



In This Issue

- [Spotlight on Preapproval Information Exchange](#)
- [Senate Asked to Continue Work on Replacing ACA](#)
- [House Passes FDA Reauthorization Act of 2017 – H.R. 2430](#)
- [AMCP Supports Medicare Funding for Quality Measures](#)
- [Reps. Seek to Aim Spotlight on Drug Pricing Transparency](#)
- [FDA Advisors Recommend Biosimilars to Two Oncology Agents](#)
- [Flexibility of Medical Device Regulatory Process](#)
- [CMS Updates Quality Payment Program](#)
- [Input on Changing Coding for Biosimilar, Reference Biologics](#)
- [Eye on State Legislatures](#)

Spotlight on Preapproval Information Exchange

House Energy and Commerce Committee’s Subcommittee on Health Considers PIE Act at July 12 Hearing Titled “Examining Medical Product Manufacturer Communications”

AMCP member Katherine Wolf Khachatourian, PharmD, MBA, Vice President of Pharmacy Services, Strategy and Delegation Oversight at Qualchoice Health Plan Services, Inc., testified in support of H.R. 2026, the Pharmaceutical Information Exchange (PIE) Act of 2017 during a July 12 hearing of the E&C Subcommittee on Health.

In remarks, she highlighted the current challenges facing preapproval information exchange: “The limitations on information we are able to obtain, results in a hindrance to patient access to novel and emerging therapies. It limits our ability to accurately forecast, plan and budget for anticipated expenditures, and it precludes our ability to contract on value rather than volume. This is the reason I am here before you today – to demonstrate the need for a legislative



framework, which will provide the key to unlock additional information needed for us to make more informed benefit decisions for better patient access to treatments.” The PIE Act closely follows recommendations on preapproval communications issued by AMCP and other stakeholders in 2016. AMCP joined more than 20 organizations in submitting a joint letter of support for H.R. 2026 to the record.

A recording of the hearing, along with Dr. Khachatourian’s testimony, and the joint sign-on letter are available [here](#).

AMCP’s press release highlighting the hearing is available [here](#). (Images from left-clockwise: Khachatourian provides testimony; Khachatourian with AMCP CEO Susan A. Cantrell, RPh, CAE; hearing scenes)

Federal Legislative Updates

White House Asks Senate to Stay Through August Recess to Work on Replacing ACA

Congress is due to recess on July 28th for the month of August and return on Sept. 5th. However due to the Senate’s continuing efforts to pass legislation designed to repeal and replace the Affordable Care Act, the President has asked them to stay until it passes a Senate bill. At this time, Senate leadership does not have enough votes to pass a bill. Discussions are ongoing about next steps.

House Passes FDA Reauthorization Act of 2017 – H.R. 2430

The full House on July 12 passed H.R. 2430, which amends the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products. The bill was received in the Senate on July 13th and currently is on the Senate Legislative Calendar.

AMCP Supports Medicare Funding for Quality Measures

On July 18, AMCP signed on to a [Friends of NQF \(National Quality Forum\) letter](#) to Rep. Kevin Brady (R-TX), Chairman of the House Ways and Means Committee, to support continuing the currently authorized \$30 Million in annual Medicare funding for NQF and quality and performance measurement. NQF is a non-profit, non-partisan organization that convenes health care experts to endorse measurement tools used to increase accountability and improve patient care. NQF endorsed measures and guidance are developed by consensus and are used within federal quality reporting programs. AMCP is a member of NQF and

Advocacy Tip

Actual legislative advocacy can involve anything from working personally with a legislator or aide on the wording of a bill to mobilizing hundreds, or even thousands, of supporters to bombard a legislature with phone calls about an issue. It includes educating legislators, supporters and the public about the issue; working with the media; continuously seeking out allies; and being persistent over long periods of time. During the upcoming August recess for members of Congress, AMCP encourages you to seek out opportunities to meet

supports development of measures to improve the quality of patient care management.

