114TH CONGRESS
1ST SESSION

H. R. _____

To provide for the disposal of covered drugs pursuant to national pharmaceutical stewardship programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. SLAUGHTER introduced the following bill; which was referred to the Committee on _____

A BILL

To provide for the disposal of covered drugs pursuant to national pharmaceutical stewardship programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmaceutical Stewardship Act of 2015''.

SEC. 2. NATIONAL PHARMACEUTICAL STEWARDSHIP PROGRAMS.

(a) REQUIRED PARTICIPATION.—Each producer of a covered drug shall participate in—

(1) the certified national pharmaceutical stewardship program of the National Pharmaceutical Stewardship Organization; or

(2) another certified national pharmaceutical stewardship program.

(b) NATIONAL PHARMACEUTICAL STEWARDSHIP ORGANIZATION.—

(1) ESTABLISHMENT.—There shall be established in accordance with this section a nonprofit private corporation to be known as the National Pharmaceutical Stewardship Organization. The Organization shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Organization shall not, by virtue of such service, be considered officers or employees of the Federal Government.

(2) PURPOSE.—The purpose of the Organization shall be to establish and, beginning not later than 2 years after the date of the enactment of this Act, implement a certified national pharmaceutical stewardship program.

(3) BOARD OF DIRECTORS.—

(A) REPRESENTATION.—The Organization shall have a board of directors with representation of each of the following:

(i) Producers of covered drugs.

(ii) Public health, pharmacy, law enforcement, and substance use disorder treatment professionals.

(iii) Water quality and waste management stakeholders.

(B) INITIAL MEMBERS.—The Secretary shall appoint the initial members of the board of directors.

(4) BYLAWS.—The board of directors shall establish the general policies of the Organization for carrying out the purpose described in paragraph (2), including the establishment of the bylaws of the Organization. The board of directors shall ensure that the bylaws of the Organization include bylaws for the following:

(A) Entering into contracts and agreements with service providers and entities as necessary, useful, or convenient to provide all or portions of the national pharmaceutical stewardship program of the Organization.

(B) Taking any legal action necessary or proper for the recovery of an assessment for, on behalf of, or against producers of a covered drug participating in such program.

(C) Performing other such functions as may be necessary or proper to carry out the purpose described in paragraph (2).

(D) Ensuring that the members of the board of directors serve without compensation, but are entitled to reimbursement (solely from the funds of the Organization) for expenses incurred in the discharge of their duties as members of the board of directors.

(E) Ensuring that the Organization does not use any Federal, State, or local government funds to carry out the purpose described in paragraph (2).

(F) Allowing the Secretary—

(i) to audit the activities of the Organization as the Secretary deems necessary; and

(ii) to access any facilities or property of the Organization as the Secretary deems necessary to conduct inspections or investigate complaints.

(5) NONPROFIT STATUS.—In carrying out the purpose described in paragraph (2), the board of directors shall establish such policies and bylaws under paragraph (4) as may be necessary to ensure that

the Organization maintains its status as an organization that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986; and

(B) is, under subsection (a) of such section, exempt from taxation.

(6) CONTRIBUTIONS TO NATIONAL PHARMACEUTICAL STEWARDSHIP ORGANIZATION NOT TREATED AS CHARITABLE CONTRIBUTIONS.—A contribution (including any payment or fee) by a producer of a covered drug to the Organization or the Organization's national pharmaceutical stewardship program shall not be treated as a charitable contribution for purposes of section 170 of the Internal Revenue Code of 1986.

(7) ARTICLES OF INCORPORATION.—The Secretary shall ensure that the initial articles of incorporation of the Organization are properly filed not later than 60 days after the date of the enactment of this Act.

(c) PROGRAM REQUIREMENTS.—To be certified (and maintain certification) under subsection (f) or (g), a program shall meet each of the following:

(1) The program is operated pursuant to an agreement among the producers of covered drugs participating in the program.

(2) Subject to subsection (d), the costs of the program are fully paid by such producers.

