voted to fund the FDA at $2.76 billion and at a similar level in the Senate. In addition, the committees appropriated $60 million to fund FDA's FY18 activities to implement certain provisions in the 21st Century Cures Law. The FDA is operating under a Continuing Resolution that flat funds Federal discretionary programs, including FDA through Dec. 8. Earlier this week, AMCP staff participated along with other members of the Alliance for a Stronger FDA in Hill Advocacy Days. Alliance members met with offices of the members of the Agriculture Appropriations Subcommittees to support funding the FDA at least at the FY17 levels.

FDA Reauthorization Act of 2017 (FDARA) Becomes Law

The President on Aug. 18 signed H.R. 2430, which amends the Federal Food, Drug, and Cosmetic Act to revise and extend user-fee programs for prescription drugs, medical devices, generic drugs and biosimilar biological products. The Act became Public Law No. 115-52. AMCP's webinar: *Implications for Managed Care Pharmacy from the FDA Reauthorization Act*, discussed the key provisions of FDARA and their implications to managed care pharmacy. The recording of that webinar is available here.

Upcoming Comment Periods

AMCP is seeking stakeholder feedback on the following proposals that are currently open for comment. Please provide feedback via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by the dates listed for incorporation into AMCP's comments on the matter. All of AMCP's final comment letters are available on the AMCP website and also included in the Legislative-Regulatory Briefing.

Topic	Feedback Due to AMCP	Comments Due
ODPHP – Healthy People 2030 Proposed Framework	Sept. 25	Sept. 29
FDA—Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements	Nov. 13	Nov. 20

Federal Regulatory Update

AMCP Submits Comments on Generic Competition Under Hatch-Waxman Act

On Sept. 18, AMCP submitted comments to FDA in response to a June 2017 request for comments titled *Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access.* To ensure a robust generic marketplace, AMCP supports closing loopholes that allow for settlement agreements between brand and generic manufacturers that delay entry of generics into the marketplace. AMCP also actively supports HR 2212, T*he Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act,* that would give FDA more authority to address abuses with the Risk Evaluation and Mitigation Strategy system that result in the delay of market entry for generic medications. AMCP's comments are available here.

AMCP Submits Comments on Draft CY2018 Medicare Part B Physician Fee Schedule

On Sept. 11, AMCP submitted comments to CMS on the Draft CY2018 Medicare Part B Physician Fee Schedule in response to the solicitation of public comments on biosimilars included in the proposed rule. AMCP's comments focused on the following elements:

1. CMS Should Critically Evaluate Coding & Reimbursement Options Under Medicare Part B to Ensure Patient Access and Affordability of Biologics and Biosimilars
2. CMS Should Require Documentation of Medicare Part B Drug Claims Using NDCs
3. CMS Should Consider Categorizing Biosimilars as Applicable Drugs under Medicare Part D

To read AMCP's full comments, please visit here.

FDA Seeks Feedback on the Impact of Direct-to-Consumer Advertising

On Aug. 21, FDA released a public notice and comment period called *Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements* on the impact of direct to consumer advertising by proposing to modify its requirements for defining "major statements" that must be included in ads. Specifically, FDA seeks input on the whether a major statement can be those that are "severe (life-threatening), serious, or actionable" if a disclosure indicates that there are other risks associated with use of the product. FDA seeks feedback on this approach, knowns as the "limited risks plus public disclosure", including available data on this approach and impact on consumers; ability of consumers to understand information and appropriate language; criteria for determining which risk information is most important to consumers versus health care providers; and how to

provide information on drug and food interactions. Comments are due Nov. 20, and AMCP is reviewing the proposal. If you have feedback, please submit it to ssaha@amcp.org by Monday, Nov. 13.

AMCP Webinar

Advancing Value-Based Contracting - Proceedings from the AMCP Partnership Forum: Wednesday, Oct. 11, 2-3pm, EDT
AMCP Members and Non-Members - Free

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