

HR 4274

BPCA and PREA Reauthorization Act of 2012

Congress: 112 (2011–2013, Ended)

Chamber: House

Policy Area: Health

Introduced: Mar 28, 2012

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Mar 30, 2012)

Official Text: <https://www.congress.gov/bill/112th-congress/house-bill/4274>

Sponsor

Name: Rep. Rogers, Mike J. [R-MI-8]

Party: Republican • **State:** MI • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Mar 28, 2012
Rep. Markey, Edward J. [D-MA-7]	D · MA		Mar 28, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 30, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 HR 5651	Related bill	Jun 4, 2012: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 420.

BPCA and PREA Reauthorization Act of 2012 - Makes permanent the provisions of the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act of 2003 (PREA).

Amends the Federal Food, Drug, and Cosmetic Act to revise provisions concerning pediatric research requirements and the granting of exclusivity.

Extends the period for mandatory reporting of adverse events to the Office of Pediatric Therapeutics to 18 months after an approved label change.

Requires a product sponsor to submit an Initial Pediatric Plan as part of the drug application process and sets forth the process for such submission.

Authorizes the Secretary of Health and Human Services (HHS) to: (1) grant a deferral extension, and sets forth the conditions for such deferral; and (2) issue a non-compliance letter to a product sponsor failing to meet post-marketing requirements, and requires the product sponsor to respond in writing.

Authorizes the Pediatric Review Committee to review deferral extensions.

Requires the Office of Pediatric Therapeutics to include a neonatologist and pediatric epidemiologist.

Reauthorizes the Pediatric Advisory Committee and the Pediatric Subcommittee of the Oncologic Drugs Advisory Committee.

Actions Timeline

- **Mar 30, 2012:** Referred to the Subcommittee on Health.
- **Mar 28, 2012:** Introduced in House
- **Mar 28, 2012:** Referred to the House Committee on Energy and Commerce.