

116TH CONGRESS  
1ST SESSION

# H. R. 987

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IN THE SENATE OF THE UNITED STATES

MAY 20, 2019

Received; read twice and referred to the Committee on Health, Education,  
Labor, and Pensions

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## AN ACT

To amend the Patient Protection and Affordable Care Act to provide for Federal Exchange outreach and educational activities.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2       This Act may be cited as the “Strengthening Health  
3 Care and Lowering Prescription Drug Costs Act”.

4 **SEC. 2. TABLE OF CONTENTS.**

5       The table of contents of this Act is as follows:

- Sec. 1. Short title.  
Sec. 2. Table of contents.

TITLE I—LOWERING PRESCRIPTION DRUG COSTS

Subtitle A—Bringing Low-Cost Options and Competition While Keeping  
Incentives for New Generics

- Sec. 101. Change conditions of first generic exclusivity to spur access and competition.

Subtitle B—Protecting Consumer Access to Generic Drugs

- Sec. 111. Unlawful agreements.  
Sec. 112. Notice and certification of agreements.  
Sec. 113. Forfeiture of 180-day exclusivity period.  
Sec. 114. Commission litigation authority.  
Sec. 115. Statute of limitations.

Subtitle C—Creating and Restoring Equal Access to Equivalent Samples

- Sec. 121. Actions for delays of generic drugs and biosimilar biological products.  
Sec. 122. REMS approval process for subsequent filers.  
Sec. 123. Rule of construction.

Subtitle D—Study on Role of Federal Assistance in Drug Development

- Sec. 131. Study on role of Federal assistance in drug development.

Subtitle E—Pharmacy School Outreach

- Sec. 141. Pharmacy school outreach.

Subtitle F—Reports

- Sec. 151. Effects of increases in prescription drug price.

TITLE II—HEALTH INSURANCE MARKET STABILIZATION

- Sec. 201. Preserving State option to implement health care marketplaces.  
Sec. 202. Providing for additional requirements with respect to the navigator program.  
Sec. 203. Federal Exchange outreach and educational activities and annual enrollment targets.  
Sec. 204. Short-term limited duration insurance rule prohibition.  
Sec. 205. Protection of health insurance coverage in certain Exchanges.  
Sec. 206. Sense of Congress relating to the practice of silver loading.  
Sec. 207. Consumer outreach, education, and assistance.

Sec. 208. GAO report.

Sec. 209. Report on the effects of website maintenance during open enrollment.

TITLE III—BUDGETARY EFFECTS

Sec. 301. Determination of budgetary effects.

1                   **TITLE I—LOWERING**  
 2                   **PRESCRIPTION DRUG COSTS**  
 3                   **Subtitle A—Bringing Low-Cost Op-**  
 4                   **tions and Competition While**  
 5                   **Keeping Incentives for New**  
 6                   **Generics**

7                   **SEC. 101. CHANGE CONDITIONS OF FIRST GENERIC EXCLU-**  
 8                   **SIVITY TO SPUR ACCESS AND COMPETITION.**

9                   Section 505(j)(5)(B)(iv) of the Federal Food, Drug,  
 10                  and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) is amend-  
 11                  ed—

12                   (1) in subclause (I), by striking “180 days  
 13                   after” and all that follows through the period at the  
 14                   end and inserting the following: “180 days after the  
 15                   earlier of—

16   “(aa) the date of the first com-  
 17   mercial marketing of the drug (includ-  
 18   ing the commercial marketing of the  
 19   listed drug) by any first applicant; or  
 20   “(bb) the applicable date speci-  
 21   fied in subclause (III).”; and

22                   (2) by adding at the end the following new sub-  
 23                   clause:

1           “(III) APPLICABLE DATE.—The appli-  
2 cable date specified in this subclause, with  
3 respect to an application for a drug de-  
4 scribed in subclause (I), is the date on  
5 which each of the following conditions is  
6 first met:

7           “(aa) The approval of such an  
8 application could be made effective,  
9 but for the eligibility of a first appli-  
10 cant for 180-day exclusivity under  
11 this clause.

12           “(bb) At least 30 months have  
13 passed since the date of submission of  
14 an application for the drug by at least  
15 one first applicant.

16           “(cc) Approval of an application  
17 for the drug submitted by at least one  
18 first applicant is not precluded under  
19 clause (iii).

20           “(dd) No application for the drug  
21 submitted by any first applicant is ap-  
22 proved at the time the conditions  
23 under items (aa), (bb), and (cc) are  
24 all met, regardless of whether such an

1 application is subsequently ap-  
2 proved.”.

3 **Subtitle B—Protecting Consumer**  
4 **Access to Generic Drugs**

5 **SEC. 111. UNLAWFUL AGREEMENTS.**

6 (a) AGREEMENTS PROHIBITED.—Subject to sub-  
7 sections (b) and (c), it shall be unlawful for an NDA or  
8 BLA holder and a subsequent filer (or for two subsequent  
9 filers) to enter into, or carry out, an agreement resolving  
10 or settling a covered patent infringement claim on a final  
11 or interim basis if under such agreement—

12 (1) a subsequent filer directly or indirectly re-  
13 ceives from such holder (or in the case of such an  
14 agreement between two subsequent filers, the other  
15 subsequent filer) anything of value, including a li-  
16 cense; and

17 (2) the subsequent filer agrees to limit or fore-  
18 go research on, or development, manufacturing,  
19 marketing, or sales, for any period of time, of the  
20 covered product that is the subject of the application  
21 described in subparagraph (A) or (B) of subsection  
22 (g)(8).

23 (b) EXCLUSION.—It shall not be unlawful under sub-  
24 section (a) if a party to an agreement described in such  
25 subsection demonstrates by clear and convincing evidence

1 that the value described in subsection (a)(1) is compensa-  
2 tion solely for other goods or services that the subsequent  
3 filer has promised to provide.

