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PIE Act (H.R. 2026) Awaits Action by Full House Energy & Commerce Committee

AMCP Ramps Up Grassroots Efforts to Encourage Passage of Legislation

AMCP continues to champion passage of the Pharmaceutical Information Exchange Act (PIE Act) by increasing its grassroots efforts and engaging stakeholders. The PIE Act (H.R. 2026) is set for a vote soon by the Full House Energy & Commerce Committee following last month's approval by the E&C Subcommittee on Health.

Working toward a successful vote, AMCP has activated its grassroots alert program to enlist AMCP members that live in key member districts. AMCP members have responded by reaching out to their lawmakers on the E&C Committee to describe the benefits of the legislation and encourage its passage. In addition, AMCP CEO Susan A. Cantrell, RPh, CAE, made the case for H.R. 2026 in an Op-Ed in *The Hill* and Soumi Saha, AMCP Director of Pharmacy and Regulatory Affairs released a video encouraging support.

Student pharmacists also are getting involved. On Jan. 25, AMCP hosted its first-ever Student Chapter Challenge Kick-Off! The Kick-Off event provided an overview of H.R. 2026 and the Chapter Challenge. The AMCP Chapter Challenge encourages student pharmacists from across the country to get involved with AMCP's strategic policy areas. The Challenge will keep student members informed and knowledgeable on relevant managed care pharmacy issues that may impact the future of the profession. Eligible AMCP Chapters responded to the Challenge by sending support letters as well as tweeting #PIEAct to their U.S. Representatives.

AMCP has been using all of its social media channels to inform and encourage members to voice their support. Use the hashtag #PIEAct.

Federal Legislative Update

AMCP Signs Joint Letter of Support for CREATES Act (H.R. 2212 and S. 974)

AMCP supports the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, a bipartisan bill designed to increase competition and patient access to safe and affordable generic and biosimilar medicines by preventing certain brand companies from using tactics to delay competition from generic drugs that are not as costly. CREATES is supported by a diverse group of stakeholders including AARP, the Association for Accessible Medicines, Patients for Affordable Drugs, and Public Citizen. Earlier this month, AMCP joined those 44 stakeholders in a letter to House and Senate leadership to support passage. Although the Act was given serious consideration in recent Congressional efforts to agree on a long term government funding bill — primarily because it is estimated to save more than $3 billion — it was not included in the final bill. However, the Act maintains bipartisan support in the House and Senate so stakeholders will continue to look for other opportunities to support passage.

Bipartisan Budget Act of 2018 Has Provisions for Closing Part D Coverage Gap, Including Biosimilars

The "Bipartisan Budget Act of 2018," signed into law on Feb. 9, includes several health care provisions that impact AMCP members. One such provision is the accelerated closure of the Medicare Part D coverage gap discount, known as the donut hole. Under the new provision, the beneficiary contribution in the coverage gap is closed in 2019 versus 2020. Beneficiaries are responsible for 25% of costs, while brand manufacturers will pay 70% and Part D plans will pay 5% of costs. This provision has been questioned by the pharmaceutical industry, which seeks to repeal it when Congress negotiates its omnibus appropriations bill for the remainder of 2018.

In addition, the Budget Act adds biosimilars as eligible for the coverage gap discounts by pharmaceutical companies. AMCP was pleased to see the inclusion of this provision because it has been important to the strategy of biosimilar adoption. Another provision eliminates biosimilars from a 304B payment incentive for new technologies that reimburses at average sales price (ASP) plus 6%. This provision will result in all biosimilars being paid at ASP minus 22% which may serve as a disincentive for prescribing. AMCP will be closely monitoring the implementation or potential changes to these provisions and advocate when necessary.

White House's 2019 Proposed Budget Includes Provisions to Curb Drug Prices, Opioid Epidemic

The Trump Administration and a Council of Economic Advisors report,

Advocacy Tip

Prior to visiting a legislator's office, make sure you understand and can clearly articulate what your "ask" is of the office. The "ask" is an action you want to see your legislator take, and can be to sponsor, support or oppose legislation. Knowing your "ask" will also help you prepare points and counterpoints to use during your visit.

released Feb. 12, outlined proposals to reduce prescription drug spending in the U.S. and to curb the opioid epidemic. One key proposal would streamline FDA approval process to encourage availability of more generics and streamline the regulatory process for biosimilars. Other proposals include a variety of suggestions for changes to federal government prescription drug programs, including Medicare Part D, Medicare Part B, and Medicaid. Under these proposals:

- Medicare Part D would allow plans more flexibility in selecting medications for formulary coverage, such as eliminating requirements for coverage of 2 products in every category and class; allowing plans more flexibility in selecting medications for formulary coverage; requiring plans to share point of sale rebates with consumers; and implementing spending caps under Medicare Part D.
- Medicare Part B would shift coverage to Medicare Part D and modify the average sales price methodology to encourage the use of cost effective medications.
- Medicaid would allow 5 states to test medication benefit designs currently used in the private sector, including formulary development and additional utilization management. Massachusetts Medicaid has already submitted a proposal for a similar waiver to CMS.

Congress must approve some of the recommended changes, such as shifting Part B drug coverage to Part D, but the Administration has the authority to implement some changes to Part D plan responsibilities, Part B pricing formulas and Medicaid waivers. Read more.

AMCP Offers Recommendations on Ways FDA Could Address Opioid Epidemic

The FDA should promote the availability of state prescription drug monitoring programs by managed care organizations as a way to help curb the opioid epidemic. That was one suggestion offered by Soumi Saha, AMCP's Director of Regulatory and Pharmacy Affairs, at a Jan. 30th FDA public hearing, "Opioid Policy Steering Committee: Prescribing Intervention—Exploring A Strategy for Implementation."