(3) The program shall not impose any fee on individuals, wholesalers, or retailers for transport and disposal of a covered drug through the program, except to the extent an individual, wholesaler, or retailer is acting as a producer of a covered drug.

(4) The program is developed with input from the public, including an opportunity for public comment and public hearings.

(5) The program provides a system to facilitate the collection and disposal of any covered drug that—

(A) is delivered to the program by the ultimate user of the covered drug in the United States; and

(B) is household waste as defined under the implementing regulations of subtitle C of title II of the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.; commonly referred to as the ''Resource Conservation and Recovery Act'').

(6) Collection and disposal of a covered drug through the program's system (described in paragraph (5)) occurs only in a manner that—

(A) is safe and secure;

(B) results in the covered drug being rendered unrecoverable in accordance with the requirements for nonretrievable disposal of controlled substances under part 1300 of title 21, Code of Federal Regulations (or any successor regulations);

(C) protects patient information;

(D) is accessible in every State, county, and city or town, including—

(i) at least one collection site that is accessible on an ongoing, year-round basis in every county of every State and at least one additional such collection site for every 30,000 county residents, giving preference to retail pharmacies that—

(I) operate secure collection receptacles in accordance with applicable regulations of the Drug Enforcement Administration; and

(II) are geographically distributed to provide reasonably convenient and equitable access;

(ii) if ongoing, year-round collection is not feasible in a specific county or city (as determined by the Secretary)—

(I) periodic collection events; or

(II) the provision of prepaid mailing envelopes or deactivation technologies to individuals in such county or city; and

(iii) prepaid mailing envelopes or deactivation technologies made available to individuals with disabilities and homebound residents upon request through the program's toll-free telephone number and website under paragraph (8); and

(E) in the case of a controlled substance, is consistent with section 302(g) of the Controlled Substances Act (21 U.S.C. 822(g)).

(7) The program—

(A) promotes the collection and disposal of covered drugs through the program; and

(B) to the extent feasible, works with local recycling facilities and officials to collect and re-

cycle covered drug packaging at collection locations.

(8) The program ensures that options for collection and disposal of covered drugs through the program are widely understood by customers, pharmacists, retailers, and health care practitioners including doctors and other prescribers, including by—

(A) maintaining a toll-free telephone number, a website optimized for mobile platforms, and a free mobile application that—

(i) publicize all currently available collection and disposal options, updated within 30 days of any change; and

(ii) provide substance use disorder treatment and referral information;

(B) preparing educational and outreach materials that—

(i) clearly explain what ''covered drugs'' are collected at each collection site;

(ii) describe where and how to dispose of covered drugs through the program; and

(iii) address the risks of diversion of covered drugs, including accidental overdose, accidental poisoning, and environmental contamination; and

(iv) raise awareness about the importance of safe storage and disposal;

(v) utilize plain language and explanatory images readily understandable by all residents, including individuals with limited English proficiency; and

(C) providing such materials to pharmacies, health care facilities, and other interested parties for dissemination.

(9) Every 4 years, the program, using an independent evaluator at the expense of the program, evaluates the effectiveness of its educational and outreach activities under paragraph (8), including with respect to—

(A) the percentage of residents of the United States who are aware of the program;

(B) the percentage of residents of the United States who report having access to a collection site, prepaid mail-back envelope, or deactivation system; and

(C) the extent to which residents of the United States find the program to be convenient; and

(10) Annually, the program, using an independent auditor at the expense of the program, au-

dits relevant information provided in the program's report to the Secretary, including—

(A) the amount, by weight, of covered drugs collected and disposed of in each State by drop-off site and, if applicable, the total amount by weight collected by mail-back method and disposed of; and

(B) the income and expenditures of the program.

