



AMCP

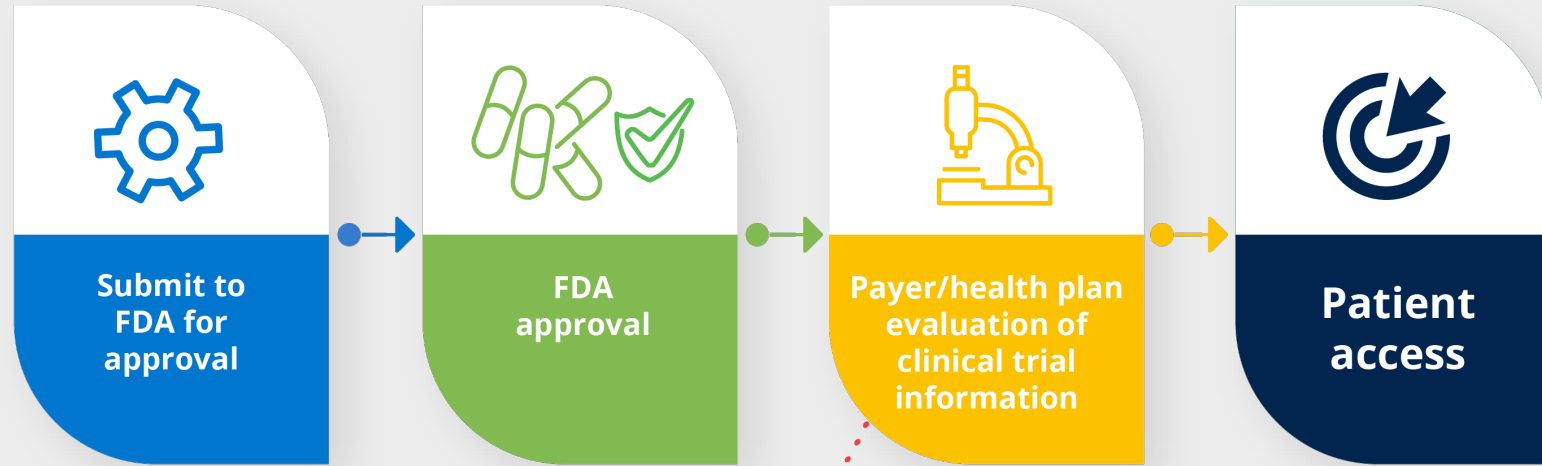
Optimizing medicine.
Improving lives.

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

Week of April 25, 2022

CURRENT SYSTEM

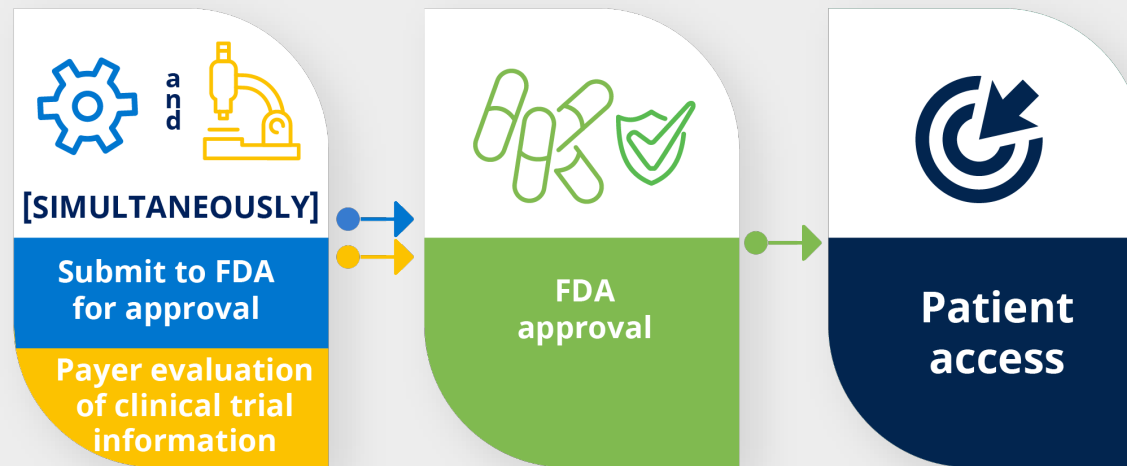
IMPACT: Patient access to medications is delayed because payers and health plans must wait to review the clinical trial information once the medication is approved by the FDA.



IMPACT OF MAKING THIS SWITCH: By distributing clinical trial information to payers and health plans earlier, the review process is able to start earlier so expedited coverage decisions can be made immediately upon FDA approval.

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](#))



Questions?

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