S 2595

Drug Shortages Prevention and Quality Improvement Act

Congress: 117 (2021–2023, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Aug 4, 2021
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. (Aug 4, 2021)
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Sponsor

Name: Sen. Cardin, Benjamin L. [D-MD]
Party: Democratic • **State:** MD • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Smith, Tina [D-MN]	D · MN		Aug 4, 2021

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Aug 4, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Aug 4, 2021)

Drug Shortages Prevention and Quality Improvement Act

This bill addresses shortages of essential drugs and related issues. (Generally, an essential drug is one that is life-supporting, life-sustaining, or intended to treat or prevent a debilitating condition.)

The Food and Drug Administration (FDA) may require a manufacturer of an essential drug to (1) submit data, or conduct studies to gather data, to determine the longest supported expiration date of a drug; or (2) make labeling changes regarding a drug's expiration period based on data provided under this bill or otherwise available to the FDA.

The bill establishes civil monetary penalties for a manufacturer that (1) refuses such a request to provide data or modify a drug label's expiration information, or (2) fails to meet certain requirements to provide to the FDA timely information about essential drug shortages.

The Government Accountability Office must conduct a study examining the process by which prescription drug manufacturers provide shelf life data to the FDA.

The FDA must establish a pilot program to assess the facilities and processes of participating manufacturers of prescription sterile injectable drugs that have been deemed essential under a specified executive order. The assessment shall cover topics including supply chain management, manufacturing strategy and operations, and workforce management.

Furthermore, the FDA must provide grants to certain nonprofit entities and institutions of higher education that agree to participate in the above pilot program. The grant funds must be used to upgrade the recipient's drug manufacturing facilities to utilize advanced manufacturing capabilities.

Actions Timeline

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