



## Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

JANUARY 2023

### The PIE Act of 2022 Becomes Law

On Dec. 29, President Biden signed the Pre-approval Information Exchange (PIE) Act into law as part of the Consolidated Appropriations Act, 2023 (H.R. 2617). This bipartisan legislation strengthens proactive information-sharing on new treatments between drug manufacturers and health plans. With PIE, payers can conduct their review of critical treatments concurrently with the Food & Drug Administration's (FDA) review, which will help expedite patients' access to treatments. AMCP especially thanks Energy & Commerce Health subcommittee leaders Representatives Brett Guthrie (R-KY) and Anna Eshoo (D-CA), as well as original co-sponsors Representatives Scott Peters (D-CA), Morgan Griffith (R-VA), Doris Matsui (D-CA), and Michael Burgess (R-TX), for their support in advancing this critical legislation. The passage of the PIE Act caps off six years of lobbying efforts by AMCP and its members, who traveled to Washington D.C. for AMCP's Legislative Days and advocated for the importance of PIE in the managed care pharmacy industry.

[Read AMCP's press release applauding the passage of the PIE Act.](#)

### Member Benefit! Stay Up to Date on IRA Guidance with Regulatory NewsBREAKs

Starting Jan. 1, several key health care provisions of the Inflation Reduction Act (IRA), such as the elimination of vaccine cost-sharing and a \$35 per-month cap on insulin prices for Medicare Part D beneficiaries, took effect. With several other important IRA provisions, such as the negotiation of prices for certain prescription drugs under Part D, set to follow suit in the coming months and years, you may be wondering how you could possibly keep track of the influx of IRA guidance from the Centers for Medicare and Medicaid Services (CMS). Luckily, AMCP releases Regulatory NewsBREAKs directly to your inbox in response to the latest regulatory guidance from CMS and other federal agencies. Check out the latest NewsBREAK for more information on the timeline for implementation of the IRA's drug price negotiation provision.

[ACCESS TODAY](#)

## Eye On Washington

### Media Coverage Captures Its Own Piece of the PIE

The passage of the PIE Act in December generated media buzz across the country. Several major outlets reached out to AMCP and its staff for comments on the development of PIE as a legislative priority, the challenges faced in passing both chambers of Congress, and the outlook for the future following PIE's passage. A Dec. 28 article from Pink Sheet highlights the long legislative journey of the PIE Act, which was first introduced in 2016 as a way of clarifying

### Advocacy Tip

Stay up-to-date: Read AMCP's [Letters, Statements and Analysis](#) on all legislation and regulation impacting managed care pharmacy.

the practice of pre-approval information exchange between drug manufacturers and payers. AMCP CEO Susan Cantrell also touched on PIE's impact on the health care landscape in a Jan. 4 article from Managed Healthcare Executive. "[PIE] doesn't fundamentally change the nature of the decision-making process for payers," Cantrell stated. "Rather, it safely accelerates patient access to covered medicines by enabling the payer's review to run in parallel with the FDA's."

[Access additional coverage on the PIE Act's passage.](#)

## Reimbursement for PDTs Could Increase Access to Emerging Treatments

Prescription Digital Therapeutics (PDTs) are FDA-cleared software-based therapies that deliver a clinical benefit to patients via a product, device, app, or other technology. However, these cost-effective treatments currently do not fit under the coverage categories defined by Medicare and Medicaid, thus excluding the nation's most vulnerable beneficiaries from access. On Dec. 20, AMCP's VP of Policy & Government Relations, Jennifer Mathieu, spoke with Mobi Health News about the most recent legislative effort to expand access to PDTs, the Access to Prescription Digital Therapeutics Act of 2022 (S 3791/H.R. 7051). Educating lawmakers about PDTs has become a primary obstacle for this effort, as Mathieu explains that "[AMCP's] biggest role throughout 2022 has been to educate members of Congress. Once we've helped them understand exactly what it is and how it benefits patients, we've had a very positive response to the bill." While the bill was not passed by the 117th Congress in 2022, AMCP intends to continue its education efforts on PDTs with Members of the 118th Congress.

[Read the full article.](#)

## Registration is Now Open for AMCP 2023 in San Antonio

Are you a managed care pharmacy practitioner looking for continuing education credit, networking opportunities, or updates on the newest products to improve patient outcomes and your job performance? Then AMCP 2023 is the place for you! Registration is now open for AMCP's annual conference, which will be hosted from March 21-24 at the Henry B. Gonzales Convention Center in San Antonio, Texas. Staff members from AMCP's Policy & Government Relations team will present a Federal Legislative & Regulatory Update, as well as a State Legislative & Regulatory Update, during the morning education sessions on March 22 and March 23, respectively. Advanced registration for the conference will remain open until Feb. 22, while Late Advanced/On-Site Registration will run from Feb. 23–March 24.

[Register now.](#)

