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Pharmaceutical Information Exchange (PIE) Act Introduced in Congress

H.R. 2026 incorporates multi-stakeholder consensus recommendations developed during the September 2016 AMCP partnership forum.

On April 6, Representative Brett Guthrie of Kentucky introduced the Pharmaceutical Information Exchange (PIE) Act of 2017 ([H.R.2026](#)). The bill incorporates the multi-stakeholder [consensus recommendations](#) developed during the September 2016 AMCP partnership forum to allow biopharmaceutical manufacturers to proactively share clinical and economic information with population health decision makers on emerging therapies in advance of Food and Drug Administration (FDA) approval, an area that is significantly restricted by current federal laws and FDA regulations. AMCP issued a [press release](#) commending Representative Guthrie for his leadership in championing this very important issue. This is a major win for AMCP and a very exciting time for us as we continue to champion issues for our members with Congress. We will be working diligently over the next few months to have the bill signed into law and look forward to your continued support of this major initiative.

Federal Legislative Update

GOP Efforts to Repeal and Replace the Affordable Care Act (ACA) Are Ongoing

Republicans vow to continue efforts to repeal and replace the

Advocacy Tip

Advocacy creates its own positive publicity. Speaking out on behalf of an issue, conducting various kinds of

Affordable Care Act (ACA) despite their initial setback. Last month the House Energy and Commerce, Ways and Means, and Budget committees passed legislative language to repeal and replace the ACA. But House Speaker Paul Ryan (R-WI) pulled the language from consideration on the House floor at the last minute when it appeared there were not enough votes available to ensure passage. The legislative language mainly focused on changing certain 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. GOP lawmakers had hoped the legislation would become part of the final budget reconciliation package. Since the legislation was pulled, GOP leaders and the White House announced efforts are still under consideration to repeal and replace the ACA. AMCP will monitor developments and report on proposals pertinent to managed care pharmacy.

Bipartisan Lawmakers Introduce Fair Access for Safe and Timely (“FAST”) Generics Act of 2017

On April 7, Reps. David McKinley (R-WV) and Peter Welch (D-VT) introduced the bipartisan FAST Generics Act (H.R. 2051). The legislation is designed to increase competition for prescription drugs and lower the cost of treatments by increasing access to samples of approved drugs and licensed biological products to enable developers to develop and test new products. The Congressional Budget Office (CBO) has estimated that similar legislation would save the government more than \$2 billion in direct savings over 10 years. AMCP joined 17 other health care organizations and consumer groups in a [letter](#) supporting the legislation.

Federal Regulatory Update

CMS Releases 2018 Final Call Letter; Updates Align With AMCP’s Feedback

On April 3, the Centers for Medicare and Medicaid Services (CMS) released the [2018 Final Call Letter](#). Overall, the Final Call Letter does not contain any major changes that are of serious concern to managed care pharmacy. AMCP is pleased that CMS made several changes to the Final Call Letter that took into consideration comments by AMCP on the Draft Call Letter. This includes:

- Medication Reconciliation Post Discharge (Part C) – CMS is withdrawing its proposal to weight this measure as an intermediate outcome measure and increase the weight from 1 to 3 beginning with the 2019 Star Ratings. Medication Reconciliation Post Discharge will be weighted 1 as a process measure for the 2019 Star Ratings. AMCP had advocated in comments to CMS that the proposed increase in weighting from 1 to 3 may be too aggressive and recommended that CMS reconsider the increase in weighting.
- Opioid Hard Edits – CMS is withdrawing the requirement that Part D sponsors incorporate hard opioid safety edits at the 200-mg morphine equivalent dose (MED) for MA and Part D plans. CMS will continue to expect plans to implement a soft opioid safety edit at a minimum threshold of greater than 90-mg MED.
- Patient Safety Reports – CMS is withdrawing its proposal to provide Patient Safety Reports quarterly versus monthly moving forward, and they will continue to be provided monthly. AMCP had advocated for CMS to carefully examine the impact and unintended consequences of less frequent reporting on smaller to mid-size plans.

public events, and getting coverage in the media all add to public awareness and understanding of what you're advocating for. Legislative advocacy can also gain you powerful allies. Working with and getting to know lawmakers and familiarizing them with your concerns can make them advocates for your cause as well, and will increase the likelihood that they'll listen to you on other issues. Establishing personal relationships with legislators gives you credibility with other lawmakers and with the community at large.

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AMCP is analyzing the Final Call Letter and preparing a detailed 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. To receive a copy of AMCP's summary of the Final Call Letter, please sign-up for the Medicare Part D Policy Issue Email List by visiting <http://www.amcp.org/List/>.

In addition, in its ongoing commitment to maintaining benefit flexibility and efficiency through the MA and Part D programs, CMS has issued a request for information (RFI) and invites stakeholders to provide ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. CMS is seeking clear and concise proposals that include data and specific examples that could be implemented within the law to increase benefit flexibility, innovation, and more affordable plan choices for beneficiaries. **The RFI is open through April 24, 2017** and AMCP will be working to provide feedback to CMS on several areas of the Part D program such as MTM, quality, formulary design and utilization management, and others. You may also provide ideas and feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by Friday, April 21st for consideration and inclusion in AMCP's comment letter to CMS.