The primary purpose of the hearing was to gain stakeholder input on how the FDA would use its authority under the Risk Evaluation and Mitigation Strategy (REMS) to improve the safety of opioid use by curbing overprescribing and limiting misuse and abuse of opioids.

AMCP's recommendations focused on urging the FDA to consider the body of research and evidence about opioids prior to considering any regulations or policies. Specifically, AMCP recommended the use of real-world evidence in clinical trial design and encouraged sharing of this information with plans to design effective benefits; greater use of post-marketing surveillance and the unintended consequences of designating novel opioids in the breakthrough category. AMCP emphasized the need for REMS to be integrated into workflow

systems for pharmacists and physicians. AMCP also emphasized areas where FDA and stakeholders could collaborate with others to improve opioid prescribing practices and reduce misuse or abuse, namely:

- Work with the Centers for Disease Control to promote adoption of a recent guideline on opioid prescribing;
- Promote use of short course unit dose packaging and provide labeling information to promote appropriate opioid use;
- Promote electronic prescribing of controlled substances; and,
- Promote the availability of state prescription drug monitoring programs by managed care organizations; and
- Ensure that health care providers, including pharmacists, have access to the comprehensive medical records of individuals who are under treatment for abuse or addiction or have been treated in the past.

To download AMCP's comments, visit here. The FDA is accepting written comments through March 16. To learn more about the meeting or watch a live or archived telecast, visit here.

Regulatory Update

Actions on Opioid Epidemic: SAMHSA Releases Final Part 2 Rule and Holds Public Listening Session

The Substance Abuse and Mental Health Services Administration (SAMHSA) held a public listening session on Jan. 31 for 42 CFR Part 2 as required under the 21st Century Cures Act. 42 CFR Part 2 restricts the disclosure and use of alcohol and substance use disorder records. The listening session provided an opportunity for input concerning the effect of 42 CFR Part 2 on patient care, health outcomes, and patient privacy as well as potential regulatory changes and future sub-regulatory guidance. Deadline for written comments is Feb. 28. For more information, visit here.

Upcoming Comment Periods

AMCP is seeking stakeholder feedback on the following proposals that are open for comment. Please respond via email to Soumi Saha, Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by the dates listed for incorporation into AMCP's comments. All of AMCP's final comment letters are available on the AMCP website here.

Topic	***Feedback Due to AMCP***	***Comments Due***
OIG – Solicitation of New Safe Harbors	Feb. 19	Feb. 26
SAMHSA – Confidentiality of Substance Use Disorder Patient Records	Feb. 21	Feb. 28
CMS – CY2019 Call Letter (released Feb. 1)	Feb. 28	March 5
FDA – Opioid Policy & Strategy	Feb. 26	March 16

Eye on States

State Legislative Activity

State legislatures are in full swing with 45 States and the District of Columbia in session. The pace of legislative activity has begun to increase, with 10 states scheduled to adjourn by the end of March. Areas of interest to AMCP include:

Biosimilars: States continue to consider legislation on biosimilars and interchangeable biosimilars, with Wyoming becoming the latest to introduce legislation. Also on Feb. 7th, South Dakota Gov. Dennis Daugaard signed Senate Bill 75 – dispensing of biological products – into law. You can follow biosimilar legislative activity here.

Opioids: With the signing of an executive order last year by Missouri Gov. Eric Greitens, all 50 states now have the authority to operate a Prescription Drug Monitoring Program (PDMP) through legislation or executive order. Legislation thus far this year has focused on setting dosage or day limits for initial prescriptions of opioids, creating a tax on opioid prescriptions sold in the state, mandating who is required to register and use the PDMP when prescribing or dispensing opioids, and requiring coverage or prohibiting step-therapy requirements on abuse-deterrent formulations (ADF) of opioids. Since the start of the 2018 legislative session, 17 states have proposed legislation to set or alter initial prescription limits. Nine states have also introduced legislation to impose taxes on prescriptions of opioids to be paid by drug manufacturers. There are 11 states this year which have introduced legislation changing requirements on who is required to access and report to the state's PDMP when prescribing and dispensing opioids. Seven states also have proposed legislation to increase access to opioid antagonists

Medication Therapy Management: Last year, AMCP urged Tennessee Gov. Bill Haslam to sign H.R. 628, which established a two-year pilot program for pharmacist provided MTM for patients in the TennCare program. In addition, AMCP activated a grassroots advocacy campaign using its new grassroots vendor, Voter Voice. Members responded by sending letters to Gov. Haslam, who signed the bill. On Feb. 5, the program received approval from the Department of Health and Human Services. Under the program, pharmacists will work with Medicaid beneficiaries to ensure medications are appropriate for their conditions, safe given their co-morbidities and other medications being used, and are taken as prescribed.

Upcoming AMCP Webinar

Implications for Managed Care Pharmacy from 2019 Part D Call Letter, Star Ratings

Tuesday, Feb. 27, 2pm EST
Registration

Join AMCP for a first look at the provisions contained in the draft 2019 CMS Medicare Part D Call Letter that was released by CMS on Feb. 1.

This webinar will deep dive the policy provisions of importance to managed care pharmacy including medication therapy management, opioid management, specialty pharmacy, and Star Ratings for 2019 and beyond. Be one of the first to know and help inform AMCP's comments to CMS!

Speakers:

- *Babette Edgar, PharmD, MBA, FAMCP*
  AMCP Immediate Past President, 2016-2017
  Principal, BluePeak Advisors
- *Mitzi Wasik, PharmD, BCPS, FAMCP, FCCP*
  AMCP President Elect, 2018-2019
  Senior Director of Patient Safety and Quality, Aetna.

Archived Webinar: **AMCP Policy & Advocacy Focus Areas in 2018, held Jan. 30.** A recording is available for free to members here.

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