4 (c) LIMITATION.—Nothing in this section shall pro-  
5 hibit an agreement resolving or settling a covered patent  
6 infringement claim in which the consideration granted by  
7 the NDA or BLA holder to the subsequent filer (or from  
8 one subsequent filer to another) as part of the resolution  
9 or settlement includes only one or more of the following:

10 (1) The right to market the covered product  
11 that is the subject of the application described in  
12 subparagraph (A) or (B) of subsection (g)(8) in the  
13 United States before the expiration of—

14 (A) any patent that is the basis of the cov-  
15 ered patent infringement claim; or

16 (B) any patent right or other statutory ex-  
17 clusivity that would prevent the marketing of  
18 such covered product.

19 (2) A payment for reasonable litigation ex-  
20 penses not to exceed \$7.5 million in the aggregate.

21 (3) A covenant not to sue on any claim that  
22 such covered product infringes a patent.

23 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
24 SION.—

1           (1) GENERAL APPLICATION.—The requirements  
2 of this section apply, according to their terms, to an  
3 NDA or BLA holder or subsequent filer that is—

4           (A) a person, partnership, or corporation  
5 over which the Commission has authority pur-  
6 suant to section 5(a)(2) of the Federal Trade  
7 Commission Act (15 U.S.C. 45(a)(2)); or

8           (B) a person, partnership, or corporation  
9 over which the Commission would have author-  
10 ity pursuant to such section but for the fact  
11 that such person, partnership, or corporation is  
12 not organized to carry on business for its own  
13 profit or that of its members.

14           (2) UNFAIR OR DECEPTIVE ACTS OR PRACTICES  
15 ENFORCEMENT AUTHORITY.—

16           (A) IN GENERAL.—A violation of this sec-  
17 tion shall be treated as an unfair or deceptive  
18 act or practice in violation of section 5(a)(1) of  
19 the Federal Trade Commission Act (15 U.S.C.  
20 45(a)(1)).

21           (B) POWERS OF COMMISSION.—Except as  
22 provided in subparagraph (C) and paragraphs  
23 (1)(B) and (3)—

24           (i) the Commission shall enforce this  
25 section in the same manner, by the same

1 means, and with the same jurisdiction,  
2 powers, and duties as though all applicable  
3 terms and provisions of the Federal Trade  
4 Commission Act (15 U.S.C. 41 et seq.)  
5 were incorporated into and made a part of  
6 this section; and

7 (ii) any NDA or BLA holder or subse-  
8 quent filer that violates this section shall  
9 be subject to the penalties and entitled to  
10 the privileges and immunities provided in  
11 the Federal Trade Commission Act.

12 (C) JUDICIAL REVIEW.—In the case of a  
13 cease and desist order issued by the Commis-  
14 sion under section 5 of the Federal Trade Com-  
15 mission Act (15 U.S.C. 45) for violation of this  
16 section, a party to such order may obtain judi-  
17 cial review of such order as provided in such  
18 section 5, except that—

19 (i) such review may only be obtained  
20 in—

21 (I) the United States Court of  
22 Appeals for the District of Columbia  
23 Circuit;

24 (II) the United States Court of  
25 Appeals for the circuit in which the



1 ultimate parent entity, as defined in  
2 section 801.1(a)(3) of title 16, Code  
3 of Federal Regulations, or any suc-  
4 cessor thereto, of the NDA or BLA  
5 holder (if any such holder is a party  
6 to such order) is incorporated as of  
7 the date that the application described  
8 in subparagraph (A) or (B) of sub-  
9 section (g)(8) or an approved applica-  
10 tion that is deemed to be a license for  
11 a biological product under section  
12 351(k) of the Public Health Service  
13 Act (42 U.S.C. 262(k)) pursuant to  
14 section 7002(e)(4) of the Biologics  
15 Price Competition and Innovation Act  
16 of 2009 (Public Law 111–148; 124  
17 Stat. 817) is submitted to the Com-  
18 missioner of Food and Drugs; or

19 (III) the United States Court of  
20 Appeals for the circuit in which the  
21 ultimate parent entity, as so defined,  
22 of any subsequent filer that is a party  
23 to such order is incorporated as of the  
24 date that the application described in  
25 subparagraph (A) or (B) of subsection

1 (g)(8) is submitted to the Commis-  
2 sioner of Food and Drugs; and

3 (ii) the petition for review shall be  
4 filed in the court not later than 30 days  
5 after such order is served on the party  
6 seeking review.

7 (3) ADDITIONAL ENFORCEMENT AUTHORITY.—

8 (A) CIVIL PENALTY.—The Commission  
9 may commence a civil action to recover a civil  
10 penalty in a district court of the United States  
11 against any NDA or BLA holder or subsequent  
12 filer that violates this section.

13 (B) SPECIAL RULE FOR RECOVERY OF  
14 PENALTY IF CEASE AND DESIST ORDER  
15 ISSUED.—

16 (i) IN GENERAL.—If the Commission  
17 has issued a cease and desist order in a  
18 proceeding under section 5 of the Federal  
19 Trade Commission Act (15 U.S.C. 45) for  
20 violation of this section—

21 (I) the Commission may com-  
22 mence a civil action under subpara-  
23 graph (A) to recover a civil penalty  
24 against any party to such order at  
25 any time before the expiration of the

1 1-year period beginning on the date  
2 on which such order becomes final  
3 under section 5(g) of such Act (15  
4 U.S.C. 45(g)); and

5 (II) in such civil action, the find-  
6 ings of the Commission as to the ma-  
7 terial facts in such proceeding shall be  
8 conclusive, unless—

9 (aa) the terms of such order  
10 expressly provide that the Com-  
11 mission's findings shall not be  
12 conclusive; or

13 (bb) such order became final  
14 by reason of section 5(g)(1) of  
15 such Act (15 U.S.C. 45(g)(1)), in  
16 which case such findings shall be  
17 conclusive if supported by evi-  
18 dence.