CMS Memorandum Provides States More Flexibility to Perform Formulary and Cost Sharing Reviews for Certain Qualified Health Plans in Federally Facilitated Marketplace

CMS's Center for Consumer Information and Insurance Oversight issued an April 13 [memorandum](#) that will allow states to perform formulary and cost sharing reviews for certain qualified health plans in the federally facilitated marketplace. The memorandum allows for state review of formulary and cost sharing in states where plans perform plan management functions. CMS will continue to conduct reviews for plans in states in the federally-facilitated marketplace that do not perform plan management. Provisions in the memorandum also allow for states to assume greater responsibility for ensuring appropriate licensure of plans, network adequacy and service provisions.

The changes were made in response to authority granted to agencies by President Trump's Executive Order 13765, giving flexibility in the implementation of provisions of the health insurance marketplaces enacted under the Affordable Care Act. The changes supersede certain provisions contained in the [Final 2018 Letter to Issuers in the Federally-Facilitated Marketplaces](#) released in February 2017.

The memorandum does not include a specific opportunity to respond or comment. The change is a reversal of policy implemented by the Obama Administration to review formularies and cost sharing for all plans, including those in the federally facilitated marketplaces. The Obama Administration conducted these reviews after some advocacy groups cited situations in certain states where marketplace plans discriminated against individuals with certain high cost chronic conditions by placing certain medications on higher cost sharing tiers or otherwise improperly restricted access to certain medications.

FDA to Hold Public Workshop, Request Comments on Training Health Care Providers on Pain Management and Safe Use of Opioids

The FDA will hold a public workshop **May 9-10** on training health care providers on the safe use of opioids. The event also will provide FDA with input on challenges associated with federal efforts to support

training and management efforts. FDA has described three main objectives for participants in this workshop:

- Discuss the role of health care provider training within the context of ongoing activities to improve management and the safe use of opioids;
- Comment on how best to provide health care providers appropriate training in pain management and safe use of opioids; and
- Discuss challenges and issues with possible changes to federal efforts to educate health care providers on pain management and the safe use of opioids.

The May 9-10 workshop will run from 8:30 a.m. to 5 p.m. at the Sheraton Silver Spring Hotel. Information on the workshop is available in the [Federal Register](#) docket published April 18. Public comments will be accepted until July 10. If you would like to submit comments for consideration by AMCP for its comments, please email ssaha@amcp.org by June 21.

FDA Oncologic Drugs Advisory Committee Meeting to Consider Biosimilar Application for Epogen/Procrit

The FDA this week announced an [Oncologic Drugs Advisory Committee Meeting](#) scheduled for **May 25** to consider a biosimilar application submitted by Hospira, Inc. for a biosimilar of Epogen/Procrit (epoetin alpha), marketed as epoetin alpha by Amgen, Inc.

The meeting will be held at FDA's White Oak Campus in Silver Spring, Maryland. The public will have a limited opportunity to provide comments upon request between 11:15 a.m.-12:15 p.m. Requests to present public comments must be submitted to FDA by May 2. AMCP has submitted a request to speak regarding its support for a robust biosimilars pathway in the United States; concerns on the final biosimilar and biologic naming convention that includes a four letter, randomized suffix for nearly all biologics and biosimilars; perspectives on the interchangeability draft guidance; and efforts to educate pharmacists, physicians, and others through the online [Biosimilars Resource Center](#).

Comments submitted to the docket by May 10 will be provided to the committee. The docket for all comments closes on May 23. AMCP will submit comments by the May 10 deadline. If you would like to submit comments for consideration, please email ssaha@amcp.org by Wednesday, May 3.

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.

Topic	Feedback to AMCP	Comments Due
CMS – Request for Information on Medicare Advantage and Part D Programs	April 21	April 24
FDA – Comments to Oncologic Drugs Advisory Committee to	May 3	May 10 for submissions to committee members.

Consider Biosimilar to Epogen/Procrit		Docket will remain open until May 23.
FDA – Comments on Draft Biosimilars Interchangeability Guidance	May 12	May 19
FDA – Comments on Training Health Care Providers on Pain Management and Safe use of Opioids	June 21	July 10

STATE REGULATORY UPDATE

Proposed Rule in Washington State Would Require Automatic Substitution of Generics and Interchangeable Biologic Products in Medicaid Program

A [proposed rule](#) issued March 29 by the Washington State Department of Labor & Industries would update the Washington Prescription Drug Program (WPDP) for Medicaid and other low income beneficiaries by requiring substitution of generic products or interchangeable biologic products when available starting July 18. Comments on the proposed rule are due by May 15. AMCP will support the automatic substitution provision.

State Legislative Update

Eye on State Legislatures

Eleven states have completed their legislative sessions for 2017 and adjourned: Georgia, Idaho, Kentucky, Maryland, Mississippi, New Mexico, South Dakota, Utah, Virginia, West Virginia, and Wyoming.

Biosimilar and Interchangeable Biologic Products: Currently, 9 states (AK, AL, AR, CT, MN, NE, NY, NV, and VT) have pending biosimilar legislation. Maryland and South Carolina legislation are pending on their respective Governor's desks. Four states (Kansas, Montana, New Mexico, and Iowa) enacted biosimilar legislation in 2017. Legislation failed to pass in Wyoming. A detailed map of current legislative activity can be found [here](#).

[AMCP Letters, Statements and Analysis](#)

[State Legislative Tracking](#)

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