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AMCP Leads Broad Advocacy Effort in Urging FDA for Timelier and More Proactive Sharing of Health Care Economic Information

Joint letter signed by 30-plus organizations support two general consensus recommendations developed during recent AMCP Partnership Forums.

The Academy gathered more than 30 organizations in a joint letter to FDA expressing support for greater proactive exchange of preapproval and post-approval health care economic information (HCEI) between payers and pharmaceutical companies. Organizations signing onto the letter included population health decision makers, biopharmaceutical and medical device manufacturers, patient advocacy groups, health care providers, and health economists.

The joint letter supports two general consensus recommendations developed during recent AMCP Partnership Forums that would improve proactive communications:

- First, the clarification and responsible expansion of Section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 to improve post-approval sharing of HCEI.
- Second, the creation of a safe harbor for the exchange of clinical and economic information for emerging therapies prior to FDA approval.

The letter responded to the FDA's docket, *Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities - Questions and Answers*. AMCP also submitted its own letter. Read the comments at http://bit.ly/2o56Ed9.

Federal Legislative Update

American Health Care Act (AHCA) Passes House, Faces Uncertain Future in Senate

The House voted this month to pass the American Health Care Act (AHCA) as a budget reconciliation bill that is part of the 2017 federal budget process. As such, it can pass the Senate by a simple majority of votes (51). The AHCA would repeal the individual mandates, employer mandates, various taxes and also make modifications to the federal Medicaid program. The House vote of 217-213 was taken prior to the Congressional Budget Office releasing a score. That score is anticipated later this month.

Meanwhile, the Senate has indicated it will write its own version of the bill. Senate Majority Leader Mitch McConnell (R-KY) created a working group on health care to craft a Senate bill. In addition to McConnell, the working group includes: Senators Lamar Alexander (R-TN), John Barrasso (R-WY), John Cornyn (R-TX), Tom Cotton (R-AR), Ted Cruz (R-TX), Mike Enzi (R-WY), Cory Gardner (R-CO), Orin Hatch (R-UT), Mike Lee (R-UT), Rob Portman (R-OH), Pat Toomey (R-PA) and John Thune (R-SD).

House and Senate Introduce Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act

Lawmakers on April 27 introduced the bipartisan CREATES Act in the House (H.R. 2212) and Senate (S. 974). The legislation is designed to promote market competition for drugs and biological products by facilitating the timely entry of low-cost generic and biosimilar versions. The Congressional Budget Office (CBO) has estimated that similar legislation would save the government more than $3 billion in direct savings overs 10 years. AMCP joined 17 other health care organizations and consumer groups in a letter supporting the legislation.

H.R. 2212 was introduced by Tom Marino (R-PA) and David Cicilline (D-RI). S. 924 was introduced by Senators Patrick Leahy (D-VT), Chuck Grassley (R-IA), Mike Lee (R-UT), Amy Klobuchar (D-MN), Tom Cotton (R-AR), Sheldon Whitehouse (D-RI), John McCain (R-AZ), Richard Blumenthal (D-CT), Susan Collins (R-ME), Claire McCaskill (D-MO), Dick Durbin (D-IL), and Diane Feinstein (D-CA).

Food and Drug Administration (FDA) Developments: New Commissioner, Funding Advocacy

On May 11, Scott Gottlieb, M.D., was sworn in as the 23rd Commissioner of FDA. Dr. Gottlieb is a physician, medical policy expert, and public health advocate who previously served as the FDA's Deputy Commissioner for Medical and Scientific Affairs, and before that as a senior advisor to the FDA Commissioner.

On April 25, AMCP staff joined more than 50 members of the Alliance for a Stronger FDA for Capitol Hill Advocacy Day. Alliance members participated in 60 meetings with members of the House and Senate committees with responsibility as either an authorizer or an appropriator of funds for the FDA. The focus of the visits was to reinforce why Congress should support and sustain current funding and personnel levels for the FDA. Underscoring the need for robust funding, Alliance members noted that the FDA's proposed budget for fiscal year

Advocacy Tip

Identify your Key Advocates: Identify the people who care most about your issues. Use an internet search to seek out likeminded coalitions, and also ask current members, to help find new individuals. Then, learn as much as you can about your advocates by asking them what they think the key issues are.

2017 is $2.75 billion, just slightly more than the appropriated budget for the Montgomery County Maryland School Board at $2.5 billion.

The House Appropriations Committees, meanwhile, increased the FDA funding by nearly $70 million and also included report language that staffing levels should not be reduced at this time. The bill must still be considered by the Senate but the Alliance is encouraged by the strong House support for adequate FDA funding.