19 (ii) RELATIONSHIP TO PENALTY FOR  
20 VIOLATION OF AN ORDER.—The penalty  
21 provided in clause (i) for violation of this  
22 section is separate from and in addition to  
23 any penalty that may be incurred for viola-  
24 tion of an order of the Commission under

1 section 5(l) of the Federal Trade Commis-  
2 sion Act (15 U.S.C. 45(l)).

3 (C) AMOUNT OF PENALTY.—

4 (i) IN GENERAL.—The amount of a  
5 civil penalty imposed in a civil action under  
6 subparagraph (A) on a party to an agree-  
7 ment described in subsection (a) shall be  
8 sufficient to deter violations of this section,  
9 but in no event greater than—

10 (I) if such party is the NDA or  
11 BLA holder (or, in the case of an  
12 agreement between two subsequent fil-  
13 ers, the subsequent filer who gave the  
14 value described in subsection (a)(1)),  
15 the greater of—

16 (aa) three times the value  
17 received by such NDA or BLA  
18 holder (or by such subsequent  
19 filer) that is reasonably attrib-  
20 utable to the violation of this sec-  
21 tion; or

22 (bb) three times the value  
23 given to the subsequent filer (or  
24 to the other subsequent filer)

1 reasonably attributable to the  
2 violation of this section; and

3 (II) if such party is the subse-  
4 quent filer (or, in the case of an  
5 agreement between two subsequent fil-  
6 ers, the subsequent filer who received  
7 the value described in subsection  
8 (a)(1)), 3 times the value received by  
9 such subsequent filer that is reason-  
10 ably attributable to the violation of  
11 this section.

12 (ii) FACTORS FOR CONSIDERATION.—

13 In determining such amount, the court  
14 shall take into account—

15 (I) the nature, circumstances, ex-  
16 tent, and gravity of the violation;

17 (II) with respect to the violator,  
18 the degree of culpability, any history  
19 of violations, the ability to pay, any  
20 effect on the ability to continue doing  
21 business, profits earned by the NDA  
22 or BLA holder (or, in the case of an  
23 agreement between two subsequent fil-  
24 ers, the subsequent filer who gave the  
25 value described in subsection (a)(1)),

1 compensation received by the subse-  
2 quent filer (or, in the case of an  
3 agreement between two subsequent fil-  
4 ers, the subsequent filer who received  
5 the value described in subsection  
6 (a)(1)), and the amount of commerce  
7 affected; and

8 (III) other matters that justice  
9 requires.

10 (D) INJUNCTIONS AND OTHER EQUITABLE  
11 RELIEF.—In a civil action under subparagraph  
12 (A), the United States district courts are em-  
13 powered to grant mandatory injunctions and  
14 such other and further equitable relief as they  
15 deem appropriate.

16 (4) REMEDIES IN ADDITION.—Remedies pro-  
17 vided in this subsection are in addition to, and not  
18 in lieu of, any other remedy provided by Federal  
19 law.

20 (5) PRESERVATION OF AUTHORITY OF COMMIS-  
21 SION.—Nothing in this section shall be construed to  
22 affect any authority of the Commission under any  
23 other provision of law.

24 (e) FEDERAL TRADE COMMISSION RULEMAKING.—  
25 The Commission may, in its discretion, by rule promul-

1 gated under section 553 of title 5, United States Code,  
2 exempt from this section certain agreements described in  
3 subsection (a) if the Commission finds such agreements  
4 to be in furtherance of market competition and for the  
5 benefit of consumers.

6 (f) ANTITRUST LAWS.—Nothing in this section shall  
7 modify, impair, limit, or supersede the applicability of the  
8 antitrust laws as defined in subsection (a) of the first sec-  
9 tion of the Clayton Act (15 U.S.C. 12(a)), and of section  
10 5 of the Federal Trade Commission Act (15 U.S.C. 45)  
11 to the extent that such section 5 applies to unfair methods  
12 of competition. Nothing in this section shall modify, im-  
13 pair, limit, or supersede the right of a subsequent filer  
14 to assert claims or counterclaims against any person,  
15 under the antitrust laws or other laws relating to unfair  
16 competition.

17 (g) DEFINITIONS.—In this section:

18 (1) AGREEMENT RESOLVING OR SETTLING A  
19 COVERED PATENT INFRINGEMENT CLAIM.—The  
20 term “agreement resolving or settling a covered pat-  
21 ent infringement claim” means any agreement  
22 that—

23 (A) resolves or settles a covered patent in-  
24 fringement claim; or

1 (B) is contingent upon, provides for a con-  
2 tingent condition for, or is otherwise related to  
3 the resolution or settlement of a covered patent  
4 infringement claim.

5 (2) COMMISSION.—The term “Commission”  
6 means the Federal Trade Commission.

7 (3) COVERED PATENT INFRINGEMENT CLAIM.—  
8 The term “covered patent infringement claim”  
9 means an allegation made by the NDA or BLA hold-  
10 er to a subsequent filer (or, in the case of an agree-  
11 ment between two subsequent filers, by one subse-  
12 quent filer to another), whether or not included in  
13 a complaint filed with a court of law, that—

14 (A) the submission of the application de-  
15 scribed in subparagraph (A) or (B) of para-  
16 graph (9), or the manufacture, use, offering for  
17 sale, sale, or importation into the United States  
18 of a covered product that is the subject of such  
19 an application—

20 (i) in the case of an agreement be-  
21 tween an NDA or BLA holder and a sub-  
22 sequent filer, infringes any patent owned  
23 by, or exclusively licensed to, the NDA or  
24 BLA holder of the covered product; or



1 (ii) in the case of an agreement be-  
2 tween two subsequent filers, infringes any  
3 patent owned by the subsequent filer; or

4 (B) in the case of an agreement between  
5 an NDA or BLA holder and a subsequent filer,  
6 the covered product to be manufactured under  
7 such application uses a covered product as  
8 claimed in a published patent application.

