HR 5440

Genomics and Personalized Medicine Act of 2010

Congress: 111 (2009–2011, Ended)
Chamber: House
Policy Area: Health
Introduced: May 27, 2010
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (May 27, 2010)
Official Text: https://www.congress.gov/bill/111th-congress/house-bill/5440

Sponsor

Name: Rep. Kennedy, Patrick J. [D-RI-1]
Party: Democratic • **State:** RI • **Chamber:** House

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Eshoo, Anna G. [D-CA-14]	D · CA		May 27, 2010
Rep. Andrews, Robert E. [D-NJ-1]	D · NJ		Jul 13, 2010
Rep. Polis, Jared [D-CO-2]	D · CO		Jul 14, 2010
Rep. Holden, Tim [D-PA-17]	D · PA		Jul 15, 2010
Rep. Hastings, Alcee L. [D-FL-23]	D · FL		Jul 21, 2010
Rep. Capuano, Michael E. [D-MA-8]	D · MA		Jul 30, 2010

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	May 27, 2010

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 27, 2010)

Genomics and Personalized Medicine Act of 2010 - Requires the Secretary of Health and Human Services (HHS) to establish the Office of Personalized Healthcare, the purpose of which shall be to coordinate HHS activities related to genomics and personalized medicine with those of other agencies and entities to ensure that personalized medicine meets the highest standards of safety, efficacy, and clinical validity and utility.

Sets forth provisions related to the collection of genetic and genomic data, including providing for a national biobank.

Requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention (CDC), to establish the Committee on the Evaluation of Genomic Applications in Practice and Prevention.

Directs the Secretary to: (1) improve genomics and personalized medicine training; (2) establish a committee to examine barriers to personalized medicine product development; and (3) review billing, coverage, and reimbursement methodologies for personalized medicine products and services.

Requires the Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services (CMS) and the Commissioner of Food and Drugs (FDA), to: (1) establish a committee to carry out a comparative analysis of laboratory review requirements; (2) facilitate the use of personalized medicine products to assess the risk for and reduce incidence of adverse drug reactions; and (3) include personalized medicine products in adverse event reporting systems.

Authorizes the Secretary, acting through the Commissioner, to require the sponsor of a drug or biological product to: (1) develop a companion diagnostic test under certain circumstances; and (2) conduct additional postmarket studies of drugs shown to be more or less effective in certain racial and ethnic subpopulations.

Requires the Commissioner to collaborate with the Federal Trade Commission (FTC) to identify and terminate advertising campaigns that make false, misleading, deceptive, or unfair claims about the benefits or risks of personalized medicine products.

Requires the Director of CDC to: (1) expand efforts to increase awareness about genomics and personalized medicine; and (2) analyze marketing of personalized medicine products for which consumers have direct access.

Actions Timeline

- **May 27, 2010:** Introduced in House
- **May 27, 2010:** Referred to the House Committee on Energy and Commerce.