HR 3204

Guidance Accountability and Transparency Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 14, 2011
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 18, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/3204

Sponsor

Name: Rep. Guthrie, Brett [R-KY-2]
Party: Republican • **State:** KY • **Chamber:** House

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Blackburn, Marsha [R-TN-7]	R · TN		Oct 14, 2011
Rep. Latta, Robert E. [R-OH-5]	R · OH		Oct 14, 2011
Rep. Paulsen, Erik [R-MN-3]	R · MN		Oct 14, 2011
Rep. Rogers, Mike J. [R-MI-8]	R · MI		Oct 14, 2011
Rep. Shimkus, John [R-IL-19]	R · IL		Oct 14, 2011
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Oct 24, 2011
Rep. Culberson, John Abney [R-TX-7]	R · TX		Oct 24, 2011
Rep. Rokita, Todd [R-IN-4]	R · IN		Jan 25, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 18, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 14, 2011)

Guidance Accountability and Transparency Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services (HHS), when issuing guidance documents that set forth initial interpretations of a statute or regulation, set forth changes in interpretation or policy that are of more than a minor nature, include complex scientific issues, or cover highly controversial issues (Level 1 guidance documents), to: (1) publish notice in the Federal Register of the Secretary's intent to prepare such a document at least three months before issuance of a draft, and (2) meet with interested stakeholders and solicit public comment during preparation and before issuance of a draft.

Includes within such guidance documents a notice to industry guidance letter, a notice to industry advisory letter, and any similar notice. Sets forth other procedures if the Secretary for good cause finds compliance with such requirements is impracticable, unnecessary, or contrary to the public interest.

Requires the Secretary: (1) upon issuing a draft, to designate it as proposed or final; and (2) to issue a final draft within 12 months after issuing a proposed draft. Treats the proposed draft as null and void if the Secretary fails to finalize the draft within such time.

Directs the Secretary to conduct a retrospective analysis of a final Level 1 guidance document not less than every five years to ensure it is not outmoded, ineffective, insufficient, or excessively burdensome and to modify or repeal the document accordingly.

Actions Timeline

- **Oct 18, 2011:** Referred to the Subcommittee on Health.
- **Oct 14, 2011:** Introduced in House
- **Oct 14, 2011:** Referred to the House Committee on Energy and Commerce.