9 (4) COVERED PRODUCT.—The term “covered  
10 product” means a drug (as defined in section 201(g)  
11 of the Federal Food, Drug, and Cosmetic Act (21  
12 U.S.C. 321(g))), including a biological product (as  
13 defined in section 351(i) of the Public Health Serv-  
14 ice Act (42 U.S.C. 262(i)).

15 (5) NDA OR BLA HOLDER.—The term “NDA  
16 or BLA holder” means—

17 (A) the holder of—

18 (i) an approved new drug application  
19 filed under section 505(b)(1) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21  
21 U.S.C. 355(b)(1)) for a covered product;

22 or

23 (ii) a biologics license application filed  
24 under section 351(a) of the Public Health

1 Service Act (42 U.S.C. 262(a)) with re-  
2 spect to a biological product;

3 (B) a person owning or controlling enforce-  
4 ment of the patent on—

5 (i) the list published under section  
6 505(j)(7) of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 355(j)(7)) in con-  
8 nection with the application described in  
9 subparagraph (A)(i); or

10 (ii) any list published under section  
11 351 of the Public Health Service Act (42  
12 U.S.C. 262) comprised of patents associ-  
13 ated with biologics license applications filed  
14 under section 351(a) of such Act (42  
15 U.S.C. 262(a)); or

16 (C) the predecessors, subsidiaries, divi-  
17 sions, groups, and affiliates controlled by, con-  
18 trolling, or under common control with any en-  
19 tity described in subparagraph (A) or (B) (such  
20 control to be presumed by direct or indirect  
21 share ownership of 50 percent or greater), as  
22 well as the licensees, licensors, successors, and  
23 assigns of each of the entities.

1           (6) PATENT.—The term “patent” means a pat-  
2           ent issued by the United States Patent and Trade-  
3           mark Office.

4           (7) STATUTORY EXCLUSIVITY.—The term  
5           “statutory exclusivity” means those prohibitions on  
6           the submission or approval of drug applications  
7           under clauses (ii) through (iv) of section  
8           505(c)(3)(E) (5- and 3-year exclusivity), clauses (ii)  
9           through (iv) of section 505(j)(5)(F) (5-year and 3-  
10          year exclusivity), section 505(j)(5)(B)(iv) (180-day  
11          exclusivity), section 527 (orphan drug exclusivity),  
12          section 505A (pediatric exclusivity), or section 505E  
13          (qualified infectious disease product exclusivity) of  
14          the Federal Food, Drug, and Cosmetic Act (21  
15          U.S.C. 355(c)(3)(E), 355(j)(5)(B)(iv), 355(j)(5)(F),  
16          360cc, 355a, 355f), or prohibitions on the submis-  
17          sion or licensing of biologics license applications  
18          under section 351(k)(6) (interchangeable biological  
19          product exclusivity) or section 351(k)(7) (biological  
20          product reference product exclusivity) of the Public  
21          Health Service Act (42 U.S.C. 262(k)(6), (7)).

22          (8) SUBSEQUENT FILER.—The term “subse-  
23          quent filer” means—

24                 (A) in the case of a drug, a party that  
25                 owns or controls an abbreviated new drug appli-

1 cation submitted pursuant to section 505(j) of  
2 the Federal Food, Drug, and Cosmetic Act (21  
3 U.S.C. 355(j)) or a new drug application sub-  
4 mitted pursuant to section 505(b)(2) of the  
5 Federal Food, Drug, and Cosmetic Act  
6 (21U.S.C. 355(b)(2)) and filed under section  
7 505(b)(1) of such Act (21 U.S.C. 355(b)(1)) or  
8 has the exclusive rights to distribute the cov-  
9 ered product that is the subject of such applica-  
10 tion; or

11 (B) in the case of a biological product, a  
12 party that owns or controls an application filed  
13 with the Food and Drug Administration under  
14 section 351(k) of the Public Health Service Act  
15 (42 U.S.C. 262(k)) or has the exclusive rights  
16 to distribute the biological product that is the  
17 subject of such application.

18 (h) EFFECTIVE DATE.—This section applies with re-  
19 spect to agreements described in subsection (a) entered  
20 into on or after the date of the enactment of this Act.

21 **SEC. 112. NOTICE AND CERTIFICATION OF AGREEMENTS.**

22 (a) NOTICE OF ALL AGREEMENTS.—Section 1111(7)  
23 of the Medicare Prescription Drug, Improvement, and  
24 Modernization Act of 2003 (21 U.S.C. 355 note) is  
25 amended by inserting “or the owner of a patent for which

1 a claim of infringement could reasonably be asserted  
2 against any person for making, using, offering to sell, sell-  
3 ing, or importing into the United States a biological prod-  
4 uct that is the subject of a biosimilar biological product  
5 application” before the period at the end.

6 (b) CERTIFICATION OF AGREEMENTS.—Section 1112  
7 of such Act (21 U.S.C. 355 note) is amended by adding  
8 at the end the following:

9 “(d) CERTIFICATION.—The Chief Executive Officer  
10 or the company official responsible for negotiating any  
11 agreement under subsection (a) or (b) that is required to  
12 be filed under subsection (c) shall, within 30 days of such  
13 filing, execute and file with the Assistant Attorney General  
14 and the Commission a certification as follows: ‘I declare  
15 that the following is true, correct, and complete to the best  
16 of my knowledge: The materials filed with the Federal  
17 Trade Commission and the Department of Justice under  
18 section 1112 of the Medicare Prescription Drug, Improve-  
19 ment, and Modernization Act of 2003, with respect to the  
20 agreement referenced in this certification—

21 “(1) represent the complete, final, and exclu-  
22 sive agreement between the parties;

23 “(2) include any ancillary agreements that are  
24 contingent upon, provide a contingent condition for,

1 were entered into within 30 days of, or are otherwise  
2 related to, the referenced agreement; and

3 ““(3) include written descriptions of any oral  
4 agreements, representations, commitments, or prom-  
5 ises between the parties that are responsive to sub-  
6 section (a) or (b) of such section 1112 and have not  
7 been reduced to writing.’”.