(d) MECHANISM FOR TRANSFER OF COSTS AMONG PRODUCERS.—To be certified (and maintain certification) under subsection (f) or (g), a program shall include a mechanism that—

(1) provides for receiving and transferring of funds among all national pharmaceutical stewardship programs that are so certified in such amounts as may be necessary, to be adjusted on at least an annual basis, to ensure that the producers of covered drugs participating in such programs bear the costs of such programs in a manner that provides for a fair and reasonable allocation of such costs across such participants; and

(2) is specified in a written agreement among all producers of covered drugs.

(e) PROGRAM REPORTING REQUIREMENTS.—

(1) IN GENERAL.—To be certified (and maintain certification) under subsection (f) or (g), a program shall agree to submit a report to the Secretary within one year following such certification, and annually thereafter.

(2) CONTENTS.—Each report submitted by a program under paragraph (1) shall describe the program's activities during the preceding calendar year, including at a minimum—

(A) a list of producers participating in the program;

(B) a specification of the amount, by weight, of covered drugs collected and disposed of in each State—

(i) by drop-off site; and

(ii) if applicable, by mail-back method;

(C) a description of the collection system in each State, including the location of each collection site and, if applicable, locations where envelopes for mail-back or deactivation technologies are provided;

(D) an identification of any safety or security problems which occurred during collection, transportation, or disposal of covered drugs during the preceding calendar year and, with

respect to any such problems, a description of the changes which have or will be made to policies, procedures, or tracking mechanisms to alleviate any such problems and to improve safety and security in the future;

(E) a description of the educational and outreach activities under subsection (c)(8) and the methodology used to evaluate such activities under subsection (c)(9);

(F) a description of how collected packaging was recycled to the extent feasible, including the recycling facility or facilities used; and

(G) the total expenditures of the program.

(3) PROCEDURES.—The Secretary shall establish procedures for reporting under this subsection not later than the date that is one year after the date of the enactment of this Act.

(4) PUBLIC AVAILABILITY.—The Secretary shall make each report submitted under this subsection available to the public.

(f) CERTIFICATION OF NATIONAL PHARMACEUTICAL STEWARDSHIP ORGANIZATION'S PROGRAM.—

(1) PROGRAM PLAN.—To seek certification of its program, the Organization shall submit a plan to

the Secretary containing such information as the Secretary may require.

(2) CONSIDERATION BY SECRETARY.—Upon receipt of a plan under paragraph (1), the Secretary—

(A) shall consult with the Administrator of the Drug Enforcement Administration on the adequacy of the proposed program's security measures for collection, transportation, and disposal of covered drugs, disposal systems, and mechanisms for secure tracking and handling;

(B) shall consult with the Administrator of the Environmental Protection Agency on the adequacy of the program's disposal methods and compliance with environmental requirements;

(C) shall consult with the Secretary of Transportation on the adequacy of the program's compliance with respect to requirements for transport of covered drugs; and

(D) within 90 days after receipt of the plan, shall—

(i) certify the program if the Secretary determines it meets the requirements of this section; or

(ii) reject the proposed program and provide a written explanation of the reasons for such rejection.

(3) RESPONSE TO REJECTION OF PROPOSED PROGRAM.—If the Secretary rejects the Organization's proposed program under paragraph (2)(D)(ii), the rejection shall be treated as final agency action, and the Organization may—

(A) revise its proposed program and submit a new plan under paragraph (1); or

(B) seek judicial review of the rejection not later than 60 days after receiving notice of the rejection.

(4) SOLICITATION OF PUBLIC COMMENT TO INFORM PROGRAM UPDATES.—

(A) IN GENERAL.—A certified national product stewardship program shall—

(i) annually invite comments from stakeholders on their satisfaction with the services provided by the program, including representatives of health care facilities, prescribers, pharmacies and pharmacists, State and local government officials, law enforcement personnel, public health organizations, substance use disorder profes-

sionals, waste management stakeholders, environmental organizations, and consumers;

(ii) compile and submit the information received through such comments to the Secretary; and

(iii) use such information in developing updates and changes to the program.

(B) USE BY SECRETARY.—The Secretary shall use information submitted under subparagraph (A)(ii) in reviewing proposed updates and revisions to certified national pharmaceutical stewardship program plans.

