Tell Congress to Pass the PIE Act!

Pre-approval information exchange (PIE) is a crucial, bipartisan policy that will get new, potentially lifesaving treatments to patients faster. PIE allows pharmaceutical manufacturers to proactively share certain economic and scientific data about emerging medications and devices with health payers ahead of Food & Drug Administration (FDA) approval. The PIE Act, which passed the House in June as Sec. 810 of the Food & Drug Amendments of 2022 (H.R. 7667), would expedite patient access to lifesaving treatments by increasing the efficiency of the drug coverage process. As the input of managed care pharmacy practitioners is pivotal for making this bill a reality, AMCP is asking our members to join the effort to pass the PIE Act in the upcoming post-election session. By participating in this grassroots campaign, AMCP members can directly contact their Senators and Representatives in Congress about the urgent need to pass this critical legislation.

JOIN THE PIE CAMPAIGN

Member Benefit! Regulatory NewsBREAKS

Last month, AMCP unveiled the Regulatory NewsBREAK as an additional member benefit. Each NewsBREAK is delivered to member inboxes as they are released in response to newly enacted regulations or newly issued sub-regulatory guidance. The most recent Regulatory NewsBREAKS highlight a Sept. 22 announcement from the Centers for Medicare and Medicaid Services (CMS) regarding a 5-year increase in Medicare Part B payments for certain biosimilar products, as well as a Sept. 28 announcement from CMS regarding Part D guidance for the implementation of several Inflation Reduction Act provisions.

ACCESS TODAY

Eye On Washington

Managed Care Practitioners Receive Legislative, Regulatory, and Midterm Updates at AMCP Nexus 2022

Advocacy Tip

Stay up-to-date: Read AMCP's Letters, Statements and Analysis on all legislation and

On Oct. 11, AMCP members from across the country convened at National Harbor, MD for the annual four-day Nexus meeting. Throughout the week, members of AMCP's Policy & Government Relations team presented updates on the federal and state regulation and legislation that impacts the work of managed care pharmacists nationwide. On Oct. 12, AMCP's Vice President of Policy & Government Relations, Jennifer Mathieu, and Director of Regulatory Affairs, Geni Tunstall, presented their Federal Legislative and Regulatory Update in front of a packed crowd of managed care pharmacy professionals. The following day, Director of Government Relations, Adam Colborn, and Manager of Policy & Government Relations, Tom Casey, provided a legislative and regulatory update centered on policy developments in all 50 state legislatures. Andrew McKechnie and Alix Burns, lobbyists with the firm Tiber Creek Group, also offered their insight into the upcoming midterm elections during a session on Oct. 13. The Federal and State Legislative and Regulatory Update sessions will be available to view for continuing pharmacy education credit on AMCP Learn within the coming weeks.

Read a full write-up of the Federal Legislative and Regulatory Update.

AMCP CEO Susan Cantrell Pens Op-Ed in Support of PIE Legislation

In support of AMCP's top federal priority, AMCP CEO Susan A. Cantrell, MHL, RPh, CAE, published an op-ed in *Health Affairs* detailing the benefits of the Pre-approval Information Exchange (PIE) Act. Titled "A Simple Way To Safely Accelerate Patient Access To New Therapies," the Oct. 7 piece describes the meticulous nature of the current FDA approval process for new therapies. "Think of the current system as a relay race where payers are only handed the baton after the FDA has completed its leg of a long and arduous race," Cantrell writes. "There is a faster way." She goes on to introduce PIE as a tool for accelerating the new drug approval process, expediting patient access to medications, and leveling the playing field for the roughly 100 million Americans who rely on Medicare and Medicaid. Cantrell explains that current PIE legislation allows these public programs to begin their new drug reviews earlier, which more efficiently meets the needs of their growing number of beneficiaries.

Read the full article.

AMCP Responds to NPRM on Nondiscrimination in Health Programs and Activities

On August 4, the Department of Health and Human Services released a Notice of Proposed Rulemaking (NPRM) on Nondiscrimination in Health Programs and Activities. With a guiding strategic priority of addressing health care disparities and the input of several AMCP members, AMCP submitted comments on Sept. 29 which applaud the administration's goal of ensuring that everyone, regardless of their race, color, national origin, sex, age, or disability, has access to quality health care coverage without being subject to discrimination. AMCP's comments also support the NPRM's proposals to prohibit discrimination on the basis of sex, along with the proposed provisions which would reduce language barriers in accessing health care.

regulation impacting managed care pharmacy.

View AMCP's comment letter.

FDA Awards $1.3 Million Grant to BBCIC

On Oct. 3, the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) announced that it received a major grant from the FDA in support of biosimilars research. The $1.3 million grant provides funding over two years for a new BBCIC study focused on increasing the efficiency of biosimilar drug development and review. "I'm thrilled the FDA has selected our study for funding, as it will have important benefits for the research community at-large, providing analytical tools for tests of interchangeability and other regulatory questions," states Cate Lockhart, executive director of the BBCIC. AMCP established the BBCIC in 2015 in response to the anticipated need for evidence generation in the rapidly evolving biosimilar space. The BBCIC currently stands as the only research network dedicated to the post-marketing assessment of biosimilars.

Read AMCP's press release.