8 **SEC. 113. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

9 Section 505(j)(5)(D)(i)(V) of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V))  
11 is amended by inserting “section 111 of the Strengthening  
12 Health Care and Lowering Prescription Drug Costs Act  
13 or” after “that the agreement has violated”.

14 **SEC. 114. COMMISSION LITIGATION AUTHORITY.**

15 Section 16(a)(2) of the Federal Trade Commission  
16 Act (15 U.S.C. 56(a)(2)) is amended—

17 (1) in subparagraph (D), by striking “or” after  
18 the semicolon;

19 (2) in subparagraph (E), by inserting “or”  
20 after the semicolon; and

21 (3) by inserting after subparagraph (E) the fol-  
22 lowing:

23 “(F) under section 111(d)(3)(A) of the  
24 Strengthening Health Care and Lowering Pre-  
25 scription Drug Costs Act;”.

1 **SEC. 115. STATUTE OF LIMITATIONS.**

2 (a) IN GENERAL.—Except as provided in subsection  
3 (b), the Commission shall commence any administrative  
4 proceeding or civil action to enforce section 111 of this  
5 Act not later than 6 years after the date on which the  
6 parties to the agreement file the Notice of Agreement as  
7 provided by section 1112(c)(2) and (d) of the Medicare  
8 Prescription Drug, Improvement, and Modernization Act  
9 of 2003 (21 U.S.C. 355 note).

10 (b) CIVIL ACTION AFTER ISSUANCE OF CEASE AND  
11 DESIST ORDER.—If the Commission has issued a cease  
12 and desist order under section 5 of the Federal Trade  
13 Commission Act (15 U.S.C. 45) for violation of section  
14 111 of this Act and the proceeding for the issuance of  
15 such order was commenced within the period required by  
16 subsection (a) of this section, such subsection does not  
17 prohibit the commencement, after such period, of a civil  
18 action under section 111(d)(3)(A) against a party to such  
19 order or a civil action under subsection (l) of such section  
20 5 for violation of such order.

21 **Subtitle C—Creating and Restoring**  
22 **Equal Access to Equivalent**  
23 **Samples**

24 **SEC. 121. ACTIONS FOR DELAYS OF GENERIC DRUGS AND**  
25 **BIOSIMILAR BIOLOGICAL PRODUCTS.**

26 (a) DEFINITIONS.—In this section—

1           (1) the term “commercially reasonable, market-  
2 based terms” means—

3           (A) a nondiscriminatory price for the sale  
4 of the covered product at or below, but not  
5 greater than, the most recent wholesale acquisi-  
6 tion cost for the drug, as defined in section  
7 1847A(c)(6)(B) of the Social Security Act (42  
8 U.S.C. 1395w–3a(c)(6)(B));

9           (B) a schedule for delivery that results in  
10 the transfer of the covered product to the eligi-  
11 ble product developer consistent with the timing  
12 under subsection (b)(2)(A)(iv); and

13           (C) no additional conditions are imposed  
14 on the sale of the covered product;

15       (2) the term “covered product”—

16           (A) means—

17           (i) any drug approved under sub-  
18 section (c) or (j) of section 505 of the Fed-  
19 eral Food, Drug, and Cosmetic Act (21  
20 U.S.C. 355) or biological product licensed  
21 under subsection (a) or (k) of section 351  
22 of the Public Health Service Act (42  
23 U.S.C. 262);

24           (ii) any combination of a drug or bio-  
25 logical product described in clause (i); or



1 (iii) when reasonably necessary to  
2 support approval of an application under  
3 section 505 of the Federal Food, Drug,  
4 and Cosmetic Act (21 U.S.C. 355), or sec-  
5 tion 351 of the Public Health Service Act  
6 (42 U.S.C. 262), as applicable, or other-  
7 wise meet the requirements for approval  
8 under either such section, any product, in-  
9 cluding any device, that is marketed or in-  
10 tended for use with such a drug or biologi-  
11 cal product; and

12 (B) does not include any drug or biological  
13 product that appears on the drug shortage list  
14 in effect under section 506E of the Federal  
15 Food, Drug, and Cosmetic Act (21 U.S.C.  
16 356e), unless—

17 (i) the drug or biological product has  
18 been on the drug shortage list in effect  
19 under such section 506E continuously for  
20 more than 6 months; or

21 (ii) the Secretary determines that in-  
22 clusion of the drug or biological product as  
23 a covered product is likely to contribute to  
24 alleviating or preventing a shortage.

1           (3) the term “device” has the meaning given  
2 the term in section 201 of the Federal Food, Drug,  
3 and Cosmetic Act (21 U.S.C. 321);

4           (4) the term “eligible product developer” means  
5 a person that seeks to develop a product for ap-  
6 proval pursuant to an application for approval under  
7 subsection (b)(2) or (j) of section 505 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or  
9 for licensing pursuant to an application under sec-  
10 tion 351(k) of the Public Health Service Act (42  
11 U.S.C. 262(k));

12           (5) the term “license holder” means the holder  
13 of an application approved under subsection (c) or  
14 (j) of section 505 of the Federal Food, Drug, and  
15 Cosmetic Act (21 U.S.C. 355) or the holder of a li-  
16 cense under subsection (a) or (k) of section 351 of  
17 the Public Health Service Act (42 U.S.C. 262) for  
18 a covered product;

19           (6) the term “REMS” means a risk evaluation  
20 and mitigation strategy under section 505–1 of the  
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 355–1);

23           (7) the term “REMS with ETASU” means a  
24 REMS that contains elements to assure safe use

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

3 (8) the term “Secretary” means the Secretary  
4 of Health and Human Services;

5 (9) the term “single, shared system of elements  
6 to assure safe use” means a single, shared system  
7 of elements to assure safe use under section 505–  
8 1(f) of the Federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. 355–1(f)); and

10 (10) the term “sufficient quantities” means an  
11 amount of a covered product that the eligible prod-  
12 uct developer determines allows it to—

13 (A) conduct testing to support an applica-  
14 tion under—

15 (i) subsection (b)(2) or (j) of section  
16 505 of the Federal Food, Drug, and Cos-  
17 metic Act (21 U.S.C. 355); or

18 (ii) section 351(k) of the Public  
19 Health Service Act (42 U.S.C. 262(k));  
20 and

21 (B) fulfill any regulatory requirements re-  
22 lating to approval of such an application.