Representatives Seek to Aim Spotlight on Drug Pricing Transparency

Several Representatives are using a procedural move in the House to press their case about high drug prices and transparency. Rep. Doug Collins (R-GA), sponsor of The Prescription Drug Price Transparency Act (H.R. 1316), has used the special order on the floor process twice this session to argue that high drug prices can best be addressed by requiring transparency of pharmacy benefit managers. Collins has been joined by Reps. Austin Scott (R-GA), Buddy Carter (R-GA), and John Duncan (R-TN) in the effort. The lawmakers are seeking a committee hearing to highlight their concerns and those of community pharmacies.

Federal Regulatory Updates

FDA Oncologic Advisory Committee Recommends Approval for Biosimilars to Two Oncology Agents

The FDA's Oncologic Advisory Committee on July 13 unanimously (16-0) recommended that the agency approve two biosimilar oncologic agents, trastuzumab (Herceptin; Genentech) and bevacizumab (Avastin; Roche). The Committee was asked to consider whether the totality of the evidence supports the approval of trastuzumab for use in metastatic breast cancer but not metastatic gastric cancer because the exclusivity does not end until October 20, 2017. Bevacizumab would be indicated for metastatic colorectal cancer, non-squamous non-small lung cancer, glioblastoma multiforme, metastatic renal cell carcinoma, and cervical cancer. Now, the FDA must consider approval of these agents for marketing.

FDA Calls for Demonstrations to Inform Flexibility of Medical Device Regulatory Process

The FDA is seeking to use an evidence-based approach to [spur innovation and increase the flexibility](#) of the regulatory process for medical devices. Through the Medical Device Innovation Consortium (MDIC), the FDA has funded the creation of the National Evaluation System for Health Technology Coordinating Center (NESTcc), which aims to use real-world evidence to inform pre- and post- marketing requirements for medical devices. On July 12, NESTcc announced a call for [Initial Demonstration Projects](#) to “develop, verify and operationalize methods of evidence generation and data use, demonstrate scalability across healthcare systems and device types and manufacturers and build out critical functions and processes for a sustainable NESTcc”. This call for demonstrations is due July 31, 2017; however, there will be additional calls for targeted demonstrations of medical devices for critical disease areas. In response to this call, AMCP is working to identify areas of need within the medical device portfolio and welcomes your feedback. Please send your feedback by July 31, 2017 to Tricia Lee Wilkins at tlwilkins@amcp.org.

Upcoming Regulatory Comment Periods

them and share your experiences on the value of managed care pharmacy.

CMS Medicare Program, CY2018 Updates to the Quality Payment Program

CMS is seeking comments to the proposed rule, "[Medicare Program, CY2018 Updates to the Quality Payment Program](#)". The rule addresses elements of MACRA not covered in the first year of the program, which suggested expansion during subsequent years including virtual groups, facility-based measurement, and improvement scoring. The proposed rule proposes several new improvement activities in the areas of achieving health equity, behavioral and mental health, population health, patient safety and practice assessment, and care coordination.

CMS Part B Physician Fee Schedule Seeks Input on Coding for Biosimilars, Reference Biologics

CMS on July 13 released its [calendar year 2018 Proposed Physician Fee Schedule](#) which includes a provision seeking input on the impact of its current policy to group biosimilars and reference biologics in the same J code. The proposed rule also seeks input on ways to generally streamline the Medicare Part B program to achieve better transparency, flexibility, program simplification, and administration. AMCP will examine the proposed rule and provide comments.

AMCP is seeking stakeholder feedback on the following proposed rules 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
CMS - Medicare Program; CY 2018 Updates to the Quality Payment Program	Aug. 14	Aug. 21
CMS - Calendar Year 2018 Proposed Physician Fee Schedule Rule	Aug. 24	Sept. 11
FDA - Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting	Sept. 11	Sept. 18

State Legislative Update

Eye on State Legislatures

Only six states are still in session: California, Ohio, Massachusetts, Michigan, New Jersey and Wisconsin.

Biosimilar and Interchangeable Biologic Products: Currently, only Michigan (HB 4472) has pending biosimilar legislation. The Michigan bill has not advanced from the committee of origin. The New York legislature has adjourned; however, Senate bill 4788 was passed by both chambers prior to adjournment. To date the NY Governor has not signed the bill.

State Legislative Tracking: Current state bills that AMCP is tracking may be accessed [here](#). AMCP's letters can be accessed at [Letters, Statements and Analysis](#).

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