

“(D) ENFORCEMENT.—

“(i) **IN GENERAL.**—This subsection, and the regulations promulgated under this subsection, shall be enforced exclusively by the Federal functional regulators and the Federal Trade Commission under applicable law in the manner provided in section 505(a) of the Gramm-Leach-Bliley Act (15 U.S.C. 6805(a)).

“(ii) **FACTORS TO BE CONSIDERED.**—In considering any enforcement action under this subsection against a payment system or person described in paragraph (2)(B), the Federal functional regulators and the Federal Trade Commission shall consider the following factors:

“(I) The extent to which the payment system or person knowingly permits restricted transactions.

“(II) The history of the payment system or person in connection with permitting restricted transactions.

“(III) The extent to which the payment system or person has established and is maintaining policies and procedures in compliance with regulations prescribed under this subsection.

“(8) **TRANSACTIONS PERMITTED.**—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, is authorized to engage in transactions with foreign pharmacies in connection with investigating violations or potential violations of any rule or requirement adopted by the payment system or person in connection with complying with paragraph (7). A payment system, or such a person, and its agents and employees shall not be found to be in violation of, or liable under, any Federal, State or other law by virtue of engaging in any such transaction.

“(9) **RELATION TO STATE LAWS.**—No requirement, prohibition, or liability may be imposed on a payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, under the laws of any state with respect to any payment transaction by an individual because the payment transaction involves a payment to a foreign pharmacy.

“(10) **TIMING OF REQUIREMENTS.**—A payment system, or a person described in paragraph (2)(B) that is subject to a regulation issued under this subsection, must adopt policies and procedures reasonably designed to comply with any regulations required under paragraph (7) within 60 days after such regulations are issued in final form.

“(11) **COMPLIANCE.**—A payment system, and any person described in paragraph (2)(B), shall not be deemed to be in violation of paragraph (1)—

“(A)(i) if an alleged violation of paragraph (1) occurs prior to the mandatory compliance date of the regulations issued under paragraph (7); and

“(ii) such entity has adopted or relied on policies and procedures that are reasonably designed to prevent the introduction of restricted transactions into a payment system or the completion of restricted transactions using a payment system; or

“(B)(i) if an alleged violation of paragraph (1) occurs after the mandatory compliance date of such regulations; and

“(ii) such entity is in compliance with such regulations.”

(b) **EFFECTIVE DATE.**—The amendment made by this section shall take effect on the day that is 90 days after the date of enactment of this Act.

(c) **IMPLEMENTATION.**—The Board of Governors of the Federal Reserve System shall promulgate regulations as required by subsection (h)(7) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as added by subsection (a), not later than 90 days after the date of enactment of this Act.

SEC. 1209. IMPORTATION EXEMPTION UNDER CONTROLLED SUBSTANCES IMPORT AND EXPORT ACT.

Section 1006(a)(2) of the Controlled Substances Import and Export Act (21 U.S.C. 956(a)(2)) is amended by striking “not import the controlled substance into the United States in an amount that exceeds 50 dosage units of the controlled substance.” and inserting “import into the United States not more than 10 dosage units combined of all such controlled substances.”

SEC. 1210. SEVERABILITY.

If any provision of this title, an amendment by this title, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this title, the amendments made by this title, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

SA 2151. Mr. MANCHIN (for himself, Mr. KIRK, Mrs. GILLIBRAND, Mr. SCHUMER, and Mr. ROCKEFELLER) submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; as follows:

At the end of subtitle C of title XI, add the following:

SEC. 1132. HYDROCODONE AMENDMENT.

Schedule III(d) in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by—

- (1) striking paragraphs (3) and (4); and
- (2) redesignating paragraphs (5), (6), (7), and (8) as paragraphs (3), (4), (5), and (6), respectively.

SA 2152. Mr. PORTMAN submitted an amendment intended to be proposed by him to the bill S. 3187, to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; which was ordered to lie on the table; as follows:

At the end of title XI, add the following:

SEC. 11 . . . RECOMMENDATIONS ON INTEROPERABILITY STANDARDS.

(a) **IN GENERAL.**—The Attorney General and the Secretary of Health and Human Services may collaborate to facilitate the development of recommendations on interoperability standards to inform and facilitate the exchange of prescription information across State lines by making grants to States under—

(1) the Harold Rogers Prescription Drug Monitoring Program established under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 2002 (Public Law 107-77; 115 Stat. 748); and

(2) the Controlled Substance Monitoring Program established under section 3990 of the Public Health Service Act (42 U.S.C. 280g-3).

(b) **REQUIREMENTS.**—The Attorney General and the Secretary of Health and Human Services shall consider the following in facilitating the development of recommendations on interoperability of prescription drug monitoring programs under subsection (a)—

- (1) open standards that are freely available, without cost and without restriction, in order to promote broad implementation;

(2) the use of exchange intermediaries, or hubs, as necessary to facilitate interstate interoperability by accommodating State-to-hub and direct State-to-State communication;

(3) the support of transmissions that are fully secured as required, using industry standard methods of encryption, to ensure that Protected Health Information and Personally Identifiable Information are not compromised at any point during such transmission; and

(4) access control methodologies to share protected information solely in accordance with State laws and regulations.

NOTICE OF HEARING**COMMITTEE ON INDIAN AFFAIRS**

Mr. AKAKA. Mr. President, I would like to announce that the Committee on Indian Affairs will meet on May 24, 2012, in room SD-628 of the Dirksen Senate Office Building, at 12:45 p.m., to conduct a hearing entitled “Programs and Services for Native Veterans.”

Those wishing additional information may contact the Indian Affairs Committee at (202) 224-2251.

AUTHORITY FOR COMMITTEES TO MEET**COMMITTEE ON ARMED SERVICES**

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Armed Services be authorized to meet during the session of the Senate on May 23, 2012, at 2:30 p.m.

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FINANCE

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Finance be authorized to meet during the session of the Senate on May 23, 2012, at 10 a.m., in room SD-215 of the Dirksen Senate Office Building, to conduct a hearing entitled “Progress in Health Care Delivery: Innovations from the Field.”

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON FOREIGN RELATIONS

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Foreign Relations be authorized to meet during the session of the Senate on May 23, 2012, at 10 a.m., to hold a hearing entitled, “The Law of the Sea Convention (Treaty Doc. 103-39): The U.S. National Security and Strategy Imperatives for Ratification.”

The PRESIDING OFFICER. Without objection, it is so ordered.

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

Mr. LAUTENBERG. Mr. President, I ask unanimous consent that the Committee on Homeland Security and Governmental Affairs be authorized to meet during the session of the Senate on May 23, 2012, at 10:30 a.m. to conduct a hearing entitled “Secret Service on the Line: Restoring Trust and Confidence.”

The PRESIDING OFFICER. Without objection, it is so ordered.