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21 U.S. Code § 360eee-1

Requirements

(a) In general

(1) Other activities

Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

(2) Initial standards

(A) In general

The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 355e of this title and shall comply with a form and format developed by a widely recognized international standards development organization.

(B) Public input

Prior to issuing the draft guidance under subparagraph (A), the Secretary shall gather comments and information from stakeholders and maintain such comments and information in a public docket for at least 60 days prior to issuing such guidance.

(C) Publication

The Secretary shall publish the standards established under subparagraph (A) not later than 1 year after November 27, 2013.

(3) Waivers, exceptions, and exemptions

(A) In general

Not later than 2 years after November 27, 2013, the Secretary shall, by guidance—

(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section, which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration

pursuant to section 247d of title 42;

(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

(iii) establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section.

(B) Content

The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of such waivers, exceptions, and exemptions, as applicable.

(C) Process

In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce consistent with this section.

(4) Self-executing requirements

Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

(5) Grandfathering product

(A) Product identifier

Not later than 2 years after November 27, 2013, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section.

(B) Tracing

For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015—

(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii);

(ii) transaction history required under this section shall begin with the owner of such product on such date; and

(iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

(6) Wholesale distributor licenses

Notwithstanding section 360eee(9)(A) of this title, until the effective date of the wholesale distributor licensing regulations under section 360eee–2 of this title, the term "licensed" or "authorized", as it relates to a wholesale distributor with respect to prescription drugs, shall mean a wholesale distributor with a valid license under State law.

(7) Third-party logistics provider licenses

Until the effective date of the third-party logistics provider licensing regulations under section 360eee–3 of this title, a third-party logistics provider shall be considered "licensed" under section 360eee(9)(B) of this title unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

(8) Label changes

Changes made to package labels solely to incorporate the product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter [1] 21, Code of Federal Regulations (or any successor regulation).

(9) Product identifiers

With respect to any requirement relating to product identifiers under this part—

(A) unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data—

(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and

(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case; and

(B) verification of the product identifier may occur by using human-readable or machine-readable methods.

(b) Manufacturer requirements

(1) Product tracing

(A) In general

Beginning not later than January 1, 2015, a manufacturer shall—

(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an [2] paper or electronic format; and

(ii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.

(B) Requests for information

Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

(C) Electronic format

(i) In general

Beginning not later than 4 years after November 27, 2013, except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.

(ii) Exception

A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in a paper format to a licensed health care practitioner authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.