23 (b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFI-  
24 CIENT QUANTITIES OF A COVERED PRODUCT.—

1           (1) IN GENERAL.—An eligible product developer  
2           may bring a civil action against the license holder  
3           for a covered product seeking relief under this sub-  
4           section in an appropriate district court of the United  
5           States alleging that the license holder has declined  
6           to provide sufficient quantities of the covered prod-  
7           uct to the eligible product developer on commercially  
8           reasonable, market-based terms.

9           (2) ELEMENTS.—

10           (A) IN GENERAL.—To prevail in a civil ac-  
11           tion brought under paragraph (1), an eligible  
12           product developer shall prove, by a preponder-  
13           ance of the evidence—

14           (i) that—

15           (I) the covered product is not  
16           subject to a REMS with ETASU; or

17           (II) if the covered product is sub-  
18           ject to a REMS with ETASU—

19           (aa) the eligible product de-  
20           veloper has obtained a covered  
21           product authorization from the  
22           Secretary in accordance with sub-  
23           paragraph (B); and

24           (bb) the eligible product de-  
25           veloper has provided a copy of

1 the covered product authorization  
2 to the license holder;

3 (ii) that, as of the date on which the  
4 civil action is filed, the product developer  
5 has not obtained sufficient quantities of  
6 the covered product on commercially rea-  
7 sonable, market-based terms;

8 (iii) that the eligible product developer  
9 has submitted a written request to pur-  
10 chase sufficient quantities of the covered  
11 product to the license holder and such re-  
12 quest—

13 (I) was sent to a named cor-  
14 porate officer of the license holder;

15 (II) was made by certified or reg-  
16 istered mail with return receipt re-  
17 quested;

18 (III) specified an individual as  
19 the point of contact for the license  
20 holder to direct communications re-  
21 lated to the sale of the covered prod-  
22 uct to the eligible product developer  
23 and a means for electronic and writ-  
24 ten communications with that indi-  
25 vidual; and

1 (IV) specified an address to  
2 which the covered product was to be  
3 shipped upon reaching an agreement  
4 to transfer the covered product; and

5 (iv) that the license holder has not de-  
6 livered to the eligible product developer  
7 sufficient quantities of the covered product  
8 on commercially reasonable, market-based  
9 terms—

10 (I) for a covered product that is  
11 not subject to a REMS with ETASU,  
12 by the date that is 31 days after the  
13 date on which the license holder re-  
14 ceived the request for the covered  
15 product; and

16 (II) for a covered product that is  
17 subject to a REMS with ETASU, by  
18 31 days after the later of—

19 (aa) the date on which the  
20 license holder received the re-  
21 quest for the covered product; or

22 (bb) the date on which the  
23 license holder received a copy of  
24 the covered product authorization

1 issued by the Secretary in ac-  
2 cordance with subparagraph (B).

3 (B) AUTHORIZATION FOR COVERED PROD-  
4 UCT SUBJECT TO A REMS WITH ETASU.—

5 (i) REQUEST.—An eligible product de-  
6 veloper may submit to the Secretary a  
7 written request for the eligible product de-  
8 veloper to be authorized to obtain suffi-  
9 cient quantities of an individual covered  
10 product subject to a REMS with ETASU.

11 (ii) AUTHORIZATION.—Not later than  
12 120 days after the date on which a request  
13 under clause (i) is received, the Secretary  
14 shall, by written notice, authorize the eligi-  
15 ble product developer to obtain sufficient  
16 quantities of an individual covered product  
17 subject to a REMS with ETASU for pur-  
18 poses of—

19 (I) development and testing that  
20 does not involve human clinical trials,  
21 if the eligible product developer has  
22 agreed to comply with any conditions  
23 the Secretary determines necessary; or

1 (II) development and testing that  
2 involves human clinical trials, if the  
3 eligible product developer has—

4 (aa)(AA) submitted proto-  
5 cols, informed consent docu-  
6 ments, and informational mate-  
7 rials for testing that include pro-  
8 tections that provide safety pro-  
9 tections comparable to those pro-  
10 vided by the REMS for the cov-  
11 ered product; or

12 (BB) otherwise satisfied the  
13 Secretary that such protections  
14 will be provided; and

15 (bb) met any other require-  
16 ments the Secretary may estab-  
17 lish.

18 (iii) NOTICE.—A covered product au-  
19 thorization issued under this subparagraph  
20 shall state that the provision of the covered  
21 product by the license holder under the  
22 terms of the authorization will not be a  
23 violation of the REMS for the covered  
24 product.



1           (3) AFFIRMATIVE DEFENSE.—In a civil action  
2 brought under paragraph (1), it shall be an affirma-  
3 tive defense, on which the defendant has the burden  
4 of persuasion by a preponderance of the evidence—

5           (A) that, on the date on which the eligible  
6 product developer requested to purchase suffi-  
7 cient quantities of the covered product from the  
8 license holder—

9           (i) neither the license holder nor any  
10 of its agents, wholesalers, or distributors  
11 was engaged in the manufacturing or com-  
12 mercial marketing of the covered product;  
13 and

14           (ii) neither the license holder nor any  
15 of its agents, wholesalers, or distributors  
16 otherwise had access to inventory of the  
17 covered product to supply to the eligible  
18 product developer on commercially reason-  
19 able, market-based terms;

20           (B) that—

21           (i) the license holder sells the covered  
22 product through agents, distributors, or  
23 wholesalers;

24           (ii) the license holder has placed no  
25 restrictions, explicit or implicit, on its

