AMENDMENT TO H.R. 1919

OFFERED BY MR. PALLONE OF NEW JERSEY

Strike section 3 of the bill and insert the following:

SEC. 3. ENHANCED DRUG DISTRIBUTION SECURITY.

(a) IN GENERAL.—Section 582 of the Federal Food, Drug, and Cosmetic Act, as added by section 2, is amended by adding at the end the following:

''(h) ENHANCED DRUG DISTRIBUTION SECURITY.—

''(1) IN GENERAL.—On the date that is 10 years after the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2013, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

''(A) The transaction information and the transaction statements as required under this section shall be exchanged in an interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (i), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

''(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

''(C) Systems and processes for verification of product at the package level shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2),(3), and (4) of subsection (i), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

''(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

''(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction informa-

tion for each transaction going back to the manufacturer, as applicable, upon request by the Secretary (or other appropriate Federal or State official), in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

''(F) A wholesale distributor shall maintain systems and processes to allow the wholesale distributor to accept saleable returns from dispensers only if the wholesale distributor can associate returned product with the transaction information and the transaction statement associated with that product.

''(2) COMPLIANCE.—

''(A) INFORMATION MAINTENANCE AGREEMENT.—A dispenser shall be permitted to enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the other obligations of the dispenser under this subsection.

''(B) ALTERNATIVE METHODS.—The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including—

''(i) establishing timelines for compliance by small businesses (including small business dispensers with 25 or fewer full time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met, if the Secretary determines that such requirements under paragraph (1) would result in undue economic hardship; and

''(ii) establishing a process by which a dispenser may request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that such requirements would result in an undue economic hardship.

''(3) ASSESSMENT.—

''(A) IN GENERAL.—Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (i), the Secretary shall enter into contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. In no case may such assessment commence later than 7.5 years after the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2013.

''(B) CONDITION.—As a condition of the award of the contract under subparagraph (A), the private, independent consulting firm shall agree to consult with dispensers with 25 or fewer full-time employees when conducting the assessment under such subparagraph.

''(C) CONTENT.—The assessment conducted under subparagraph (A) shall assess whether—

''(i) the necessary software and hardware is readily accessible to such dispensers;

''(ii) the necessary software and hardware is not prohibitively expensive to obtain, install, and maintain for such dispensers; and

''(iii) the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.

''(D) PUBLICATION.—The Secretary shall—

''(i) publish the statement of work for the assessment conducted under subparagraph (A) for public comment prior to beginning the assessment;

''(ii) publish the final assessment for public comment not later than 30 calendar days after receiving such assessment; and

''(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

''(4) PROCEDURE.—Notwithstanding section 553 of title 5, United States Code, the Secretary, in promulgating any regulation pursuant to this section, shall—

''(A) provide appropriate flexibility by—

''(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

''(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or set forth in regulations implementing such requirements, including timelines—

''(I) for small businesses to comply with the requirements set forth in the regulations in order to ensure that such requirements do not impose undue economic hardship for small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met), if the Secretary determines that such requirements would result in undue economic hardship; and

''(II) which shall include establishing a process by which a dispenser may request a waiver from any of the requirements set forth in such regulations if the Secretary determines that such requirements would result in an undue economic hardship; and

''(iii) taking into consideration—

''(I) the results of pilot projects, including pilot projects pursuant to this section;

''(II) the public meetings held and related guidance documents issued under this section;

''(III) the public health benefits of any additional regulations in comparison to the cost of compliance with such requirements, including on entities of varying sizes and capabilities;

''(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

''(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

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

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

''(D) publish the final regulation not less than 2 years prior to the effective date of the regulation.

''(i) GUIDANCE DOCUMENTS.—

''(1) IN GENERAL.—For the purposes of facilitating the successful and efficient adoption of secure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health, the Secretary shall issue the guidance documents as provided for in this subsection.