(C) GUIDANCE.—The Secretary shall issue guidance on the process for complying with this paragraph.

(5) TERM OF CERTIFICATION; RECERTIFICATION.—The term of a certification (including a recertification) under paragraph (2)(D)(i) shall be not more than 2 years. To have its program recertified, the Organization shall submit a new plan under paragraph (1), including any relevant updates, for approval under paragraph (2)(D)(i).

(6) CHANGES TO CERTIFIED PROGRAM.—Before making any significant change to its certified na-

tional pharmaceutical stewardship program, the Organization shall seek and obtain approval for the change from the Secretary. Not later than 15 days after submission of a request for a change under the preceding sentence, the Secretary shall approve the change or reject the change and provide a written explanation of the reasons for the rejection.

(7) SUBMISSION REQUIREMENTS.—

(A) PUBLICATION.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall publish requirements for the submission of program plans under paragraph (1) and requests for changes under paragraph (6), including requirements for the contents of such submissions.

(B) FAILURE TO PUBLISH.—If the Secretary fails to publish such requirements by the deadline specified in subparagraph (A), the requirements of this section applicable to producers of covered drugs shall nonetheless apply.

(g) CERTIFICATION OF OTHER PROGRAMS.—

(1) APPLICATION.—In lieu of participating in the certified national pharmaceutical stewardship program of the Organization, one or more producers of a covered drug may submit a stewardship plan to

the Secretary seeking certification of a separate national pharmaceutical stewardship program.

(2) GOVERNING PROVISIONS.—The provisions of subsection (f) shall apply with respect to a stewardship plan for certification of a program under paragraph (1) to the same extent and in the same manner as such provisions apply to a program plan for certification of a program by the Organization under subsection (f), except as follows:

(A) The reference to 90 days in subsection (f)(2)(D) (relating to the period of the Secretary's review of a program plan) shall be treated as a reference to 120 days.

(B) If the Secretary rejects the proposed stewardship plan, in lieu of submitting a new stewardship plan under paragraph (1) or seeking judicial review of the rejection, the producers may choose to participate in the certified national pharmaceutical stewardship program of the Organization.

(C) The reference to 2 years in subsection (f)(5) (relating to the term of certification) shall be treated as references to 1 year.

(h) SUSPENSION OF PROGRAM.—

(1) IMMINENT DANGER.—The Secretary may suspend, in whole or in part, the certification of any national pharmaceutical stewardship program under this section if the Secretary determines that such action is necessary to protect the public from imminent danger.

(2) FAILURE TO COMPLY.—If the Secretary determines that a national pharmaceutical stewardship is in violation of the requirements of this section, the Secretary—

(A) within 30 days of learning of the violation, may issue a written warning to the program stating that the program is in violation of this section; and

(B) if the program has not rectified each violation identified in such warning within 30 days of receipt of such warning, may suspend, in whole or in part, the certification of the program.

(i) CIVIL PENALTIES.—Beginning on the date that is 2 years after the date of enactment of this Act, a producer of a covered drug shall be liable for a civil penalty of not more than $50,000 for each calendar day on which, as determined by the Secretary, the producer—

(1) is not participating in a certified national pharmaceutical program; or

(2) is in violation of its obligation to contribute to the costs of such a program under subsection (c)(2).

(j) REGULATORY POWER.—The Secretary may adopt rules or guidance necessary to implement, administer, and enforce this section. The Secretary, in consultation with the Administrator of the Environmental Protection Agency, the Administrator of the Drug Enforcement Administration, the Director of National Drug Control Policy, the Secretary of Transportation, and the Commissioner of Food and Drugs, may include in such regulations or guidance any performance standards determined appropriate for implementing the program requirements specified in this section.

(k) STATE, TRIBAL, AND LOCAL REGULATION.—Any requirement of a State, tribal, or local government relating to the safe and secure disposal of covered drugs is preempted unless it is more stringent than the requirements of this Act.

