



## In This Issue

- [Academy Holds Annual Legislative Days Event](#)
- [GOP House Efforts Continue to Repeal and Replace ACA](#)
- [Congressional Budget Office Releases Report on AHCA](#)
- [Pharmacy-Related Bills Reintroduced in 115th Congress](#)
- [CREATES and FAST ACTs Bills Expected Soon](#)
- [Senate Confirms HHS, CMS Heads](#)
- [AMCP Submits Comments on 2018 Draft Call Letter](#)
- [Upcoming Regulatory Comment Periods](#)
- [Upcoming Webinars](#)
- [Eye on State Legislatures](#)

## Academy Holds Annual Legislative Days Event

AMCP Leaders, Staff Urge Congress to Take Action on PIE; Tap Managed Care Pharmacy's Expertise in Designing and Managing Pharmacy Benefits

AMCP volunteer leaders and staff gathered in Washington, D.C., on March 6-8 for the Academy's annual Legislative Days event. In more than 50 Capitol Hill meetings, led by AMCP staff, Academy Board members and Committee Chairs (Public Policy and LRAC) discussed the need to codify into law a preapproval information exchange (PIE) safe harbor to share clinical and economic information on emerging therapies in advance of Food and Drug Administration approval.

Read AMCP's position on PIE [here](#).

AMCP members and staff explained that even though the FDA issued draft guidance in January that included an allowance for PIE, a more permanent, legislative solution is necessary to provide assurances that the correct procedure is incorporated into FDA laws.



The meetings focused on lawmakers who serve on key committees with responsibility for FDA policy, namely, the House Energy & Commerce Committee and the Senate Health, Education, Labor, and Pensions (HELP) Committee. Other meetings focused on Congressional Members' offices who attended AMCP sponsored House and Senate briefings in October 2016 on FDA communication issues and those Members who directly represent AMCP members.

*(From top left clockwise: Caroline Atwood, Brandon Cheslock, Rep. Gerry Connolly (D-VA), and Marissa Schlaifer; Denise Kehoe and Rep. Peter Roskam (R-IL); Atwood and Rep. Darrell Issa (R-CA), U.S. Capitol; Timothy Antonelli)*

## FEDERAL LEGISLATIVE UPDATE

### House GOP Continues Effort to Repeal and Replace ACA With the American Health Care Act (AHCA)

As AMCP members arrived in Washington on March 7 for Legislative Days, House Republicans released a health plan called the American Health Care Act (AHCA). On March 8, the House Energy and Commerce and Ways and Means Committees held mark-up hearings on the bill. The legislation focused mostly on changing certain Affordable Care Act subsidies to tax credits, scaling back Medicaid expansion, removing the individual mandate with a requirement to maintain continuous coverage, and reducing restrictions on the provision of health insurance.

AMCP did not take a position on the specific provisions in the AHCA during the Congressional meetings. However, AMCP did provide information to Members and their staff on our expertise in managing and developing the pharmacy benefit for health plans and government funded programs. AMCP advocated for a comprehensive prescription drug benefit for Americans that is implemented by pharmacists, physicians and nurses with expertise in this area, and should not contain overly prescriptive mandates. AMCP also emphasized that health care delivery models should focus on value-based programs that are designed to ensure that patients have access to appropriate treatment at affordable prices. Following the mark-up, both Committees voted along party lines to pass the legislation. (The nonpartisan Congressional Budget Office [CBO] had not released its report prior to the Committee votes.)

The AHCA is now before the Budget Committee. The Budget Committee now has the responsibility to review the language as part of the budget reconciliation process. Given concerns with the AHCA raised by a number of interest groups and Republican and Democratic Representatives, as well as members of the Senate, the bill is likely to undergo changes before it reaches the President's desk.

## Advocacy Tip

### Phone Contact Tips

1. Before you place a call, write down notes about the points you want to make. That way, you won't forget anything.
2. Be sure to let them know that you are a health care provider.
3. Legislators are often too busy to take phone calls, and rely on their staff to keep them informed. Ask for the staff person who covers your issue area.
4. If you request a return call, you will usually get one from the staff if you are a constituent.

Section by Section Summary prepared by House Ways and Means Committee staff can be found [here](#).

## **CBO Releases Analysis of Potential AHCA Impact**

Earlier this week, the CBO released its report on AHCA provisions adopted last week by two House committees. The CBO and staff of the Joint Committee on Taxation (JCT) estimate that enacting the legislation—which would repeal or modify many provisions of the ACA—would reduce federal deficits by \$337 billion over the coming decade. The report also estimates that by next year, 14 million more people would be uninsured under the AHCA than under current law. The number of uninsured people would rise to 21 million in 2020 and to 24 million in 2026 after additional changes take effect to subsidies for insurance purchased in the nongroup market and Medicaid program.

## **Pharmacy Bills Reintroduced in 115th Congress**

Several pharmacy related bills from previous sessions of Congress have been reintroduced. These include: Pharmacy & Medically Underserved Areas Enhancement Act (H.R. 592 and S. 109), Medicare Prescription Drug Price Negotiation Act (H.R. 242 and S. 41), Prescription Drug Transparency Act (H.R. 1316) and the Affordable and Safe Prescription Drug Importation Act (S. 469).