1 agents, distributors, or wholesalers to sell  
2 covered products to eligible product devel-  
3 opers; and

4 (iii) the covered product can be pur-  
5 chased by the eligible product developer in  
6 sufficient quantities on commercially rea-  
7 sonable, market-based terms from the  
8 agents, distributors, or wholesalers of the  
9 license holder; or

10 (C) that the license holder made an offer  
11 to the individual specified pursuant to para-  
12 graph (2)(A)(iii)(III), by a means of commu-  
13 nication (electronic, written, or both) specified  
14 pursuant to such paragraph, to sell sufficient  
15 quantities of the covered product to the eligible  
16 product developer at commercially reasonable  
17 market-based terms—

18 (i) for a covered product that is not  
19 subject to a REMS with ETASU, by the  
20 date that is 14 days after the date on  
21 which the license holder received the re-  
22 quest for the covered product, and the eli-  
23 gible product developer did not accept such  
24 offer by the date that is 7 days after the  
25 date on which the eligible product devel-

1           oper received such offer from the license  
2           holder; or

3                   (ii) for a covered product that is sub-  
4           ject to a REMS with ETASU, by the date  
5           that is 20 days after the date on which the  
6           license holder received the request for the  
7           covered product, and the eligible product  
8           developer did not accept such offer by the  
9           date that is 10 days after the date on  
10          which the eligible product developer re-  
11          ceived such offer from the license holder.

12          (4) REMEDIES.—

13                   (A) IN GENERAL.—If an eligible product  
14          developer prevails in a civil action brought  
15          under paragraph (1), the court shall—

16                           (i) order the license holder to provide  
17          to the eligible product developer without  
18          delay sufficient quantities of the covered  
19          product on commercially reasonable, mar-  
20          ket-based terms;

21                           (ii) award to the eligible product de-  
22          veloper reasonable attorney’s fees and costs  
23          of the civil action; and

24                           (iii) award to the eligible product de-  
25          veloper a monetary amount sufficient to

1           deter the license holder from failing to pro-  
2           vide eligible product developers with suffi-  
3           cient quantities of a covered product on  
4           commercially reasonable, market-based  
5           terms, if the court finds, by a preponder-  
6           ance of the evidence—

7                   (I) that the license holder delayed  
8                   providing sufficient quantities of the  
9                   covered product to the eligible product  
10                  developer without a legitimate busi-  
11                  ness justification; or

12                  (II) that the license holder failed  
13                  to comply with an order issued under  
14                  clause (i).

15           (B) **MAXIMUM MONETARY AMOUNT.**—A  
16           monetary amount awarded under subparagraph  
17           (A)(iii) shall not be greater than the revenue  
18           that the license holder earned on the covered  
19           product during the period—

20                   (i) beginning on—

21                   (I) for a covered product that is  
22                   not subject to a REMS with ETASU,  
23                   the date that is 31 days after the date  
24                   on which the license holder received  
25                   the request; or

1 (II) for a covered product that is  
2 subject to a REMS with ETASU, the  
3 date that is 31 days after the later  
4 of—

5 (aa) the date on which the  
6 license holder received the re-  
7 quest; or

8 (bb) the date on which the  
9 license holder received a copy of  
10 the covered product authorization  
11 issued by the Secretary in ac-  
12 cordance with paragraph (2)(B);  
13 and

14 (ii) ending on the date on which the  
15 eligible product developer received suffi-  
16 cient quantities of the covered product.

17 (C) AVOIDANCE OF DELAY.—The court  
18 may issue an order under subparagraph (A)(i)  
19 before conducting further proceedings that may  
20 be necessary to determine whether the eligible  
21 product developer is entitled to an award under  
22 clause (ii) or (iii) of subparagraph (A), or the  
23 amount of any such award.

24 (c) LIMITATION OF LIABILITY.—A license holder for  
25 a covered product shall not be liable for any claim under

1 Federal, State, or local law arising out of the failure of  
2 an eligible product developer to follow adequate safeguards  
3 to assure safe use of the covered product during develop-  
4 ment or testing activities described in this section, includ-  
5 ing transportation, handling, use, or disposal of the cov-  
6 ered product by the eligible product developer.

7 (d) NO VIOLATION OF REMS.—Section 505–1 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–  
9 1) is amended by adding at the end the following new sub-  
10 section:

11 “(1) PROVISION OF SAMPLES NOT A VIOLATION OF  
12 STRATEGY.—The provision of samples of a covered prod-  
13 uct to an eligible product developer (as those terms are  
14 defined in section 121(a) of the Strengthening Health  
15 Care and Lowering Prescription Drug Costs Act) shall not  
16 be considered a violation of the requirements of any risk  
17 evaluation and mitigation strategy that may be in place  
18 under this section for such drug.”.

19 (e) RULE OF CONSTRUCTION.—

20 (1) DEFINITION.—In this subsection, the term  
21 “antitrust laws”—

22 (A) has the meaning given the term in  
23 subsection (a) of the first section of the Clayton  
24 Act (15 U.S.C. 12); and

1 (B) includes section 5 of the Federal  
2 Trade Commission Act (15 U.S.C. 45) to the  
3 extent that such section applies to unfair meth-  
4 ods of competition.

5 (2) ANTITRUST LAWS.—Nothing in this section  
6 shall be construed to limit the operation of any pro-  
7 vision of the antitrust laws.

