(A) An assessment of the steps taken under subsections (b) through (e) to build capacity for a unit-level system, including the impact of the requirements of such subsections on—

(i) the ability of the health care system collectively to maintain patient access to medicines;

(ii) the scalability of such requirements, including as it relates to product lines; and

(iii) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier.

(B) The system attributes necessary to support the requirements set forth under subsection (g), including the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

(C) Best practices in each of the different sectors within the pharmaceutical distribution supply chain to implement the requirements of this section.

(D) The costs and benefits of the implementation of this section, including the impact on each pharmaceutical distribution supply chain sector and on public health.

(E) Whether electronic tracing requirements, including tracing of product at the package level, are feasible, cost effective, and needed to protect the public health.

(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

(G) The technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level.

(H) The impact that such additional requirements would have on patient safety, the drug supply, cost and regulatory burden, and timely patient access to prescription drugs.

(I) Other topics, as determined appropriate by the Secretary.

(j) Pilot projects

(1) In general

The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Such projects shall build upon efforts, in existence as of November 27, 2013, to enhance the safety and security of the pharmaceutical distribution supply chain, take into consideration any pilot projects conducted prior to November 27, 2013, including any pilot projects that use aggregation and inference, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (h).

(2) Content

(A) In general

The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the pharmaceutical distribution supply chain and that the pilot projects, when taken as a whole, include participants representative of every sector, including both large and small businesses.

(B) Project design

The pilot projects under paragraph (1) shall be designed to—

(i) utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

(ii) improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;

(iii) identify system attributes that are necessary to implement the requirements established under this section; and

(iv) complete other activities as determined by the Secretary.

(k) Sunset

The following requirements shall have no force or effect beginning on the date that is 10 years after November 27, 2013:

(1) The provision and receipt of transaction history under this section.

(2) The requirements set forth for returns under subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and (e)(4)(E).

(3) The requirements set forth under subparagraphs (A)(v)(II) and (D) of subsection (c)(1), as applied to lot level information only.

***(l)* Rule of construction**

The requirements set forth in subsections (g)(4), (i), and (j) shall not be construed as a condition, prohibition, or precedent for precluding or delaying the provisions becoming effective pursuant to subsection (g).

(m) Requests for information

On the date that is 10 years after November 27, 2013, the timeline for responses to requests for information from the Secretary, or other appropriate Federal or State official, as applicable, under subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be not later than 24 hours after receiving the request from the Secretary or other appropriate Federal or State official, as applicable, or in such other reasonable time as determined by the Secretary based on the circumstances of the request.

(June 25, 1938, ch. 675, § 582, as added and amended Pub. L. 113–54, title II, §§ 202, 203, Nov. 27, 2013, 127 Stat. 605, 623.)

AMENDMENTS

2013—Subsecs. (g) to (m). Pub. L. 113–54, § 203, added subsecs. (g) to (m).

§ 360eee–2. National standards for prescription drug wholesale distributors

(a) In general

The Secretary shall, not later than 2 years after November 27, 2013, establish by regulation standards for the licensing of persons under sec-

tion 353(e)(1) of this title, including the revocation, reissuance, and renewal of such license.

(b) Content

For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 353(e)(1) of this title and shall include standards for the following:

(1) The storage and handling of prescription drugs, including facility requirements.

(2) The establishment and maintenance of records of the distributions of such drugs.

(3) The furnishing of a bond or other equivalent means of security, as follows:

(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

(ii) For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

(B) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State shall be waived.

(4) Mandatory background checks and fingerprinting of facility managers or designated representatives.

(5) The establishment and implementation of qualifications for key personnel.

(6) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with subsection (c).

(7) In accordance with subsection (d), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

(c) Inspections

To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

(d) Prohibited persons

The standards established under subsection (a) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 331 of this title, or any felony violation of section 1365 of title 18 relating to product tampering; or

(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

(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