Week of April 25, 2022

In PIE We Crust – Pre-approval Information Exchange (PIE) Act of 2022
CURRENT SYSTEM

IMPACT: Patient access to medications is delayed because payers and health plans must wait to review the clinical trial information once the medication is approved by the FDA.

A BETTER SYSTEM

IMPACT: Proactive distribution of clinical trial information to payers and health plans so they can make expedited coverage decisions upon FDA approval.
Pre-approval Information Exchange Act (H.R. 7008)

- Introduced by Congressman Brett Guthrie (R-KY-02) on March 9
- Creates legislative safe-harbor for proactive PIE by manufacturers + clarifies scope of permissible communications under 2018 FDA guidance
- House Energy & Commerce legislative hearing on March 17 – 22 bills considered
- Pre-hearing Sign-on Letter
- PIE Coalition
- House Energy & Commerce markup in May
PIE Coalition

- No financial expectation of members
- No regular meeting cadence currently*
- General expectations
  - Letter of support (May)
  - Positive promotion of PIE Act to members/customers & external entities
  - Share PIE advocacy materials
  - Congressional advocacy
  - Advocacy Alert participation
  - Share Advocacy Alerts
  - Promotion of future PIE Act materials
PIE Resources

• Legislative Text + Bill Actions (link)
• AMCP’s PIE Webpage (link)
  • Press Release (link)
  • Issue Brief/One-pager (link)
  • Frequently Asked Questions (link)
  • 3/17/22 Energy & Commerce Hearing Sign-on Letter (link)
  • Grassroots Advocacy Campaign (link)