''(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

''(A) IN GENERAL.—Not later than 180 days after enactment of the Safeguarding

America's Pharmaceuticals Act of 2013, the Secretary shall issue a guidance document to aid trading partners in the identification of a suspect product and notification termination. Such guidance document shall—

''(i) identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain;

''(ii) provide recommendation on how trading partners may identify such product and make a determination if the product is a suspect product as soon as practicable; and

''(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers shall terminate notifications in consultation with the Secretary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), (e)(4)(B), and (f)(B).

''(B) REVISED GUIDANCE.—If the Secretary revises the guidance issued under sub-

paragraph (A), the Secretary shall follow the procedure set forth in paragraph (5).

''(3) UNIT LEVEL TRACING.—

''(A) IN GENERAL.—In order to enhance drug distribution security at the package level, not later than 18 months after conducting a public meeting on the system attributes necessary to enable tracing of product at the package level, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable tracing at the package level as required under the requirements established under subsection (h). Such guidance document shall—

''(i) define the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in the most efficient manner practicable, infer the contents of a case, pallet, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or other-

wise individually scanning each package; and

''(ii) identify methods and processes to enhance tracing of product at the package level, such as enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, or package security features.

''(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

''(4) STANDARDS FOR INTEROPERABLE DATA EXCHANGE.—

''(A) IN GENERAL.—In order to enhance tracing of a product at the package level, the Secretary, not later than 18 months after conducting a public meeting on the interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain, shall update the guidance issued pursuant to subsection (a)(2), as necessary and appropriate,

and finalize such guidance document so that the guidance document—

''(i) identifies and makes recommendation with respect to the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization;

''(ii) takes into consideration standards established pursuant to subsection (a)(2) and section 505D;

''(iii) facilitates the creation of a uniform process or methodology for product tracing; and

''(iv) ensures the protection of confidential commercial information and trade secrets.

''(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

''(5) PROCEDURE.—In issuing or revising any guidance issued pursuant to this subsection or subsection (h), except the initial guidance issued under paragraph (2)(A), the Secretary shall—

''(A) publish a notice in the Federal Register announcing that the draft or revised draft guidance is available;

''(B) post the draft guidance document on the Internet Web site of the Food and Drug Administration and make such draft guidance document available in hard copy;

''(C) provide an opportunity for comment and review and take into consideration any comments received;

''(D) revise the draft guidance, as appropriate;

''(E) publish a notice in the Federal Register announcing that the final guidance or final revised guidance is available;

''(F) post the final guidance document on the Internet Website of the Food and Drug Administration and make such final guidance document available in hard copy; and

''(G) provide for an effective date of not earlier than 1 year after such guidance becomes final.

''(j) PUBLIC MEETINGS.—

''(1) IN GENERAL.—The Secretary shall hold not less than 3 public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide for comment. The Secretary may hold the first such public meeting not earlier than 1 year after the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2013. In carrying out the public meetings described in this paragraph, the Secretary shall—

''(A) prioritize topics necessary to inform the issuance of the guidance described in paragraphs (3) and (4) of subsection (i); and

''(B) take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

''(2) CONTENT.—Each of the following topics shall be addressed in at least one of the public meetings described in paragraph (1):

''(A) An assessment of the steps taken under subsections (b) through (f) to build capacity for a unit-level system, including the im-

pact 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 (h), 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 public health.

''(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level.

''(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.

''(k) PILOT PROJECTS.—

''(1) IN GENERAL.—The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, third-party logistics providers, 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 the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2013, to enhance the safety and security of the pharmaceutical distribution supply chain, take into consideration any pilot projects conducted prior to such date of enactment, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (i).

''(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.

''(l) SUNSET.—The following requirements shall have no force or effect beginning on the date that is 10 years after the date of enactment of the Safeguarding America's Pharmaceuticals Act of 2013:

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

''(2) The requirements set forth for returns under subsection (c)(1)(B)(i).

''(m) RULE OF CONSTRUCTION.—The requirements set forth in subsections (h)(4), (j), and (k) shall not be construed as a condition, prohibition, or precedent for pre-

cluding or delaying the provisions becoming effective pursuant to subsection (h).''.