Senate HELP Committee Rejects Prescription Drug Importation Proposal

The Senate Committee on Health, Education, Labor, and Pension (HELP) rejected amendments by Sen. Bernie Sanders (I-VT) to the FDA Reauthorization Act of 2017 (S.934) that would have allowed the importation of prescription drugs from foreign pharmacies. AMCP sent an action alert to members who had a Senator on the HELP committee urging them to ask their Senator to oppose the two amendments. Sens. Lamar Alexander (R-TN) and Al Franken (D-MN) received the most contacts by AMCP members.

Federal Regulatory Updates

AMCP Advocates for Transforming and Modernizing Medicare Part D to Best Meet Needs of Beneficiaries

The Academy is suggesting various changes to improve the Medicare Advantage (MA) and Part D programs, including in areas of MTM, quality, formulary design and utilization management, health IT and data interoperability, opioid management, and fraud, waste and abuse. The suggestions are part of comments AMCP submitted to CMS in response to its request for information for MA and Part D programs in the 2018 Final Call Letter, released April 3. AMCP's comments provided options for regulatory, subregulatory, policy, practice and procedural changes to meet the goals of CMS. The comments also provided options for statutory changes to the MA and Part D programs, where applicable, that would help to better meet the needs of beneficiaries. AMCP's full comments are available at http://bit.ly/2piyVKR.

AMCP Submits Comments to PQA on Three New Measures Under Consideration for Endorsement

AMCP submitted comments to the Pharmacy Quality Alliance (PQA) on three new measures under consideration for endorsement. In general, AMCP urged PQA to:

- Move away from traditional process-based measures and begin the shift towards outcomes-based measures.
- Consider the cost-effectiveness associated with new or revised measures before endorsement.
- Work with other measure developers and quality organizations to evaluate currently endorsed measures for duplication and remove any overlapping measures.

In regards to the three measures under consideration, AMCP commented as follows:

- ***Treatment of Chronic Hepatitis C:*** Completion of Therapy - AMCP strongly encouraged PQA to reconsider this measure and to develop an outcomes-based measure that utilizes SVR as the marker for successful completion of HCV therapy.
- ***Polypharmacy:*** Use of Multiple CNS-Active Medications in Older Adults - AMCP encouraged PQA to reconsider this

measure to account for situations where the benefit to the patient outweighs the risk and to streamline the measure with the existing HRM measure.

- ***Polypharmacy:*** Use of Multiple Anticholinergic Medications in Older Adults - AMCP encouraged PQA to reconsider this measure to account for situations where the benefit to the patient outweighs the risk and to streamline the measure with the existing HRM measure.

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

Eye on States

AMCP Submits Comments on Washington Proposed Rule for Interchangeable Biologic Products

AMCP submitted comments to the Washington Department of Labor & Industries supporting a proposed rule that would require the dispensing of an interchangeable biological product when available unless the provider specifically indicates that substitution is not permitted for the Washington Prescription Drug Program. Moving forward, AMCP encouraged the Washington Department of Labor & Industries to ensure that any updates to laws or regulations governing interchangeable biological products continue to align with the provisions of the Biologics Price Competition and Innovation Act and its implementing regulations and guidance documents. Read the full comments here.

Upcoming Regulatory Comment Periods

AMCP is seeking stakeholder feedback on the following proposed rules that are currently open for comment. Please provide feedback via email to Soumi Saha, Assistant 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 Newsletter that is sent to all AMCP members.

Topic	Stakeholder Feedback to AMCP Due	Comments Due
ICER – ADF Opioids Draft Report	May 26th	June 2nd
FDA – Comments on Training Health Care Providers on Pain Management and Safe use of Opioids	June 21st	July 10

Eye on State Legislatures

Roughly half of the states have completed, or soon will finish, their legislative sessions for 2017. Some recent action:

Biosimilar and Interchangeable Biologic Products
Eight states have pending biosimilar legislation: AK (session ends Wednesday), AL (session ends Thursday), CT, MI, MN, NV, NY, and VT. The Maryland legislation is awaiting the Governor's signature. AMCP recently sent a letter to the Connecticut legislature seeking amendments to its proposed legislation.

Detailed map of biosimilars legislative activity can be found here.

Medication Therapy Management
Tennessee House Bill No. 628, which was signed into law recently, will implement a pilot medication therapy management (MTM) program for

patients in the TennCare program. AMCP sent letters to House and Senate leadership supporting the legislation. Once the legislation passed, AMCP sent a letter to Gov. Haslam, asking him to sign the bill. Then AMCP members, using the new grassroots vendor Voter Voice, responded to the AMCP action alert by sending letters to the Governor also seeking his support. The Tennessee Pharmacists Association, the Speaker of the House, and Office of the Governor thanked AMCP for its interest and support of the legislation.

AMCP Letters, Statements and Analysis
State Legislative Tracking

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