S 957

Drug Supply Chain Security Act

Congress: 113 (2013–2015, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 15, 2013
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. (May 15, 2013)
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Sponsor

Name: Sen. Bennet, Michael F. [D-CO]
Party: Democratic • **State:** CO • **Chamber:** Senate

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Alexander, Lamar [R-TN]	R · TN		May 15, 2013
Sen. Burr, Richard [R-NC]	R · NC		May 15, 2013
Sen. Harkin, Tom [D-IA]	D · IA		May 15, 2013
Sen. Isakson, Johnny [R-GA]	R · GA		May 15, 2013
Sen. Mikulski, Barbara A. [D-MD]	D · MD		Sep 19, 2013

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 15, 2013

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
113 HR 3204	Related bill	**Nov 27, 2013:** Became Public Law No: 113-54.
113 S 959	Related bill	**Jun 19, 2013:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 89.

Summary (as of May 15, 2013)

Drug Supply Chain Security Act - Amends the Federal Food, Drug, and Cosmetic Act to establish requirements to facilitate the tracing of drug products through the pharmaceutical supply distribution chain.

Provides requirements of standards for the exchange of transaction documentation, to be established by the Secretary.

Requires the Secretary to establish processes to: (1) provide waivers of requirements, including for undue economic hardship or emergency medical reasons; (2) provide exceptions to requirements relating to product identifiers if a product is packaged without sufficient space to bear the information; and (3) determine other products or transactions that should be exempt from the requirements of this section.

Permits certain requirements of this Act applicable to manufacturers, repackagers, wholesale distributors, third-party logistics providers, and dispensers to be enforced without further regulations or guidance from the Secretary.

Requires the Secretary to finalize guidance within two years specifying whether and under what circumstances a product that is not labeled with a product identifier, and that is in the pharmaceutical distribution supply chain when applicable requirements go into effect, shall be exempted from such requirements. Exempts products that entered the pharmaceutical distribution supply chain before the date that is one year after enactment of this Act from requirements related to transaction documentation.

Requires drug manufacturers to provide transaction documentation before, or at the time of, each transfer of ownership of a product or transfer of possession to a third-party logistics provider for subsequent transfer of ownership.

Requires a wholesale distributor, dispenser, or repackager to provide to the subsequent purchaser transaction documentation for the product.

Prohibits a wholesale distributor, dispenser, or repackager from accepting ownership of a product unless the previous owner before, or at the time of, the transaction provides such transaction documentation. Prohibits a third-party logistics provider from accepting possession of a product unless such documentation is provided.

Requires the manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider to maintain the transaction documentation for each transaction (or, for a third-party logistics provider, each transfer of possession) for at least six years.

Requires a manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, to provide within 24 hours (or, for a dispenser, within two business days), or in such other reasonable time as determined by the Secretary, the applicable transaction documentation upon request by the Secretary or other appropriate federal or state official.

Requires a manufacturer within four years (for repackagers, within five years) to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Requires a manufacturer and repackager to maintain product identifier information for at least six years from the date of transaction.

Allows a wholesale distributor, dispenser, repackager, or third-party logistics provider to engage in transactions involving a product, or accept possession of a product, only if the product has a product identifier. Sets the effective date of this requirement for repackagers at five years after enactment, with later effective dates for the other entities.

Requires the trading partners of a manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider to be authorized trading partners (i.e., properly registered or licensed by the state).

Requires a manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider to have systems in place to: (1) quarantine a suspect product; (2) promptly conduct an investigation to determine whether the product is an illegitimate product or, for a third-party logistics provider, notify the owner of the need to conduct such an investigation; and (3) for manufacturers, beginning four years after enactment, verify the product at the package level, including the standardized numerical identifier. Requires entities to maintain records of such activities for six years.

