

# Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

MAY 2022

# PIE Act Included in the Food and Drug Amendments of 2022

On May 11, the House Energy and Commerce Subcommittee on Health held a markup to consider legislation reauthorizing the FDA's user fee programs, known as the Food and Drug Amendments (FDA) of 2022. The Preapproval Information Exchange (PIE) Act was included as Sec. 809 of the FDA of 2022, along with provisions authorizing ARPA-H, promoting competition for generic drugs, and increasing diversity in clinical trials. Ranking Member Brett Guthrie (R-KY-02) reiterated his support for the PIE Act during his opening remarks, stating that "patients would ultimately be able to access breakthrough therapies more quickly once these products are approved by the FDA." The FDA Act will now move to the full Energy and Commerce Committee, with a markup on May 18.

Learn more about the PIE Act.

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## New Member Benefit! Interactive State Policy Map

We are happy to announce the launch of the <u>interactive state policy map</u> as a new members-only benefit. With the ability to filter by state and issue area, you can now easily view state-level legislation that AMCP is tracking and monitoring. Never miss a new piece of legislation when AMCP's tracking software updates the state policy map daily. Locate the map on the "<u>Find Legislation</u>" page under the Policy & Advocacy dropdown menu.

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# **Eye On Washington**

## Pharmacy Pay-for-Performance Principles Update

AMCP released the Pharmacy Pay-for-Performance Principles in 2021 to establish our position on performance-based reimbursement for pharmacists' health care services. Two of the principles outline AMCP's support for the adoption by CMS of an appropriate, standardized set of pharmacy performance measures that maintains flexibility for plan sponsors to implement their own metrics; and enumerates appropriate types of price concessions. At its last meeting, the AMCP Board of Directors approved changes to the principles that clarify what constitutes an inappropriate look-back payment and highlights work done by independent standard development organizations to develop consensus-based performance metrics that would be appropriate to valuebased care models and specialty pharmacies.

Read the updated Pharmacy Pay-for-Performance Principles.

### Advocacy Tip

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

#### AMCP Urges Congress to Replenish the COVID-19 Uninsured Relief Fund

On April 27, AMCP joined a broad coalition of health care stakeholders in urging Congress to protect American's access to COVID-19 testing, treatments, and vaccines, regardless of insurance status, by replenishing the COVID-19 Uninsured Relief Fund. HRSA, which administers the fund, stopped processing claims for testing and treatments on March 22 and halted vaccine coverage on April 5 due to lack of funds. Without access to these critical services, many of our nation's most vulnerable communities may be at risk of COVID-19 infection.

Read the letter.

#### AMCP Officially Named Healthy People 2030 Champion

After HHS released the Healthy People 2030 framework in 2020, the Office of Disease Prevention and Health Promotion (ODPHP) invited organizations that support the Healthy People program's vision to become Champions. AMCP highlighted our members' commitment to increase access to quality health care, address health care disparities, and promote innovative technologies that can improve care delivery. AMCP was officially accepted as a Healthy People Champion this month.

Read AMCP's press release.

#### ICYMI: Come (Learn) PIE with Me eLearning Days Webinar

PIE allows manufacturers to communicate certain information about investigational therapies and new indications with payers and health plans to facilitate timely formulary reviews, coverage, and reimbursement decisions for these products. During this month's eLearning Days, AMCP's Policy and Government Relations team examined outstanding issues discouraging PIE communications under current sub-regulatory guidance and outlined current legislative proposals to promote PIE. Attendees will learn about AMCP's support for a legislative safe harbor for proactive PIE communications and how they can become involved in advocacy efforts supporting this legislation.

View the session.

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