

(e) Requirements

The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5—

- (1) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;
- (2) provide a period of not less than 60 days for comments on the proposed regulation; and
- (3) provide that the final regulation take effect on the date that is 2 years after the date such final regulation is published.

(June 25, 1938, ch. 675, §583, as added Pub. L. 113-54, title II, §204(a)(5), Nov. 27, 2013, 127 Stat. 634.)

EFFECTIVE DATE

Section effective Jan. 1, 2015, see section 204(c) of Pub. L. 113-54, set out as an Effective Date of 2013 Amendment note under section 353 of this title.

§ 360eee-3. National standards for third-party logistics providers**(a) Requirements**

No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider—

- (1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or
- (B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and
- (2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

(b) Reporting

Beginning 1 year after November 27, 2013, a facility of a third-party logistics provider shall report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

- (1) the State by which the facility is licensed and the appropriate identification number of such license; and
- (2) the name and address of the facility and all trade names under which such facility conducts business.

(c) Costs**(1) Authorized fees of Secretary**

If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual

basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(2) State licensing fees**(A) State established program**

Nothing in this chapter shall prohibit a State that has established a program to license a third-party logistics provider from collecting fees from a third-party logistics provider for such a license.

(B) No State established program

A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohibited from collecting a State licensing fee from a third-party logistics provider.

(d) Regulations**(1) In general**

Not later than 2 years after November 27, 2013, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of such license, to third-party logistics providers under this section.

(2) Content

Such regulations shall—

(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;

(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

(C) require that the entity complies with storage practices, as determined by the Secretary for such facility, including—

- (i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;
- (ii) maintaining adequate security; and
- (iii) having written policies and procedures to—

(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

(II) identify, record, and report confirmed losses or thefts in the United States;

(III) correct errors and inaccuracies in inventories;

(IV) provide support for manufacturer recalls;

(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repacker or destroyed;

(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

(D) provide for periodic inspection by the licensing authority, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

(E) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of subsection (i) or (k) of section 331 of this title or any violation of section 1365 of title 18, relating to product tampering;

(F) provide for mandatory background checks of a facility manager or a designated representative of such manager;

(G) require a third-party logistics provider to provide the applicable licensing authority, upon a request by such authority, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility; and

(H) include procedures under which any third-party logistics provider license—

(i) expires on the date that is 3 years after issuance of the license; and

(ii) may be renewed for additional 3-year periods.

(3) Procedure

In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5—

(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

(B) provide a period of not less than 60 days for comments on the proposed regulation; and

(C) provide that the final regulation takes effect upon the expiration of 1 year after the date that such final regulation is issued.

(e) Validity

A license issued under this section shall remain valid as long as such third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logis-

tics provider receiving accreditation, pursuant to subsection (d)(2)(A).

(June 25, 1938, ch. 675, § 584, as added Pub. L. 113-54, title II, § 205, Nov. 27, 2013, 127 Stat. 636.)

§ 360eee-4. Uniform national policy

(a) Product tracing and other requirements

Beginning on November 27, 2013, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 353(e) of this title or this part (or regulations issued thereunder), or which are inconsistent with—

(1) any waiver, exception, or exemption pursuant to section 360eee or 360eee-1 of this title; or

(2) any restrictions specified in section 360eee-1 of this title.

(b) Wholesale distributor and third-party logistics provider standards

(1) In general

Beginning on November 27, 2013, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 353(e) of this title, in the case of a wholesale distributor, or section 360eee-3 of this title, in the case of a third-party logistics provider.

(2) State regulation of third-party logistics providers

No State shall regulate third-party logistics providers as wholesale distributors.

(3) Administration fees

Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 353(e), 360eee-2, and 360eee-3 of this title.

(4) Enforcement, suspension, and revocation

Notwithstanding paragraph (1), a State—

(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 353(e) of this title or this part;

(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

(C) upon conviction of violations of Federal, State, or local drug laws or regulations,