

HR 5341

Sentinel Assurance for Effective Devices Act of 2012

Congress: 112 (2011–2013, Ended)

Chamber: House

Policy Area: Health

Introduced: May 7, 2012

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (May 11, 2012)

Official Text: <https://www.congress.gov/bill/112th-congress/house-bill/5341>

Sponsor

Name: Rep. Capps, Lois [D-CA-23]

Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 11, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 7, 2012)

Sentinel Assurance for Effective Devices Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services (HHS) to: (1) amend the new drug approval application procedures to make the postmarket risk identification and analysis system applicable, with certain exceptions, to devices; (2) give priority to class II and class III devices; and (3) engage outside stakeholders in development of the system and gather information from them regarding the content of an effective sentinel program through measures involving the public.

Exempts the collection of voluntary information from health care providers for purposes of postmarket risk identification for devices from application of provisions for the coordination of federal information policy.

Requires the Secretary to issue final regulations concerning a unique device identification system no later than December 31, 2012, and to implement such system for class III devices no later than one year after the date of issuance of final regulations; for implantable, life-sustaining, and life-supporting devices no later than three years after such date; and for all other devices no later than five years after such date.

Actions Timeline

- **May 11, 2012:** Referred to the Subcommittee on Health.
- **May 7, 2012:** Introduced in House
- **May 7, 2012:** Referred to the House Committee on Energy and Commerce.

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