## **CREATES and FAST Acts Bills Expected Soon**

Other bills pertinent to managed care pharmacy are expected soon. These include The Creating and Restoring Equal Access to Equivalent Samples (“CREATES”) Act and the Fair Access for Safe and Timely (“FAST”) Generics Act. The legislation is designed to address common abuses of both Risk Evaluation and Mitigation Strategies (REMS) and non-REMS restricted access programs, while maintaining necessary safety protections for patient safety and public health.

## **Federal Regulatory Updates**

### **Senate Confirms HHS, CMS Heads; Trump Administration Nominates FDA Commissioner**

The Senate confirmed Rep. Tom Price (R-Ga.) on Feb. 9 as Secretary of the Department of Health and Human Services (HHS). Secretary Price, an orthopedic surgeon, will lead the implementation process to replace the ACA. On March 14, the Senate also confirmed Seema Verma, president and founder of SVC, Inc. as Administrator for the Centers for Medicare and Medicaid Services (CMS). Meanwhile, President Trump has nominated Scott Gottlieb, a physician who supports streamlined regulations, as Commissioner of the Food and Drug Administration. Gottlieb’s confirmation process is expected to take at least six to eight weeks, due to various clearances and financial reporting required by the Senate and the current backlog of positions under consideration.

### **AMCP Submits Comments on 2018 Draft Call Letter**

AMCP submitted [comments](#) this month on CMS’s [2018 Draft Call Letter](#). AMCP focused on four areas: (1) Biosimilars, (2) Tiering Exceptions, (3) Star Ratings & Display Measures, and (4) Follow-Up from 2017 Final Call Letter. AMCP has prepared a [detailed summary](#) of key AMCP issues and other payment methodology and policy provisions of interest to managed care pharmacy. Overall the Draft Call Letter,

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released last month, did not contain any major changes that were of serious concern to managed care pharmacy; although there were some issues that AMCP sought member feedback on. AMCP held a Feb. 24 [webinar](#) to review the issues and solicit member feedback. The 2018 Final Call Letter will be released on April 3. AMCP will review the 2018 Final Call Letter and provide a side-by-side comparison of the key AMCP issues and other payment methodology and policy provisions contained in the Draft Call Letter versus the Final Call Letter.

## Upcoming Regulatory Comment Periods

Topics	Feedback to AMCP Due	Comments Due
FDA: <a href="#">Medical Product Communications That Are Consistent With the FDA-Required Labeling — Q&amp;A</a>	April 10	April 19
FDA: <a href="#">Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Q&amp;A</a>	April 10	April 19
FDA: <a href="#">Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products</a>	April 10	April 19

AMCP is seeking stakeholder feedback on the above proposed rules that are open for comment. Please provide feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at [ssaha@amcp.org](mailto: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 [here](#).

## Upcoming Webinars

To register for upcoming webinars, please visit [www.amcp.org/calendar/](http://www.amcp.org/calendar/)

### ***Driving Value and Outcomes in Oncology - Proceedings from the AMCP Partnership Forum***

Wednesday, March 22, 2-3pm, ET

## State Legislative Update

### Eye on State Legislatures

Three states have already completed their legislative agenda for 2017 and adjourned: Virginia (2/25), Wyoming (3/3), and Utah (3/9). The remaining states are currently in session with the exception of Louisiana which will begin in early April.

***Biosimilar and Interchangeable Biologic Products:*** Currently, 13 states (AK, AL, AR, CT, KS, MD, MN, NE, NM, NY, NV, SC, and VT) have pending biosimilar legislation. Montana became the first state to enact biosimilar legislation in 2017 and Iowa recently sent its bill to its governor. These bills have language similar to the bills we saw in 2016 concerning the post dispensing notification requirements for the pharmacist. However, they generally permit interchangeable biological substitution by a pharmacist when not expressly prohibited by a prescribing physician. We are also seeing inaccurate references to the "Orange Book" as a source for interchangeable biologics that are therapeutically similar.

[Map of State Biosimilars Bills](#)

**Medication Synchronization:** Eight states (FL, GA, MD, MS, NH, OK, TN, and TX) have pending legislation that would mandate coverage for medication synchronization if a pharmacy or prescriber and a patient believe it is in the patient's best interest. A benefit is covered only if it meets the criteria specified under the terms of the patient's health benefit policy not because a prescriber or patient says it is in the patient's best interest. AMCP opposes legislation that mandates medication synchronization and requires a specific government framework as an unnecessary barrier to best practices underway.

**Step Therapy:** Seven states (HI, KS, OH, OR, RI, WA and WV) have pending legislation that would mandate requirements for step therapy programs used by health insurers. AMCP is concerned that mandated requirements for a medical exceptions process and mandated time lines for responses will usurp health insurers' ability to manage medication benefits for the patient population served. AMCP opposes those restrictive provisions.

#### [State Legislative Tracking](#)

AMCP's letters can be accessed here: [Letters, Statements and Analysis](#).

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