Requires a manufacturer, wholesale distributor, dispenser, or repackager, upon a determination that a product in its possession or control is an illegitimate product, to: (1) quarantine the product (except that this does not apply to dispensers), (2) remove the product from the pharmaceutical distribution supply chain, (3) take reasonable and appropriate steps to assist a trading partner to remove such product from the supply chain, (4) retain a sample of the product for further physical examination or laboratory analysis, and (5) notify the Secretary and all immediate trading partners within 24 hours. Requires a third-party logistics provider, upon such a determination, to promptly notify the owner of the need to remove the product from the pharmaceutical distribution supply chain, promptly transfer possession of the product to the owner, and notify the Secretary within 24 hours.

Requires a manufacturer to notify the Secretary and immediate trading partners within 24 hours if the manufacturer has reason to believe that there is a high risk that a product in the trading partner’s possession is an illegitimate product.

Requires a manufacturer or repackager to respond within 24 hours or in other reasonable time as determined by the Secretary after receiving a verification request from an authorized repackager, wholesale distributor, or dispenser whether the product identifier corresponds to the product identifier it affixed or imprinted.

Requires the manufacturer, wholesale distributor, or repackager to verify the product identifier of a returned product that it intends to further distribute.

Allows the wholesale distributor to accept a returned product from a dispenser and distribute it without the transaction history for the next six years. Permits a wholesale distributor, beginning six years after enactment, to accept a returned product from a dispenser only if the wholesale distributor can associate the returned product with the transaction information and transaction statement associated with that product.

Allows a dispenser or repackager to return a product to the trading partner from which the dispenser purchased the product without providing the transaction documentation.

Authorizes a dispenser to enter into an agreement under which a third party confidentially maintains transaction documentation on the dispenser's behalf.

Exempts a wholesale distributor that does not physically handle or store products from the provisions of this Act, except the notification requirements related to illegitimate products, provided the transaction documentation is given to the dispenser by the manufacturer, repackager, or other wholesale distributor that distributes the product.

Establishes package level requirements for the interoperable, electronic tracing of products that shall go into effect 10 years after enactment of this Act.

Requires the Secretary to provide alternative methods of compliance with such requirements, including establishing a time line for compliance by small businesses.

Directs the Secretary to enter into a contract with a consulting firm to conduct a technology and software assessment that looks at the feasibility of dispensers conducting interoperable, electronic tracing of products at the package level.

Sets forth guidance documents to be issued by the Secretary related to suspect and illegitimate products, secure tracing at the package level, and the interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain.

Requires the Secretary to establish pilot projects to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain.

Requires wholesale distributors operating in a state without licensure requirements to be licensed by the Secretary. Requires wholesale distributors to be licensed by the state into which the drug is distributed if the state requires it.

Establishes annual reporting requirements for wholesale distributors. Requires the Secretary to establish a database of licensed wholesale distributors. Authorizes the Secretary to collect fees for licensure.

Requires third-party logistics providers to obtain a license from the Secretary, but not a license as a wholesale distributor if the entity never assumes an ownership interest in the products it handles.

Requires the Secretary to establish minimum standards, terms, and conditions for the state or federal licensing of wholesale distributors. Lists the requirements for such minimum standards.

Prohibits a third-party logistics provider in any state from conducting activities unless each facility of the provider is: (1) licensed by the state from which the drug is distributed by the provider and the state into which the drug is distributed, or (2) licensed by the Secretary if the state has not established a licensure requirement. Establishes annual reporting requirements for the facilities of a third-party logistics provider. Authorizes the Secretary to assess licensure fees. Requires the Secretary to establish minimum requirements for the licensure of third-party logistics providers.

Preempts state or local government requirements for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements under this Act, or which are inconsistent with any waiver, exception, exemption, or restriction under this Act.

Prohibits any state or or local government from establishing or continuing any standards, requirements, or regulations with respect to the licensing of wholesale prescription drug distributors or third-party logistics providers that are less stringent than the standards under this Act. Prohibits a state from regulating a third-party logistics providers as a wholesale distributor.

Deems a drug to be misbranded if it does not contain a product identifier as required by this Act.

Actions Timeline

- **May 15, 2013:** Introduced in Senate
- **May 15, 2013:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.