

## S 4349

A bill to amend the Federal Food, Drug, and Cosmetic Act with respect to notifications of emerging signals concerning devices.

**Congress:** 117 (2021–2023, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Jun 6, 2022

**Current Status:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jun 6, 2022)

**Official Text:** <https://www.congress.gov/bill/117th-congress/senate-bill/4349>

### Sponsor

**Name:** Sen. Marshall, Roger [R-KS]

**Party:** Republican • **State:** KS • **Chamber:** Senate

### Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Braun, Mike [R-IN]	R · IN		Jun 6, 2022

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Jun 6, 2022

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
117 HR 7646	Related bill	May 3, 2022: Referred to the House Committee on Energy and Commerce.

### Summary (as of Jun 6, 2022)

This bill establishes certain requirements relating to the Food and Drug Administration's (FDA's) public notices on the potential new risks of approved medical devices (i.e., emerging signals), including with respect to the standards of evidence needed for such notices. The FDA must update its current guidance on emerging signals to align with the bill's requirements.

### Actions Timeline

• **Jun 6, 2022:** Introduced in Senate

• **Jun 6, 2022:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.