(l) REPORT TO CONGRESS.—Not later than 5 years after the date of enactment of this Act, the Secretary shall report to the appropriate committees of the Congress concerning the status of the national pharmaceutical steward-

ship programs under this section, including any recommendations for changes to this section.

(m) SEVERABILITY.—If any provision of this section or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this section, and the application of the provisions of such remainder to any person or circumstance, shall not be affected thereby.

(n) EVALUATION.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, and annually thereafter, the Director of the Office of the National Drug Control Policy, in consultation with the Secretary of Health and Human Services, the Attorney General, and the Administrator of the Drug Enforcement Administration, shall—

(A) conduct an evaluation of the effectiveness of the national pharmaceutical stewardship programs under this section; and

(B) submit a report to the Congress on the results of each such evaluation, including recommendations for improving the programs.

(2) METRICS.—The evaluation under paragraph (1) shall address each of the following:

(A) Public access to national pharmaceutical stewardship programs under this section.

(B) Public awareness of such programs, including awareness of the risks of diversion of drugs and awareness of the importance of safe storage and safe disposal of pharmaceuticals.

(C) Impact of the programs on prescription drug abuse, including analysis of hospital admissions for prescription drug overdoses, per capita deaths due to prescription drug overdoses, and arrests for illegal possession of controlled substances in schedule II, III, IV, or V.

(o) ANNUAL FEES.—The Secretary may assess, collect, and use, without further appropriation, annual fees from producers of covered drugs to pay the administrative costs of carrying out this section.

(p) DELAYED APPLICABILITY.—In the case of producer that first offers a covered drug for sale in interstate commerce (including by importing the covered drug) after the date of enactment of this Act, the requirements of this Act apply with respect to such producer beginning on the date that is 180 days after the date on which the producer

first offers the covered drug for sale in interstate commerce.

(q) DEFINITIONS.—In this section:

(1) The term ''board of directors'' means the board of directors of the Organization.

(2) The term ''producer'', with respect to a covered drug, means the holder of an approved application for the covered drug under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(3) The term ''certified national pharmaceutical stewardship program'' means a national pharmaceutical stewardship program with a certification in effect under subsection (f) or (g).

(4) The term ''controlled substance'' means a controlled substance (as such term is defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) in schedule II, III, IV, or V under section 202 of such Act (21 U.S.C. 812).

(5) The term ''covered drug'' means a drug (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is marketed in the United States other than—

(A) a drug for which a take-back program is in effect pursuant to a risk evaluation and

mitigation strategy under section 505–1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1);

(B) a vitamin or dietary supplement (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321));

(C) an herbal-based remedy or homeopathic drug, product, or remedy;

(D) a soap (with or without germicidal agents), laundry detergent, bleach, household cleaning product, shampoo, sunscreen, toothpaste, lip balm, antiperspirant, or other product that is regulated under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) exclusively as a cosmetic;

(E) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262)); or

(F) a pesticide (as defined in section 2 of the Federal Insecticide, Fungicide, and Rodenticide (7 U.S.C. 136)) that is contained in a collar, powder, shampoo, topical application, or other system for delivery or application to a pet.

(6) The term ''Organization'' means the National Pharmaceutical Stewardship Organization established in accordance with subsection (b).

(7) The term ''Secretary'' means the Secretary of Health and Human Services.

(8) The term ''ultimate user'' has the meaning given to such term in section 102 of the Controlled Substances Act (21 U.S.C. 802).

SEC. 3. COORDINATED EDUCATION CAMPAIGN ON DRUG DISPOSAL.

Not later than 18 months after the date of the enactment of this Act, the Director of the Office of National Drug Control Policy, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, shall establish and begin implementation of a coordinated education and outreach campaign—

(1) to increase awareness among members of the public regarding how drugs may be safely and securely disposed consistent with public safety, public health, and environmental protection through national pharmaceutical stewardship programs established under section 2 and by other appropriate means; and

(2) to link members of the public to the national and local educational and outreach activities conducted by such programs.