

S 1420

Medical Device User Fee Stabilization Act of 2005

Congress: 109 (2005–2007, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jul 18, 2005

Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 173.

Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 173. (Jul 25, 2005)

Official Text: <https://www.congress.gov/bill/109th-congress/senate-bill/1420>

Sponsor

Name: Sen. Enzi, Michael B. [R-WY]

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

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Burr, Richard [R-NC]	R · NC		Jul 18, 2005
Sen. DeWine, Mike [R-OH]	R · OH		Jul 18, 2005
Sen. Dodd, Christopher J. [D-CT]	D · CT		Jul 18, 2005
Sen. Kennedy, Edward M. [D-MA]	D · MA		Jul 18, 2005
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Jul 18, 2005
Sen. Murray, Patty [D-WA]	D · WA		Jul 18, 2005
Sen. Hatch, Orrin G. [R-UT]	R · UT		Jul 22, 2005

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Jul 25, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 3423	Related bill	Aug 1, 2005: Became Public Law No: 109-43.

Medical Device User Fee Stabilization Act of 2005 - Amends the Federal Food, Drug, and Cosmetic Act to adjust medical device user fees.

Repeals the fee revenue target amounts for FY2006 and FY2007.

Eliminates the inflation, workload, compensating, and final year adjustments of revenues used for setting fees.

Sets the premarket application fee for devices for FY2006 and FY2007.

Allows the Secretary of Health and Human Services to use unobligated carryover balances from fees collected in previous fiscal years with notice to the appropriate congressional committees.

Increases the annual gross receipts or sales threshold below which businesses are eligible for reduced fees or a waiver of fees by the Secretary.

Removes the prohibition against the Secretary assessing fees unless certain cumulative fee revenues were met for FY2003 through 2006.

Requires the Secretary to include in its annual reports to Congress: (1) information on the number and total amount of fees paid for each different type of application or notification from small businesses; and (2) a certification by the Secretary that the amounts obligated for the performance of functions other than the review of device applications is not less than such amount for FY2002 multiplied by the adjustment factor.

Deems as misbranded any reprocessed single use device unless the device or an attachment identifies the manufacturer of the reprocessed device, or the identity of the manufacturer of the original device is provided by a detachable label intended to be affixed to the medical record of a patient.

Actions Timeline

- **Jul 25, 2005:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. With written report No. 109-107. Additional views filed.
- **Jul 25, 2005:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Enzi with an amendment in the nature of a substitute. With written report No. 109-107. Additional views filed.
- **Jul 25, 2005:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 173.
- **Jul 20, 2005:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jul 18, 2005:** Introduced in Senate
- **Jul 18, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.