8 **SEC. 122. REMS APPROVAL PROCESS FOR SUBSEQUENT**  
9 **FILERS.**

10 Section 505–1 of the Federal Food, Drug, and Cos-  
11 metic Act (21 U.S.C. 355–1), as amended by section 121,  
12 is further amended—

13 (1) in subsection (g)(4)(B)—

14 (A) in clause (i) by striking “or” after the  
15 semicolon;

16 (B) in clause (ii) by striking the period at  
17 the end and inserting “; or”; and

18 (C) by adding at the end the following:

19 “(iii) accommodate different, com-  
20 parable aspects of the elements to assure  
21 safe use for a drug that is the subject of  
22 an application under section 505(j), and  
23 the applicable listed drug.”;

24 (2) in subsection (i)(1), by striking subpara-  
25 graph (C) and inserting the following:

1           “(C)(i) Elements to assure safe use, if re-  
2           quired under subsection (f) for the listed drug,  
3           which, subject to clause (ii), for a drug that is  
4           the subject of an application under section  
5           505(j) may use—

6                     “(I) a single, shared system with the  
7                     listed drug under subsection (f); or

8                     “(II) a different, comparable aspect of  
9                     the elements to assure safe use under sub-  
10                    section (f).

11                   “(ii) The Secretary may require a drug  
12                   that is the subject of an application under sec-  
13                   tion 505(j) and the listed drug to use a single,  
14                   shared system under subsection (f), if the Sec-  
15                   retary determines that no different, comparable  
16                   aspect of the elements to assure safe use could  
17                   satisfy the requirements of subsection (f).”;

18                   (3) in subsection (i), by adding at the end the  
19                   following:

20                   “(3) SHARED REMS.—If the Secretary ap-  
21                   proves, in accordance with paragraph (1)(C)(i)(II), a  
22                   different, comparable aspect of the elements to as-  
23                   sure safe use under subsection (f) for a drug that  
24                   is the subject of an abbreviated new drug application  
25                   under section 505(j), the Secretary may require that



1 such different comparable aspect of the elements to  
2 assure safe use can be used with respect to any  
3 other drug that is the subject of an application  
4 under section 505(j) or 505(b) that references the  
5 same listed drug.”; and

6 (4) by adding at the end the following:

7 “(m) SEPARATE REMS.—When used in this section,  
8 the terms ‘different, comparable aspect of the elements to  
9 assure safe use’ or ‘different, comparable approved risk  
10 evaluation and mitigation strategies’ means a risk evalua-  
11 tion and mitigation strategy for a drug that is the subject  
12 of an application under section 505(j) that uses different  
13 methods or operational means than the strategy required  
14 under subsection (a) for the applicable listed drug, or  
15 other application under section 505(j) with the same such  
16 listed drug, but achieves the same level of safety as such  
17 strategy.”.

18 **SEC. 123. RULE OF CONSTRUCTION.**

19 (a) IN GENERAL.—Nothing in this subtitle, the  
20 amendments made by this subtitle, or in section 505–1  
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 355–1), shall be construed as—

23 (1) prohibiting a license holder from providing  
24 an eligible product developer access to a covered

1 product in the absence of an authorization under  
2 this subtitle; or

3 (2) in any way negating the applicability of a  
4 REMS with ETASU, as otherwise required under  
5 such section 505–1, with respect to such covered  
6 product.

7 (b) DEFINITIONS.—In this section, the terms “cov-  
8 ered product”, “eligible product developer”, “license hold-  
9 er”, and “REMS with ETASU” have the meanings given  
10 such terms in section 121(a).

11 **Subtitle D—Study on Role of Fed-  
12 eral Assistance in Drug Devel-  
13 opment**

14 **SEC. 131. STUDY ON ROLE OF FEDERAL ASSISTANCE IN  
15 DRUG DEVELOPMENT.**

16 (a) IN GENERAL.—Not later than 2 years after the  
17 date of the enactment of this Act, the Secretary of the  
18 Health and Human Services shall enter into a contract  
19 with the National Academy of Medicine to conduct a study  
20 on, and submit to Congress a report on, the following:

21 (1) The percentage of drugs developed in the  
22 United States using at least some amount of Federal  
23 funding from any Federal source.

24 (2) The average cost incurred by a drug devel-  
25 oper to develop a drug.

1           (3) The average amount of revenue and profits  
2           made by drug developers from the sales of drugs.

3           (4) The percentage of such revenue and profits  
4           that are reinvested into research and development of  
5           new drugs.

6           (5) The appropriate percentage, if any, of such  
7           revenue and profits the Secretary, in consultation  
8           with the National Academy of Medicine, rec-  
9           ommends should be returned to Federal entities for  
10          Federal funding used in the development of the  
11          drugs involved.

12          (b) ENFORCEMENT.—A drug developer shall, as a  
13          condition of receipt of any Federal funding for the devel-  
14          opment of drugs, comply with any request for the data  
15          necessary to perform the study under subsection (a).

16          (c) CONFIDENTIALITY.—This section does not au-  
17          thorize the disclosure of any trade secret, confidential  
18          commercial or financial information, or other matter listed  
19          in section 552(b) of title 5, United States Code.

20          (d) DEFINITIONS.—In this section:

21                 (1) The term “drug” has the meaning given  
22                 such term in section 201 of the Federal Food, Drug,  
23                 and Cosmetic Act (21 U.S.C. 321).

24                 (2) The term “drug developer” means an entity  
25                 that submitted, and received approval of, an applica-

1       tion under section 505 of the Federal Food, Drug,  
2       and Cosmetic Act (21 U.S.C. 355) or section 351 of  
3       the Public Health Service Act (42 U.S.C. 262).

4               **Subtitle E—Pharmacy School**  
5                       **Outreach**

6       **SEC. 141. PHARMACY SCHOOL OUTREACH.**

7               The Secretary of Health and Human Services and the  
8       Secretary of Education shall make every effort necessary  
9       to ensure appropriate outreach to institutions of higher  
10       education to ensure that students and faculty at schools  
11       of pharmacy are provided with materials regarding generic  
12       drugs and biosimilar biological products, including mate-  
13       rials on—

14               (1) how generic drugs and biosimilar biological  
15       products are equivalent or similar to brand-name  
16       drugs;

17               (2) the approval process at the Food and Drug  
18       Administration for generic drugs and biosimilar bio-  
19       logical products;

20               (3) how to make consumers aware of the avail-  
21       ability of generic drugs and biosimilar biological  
22       products;

23               (4) requirements for substituting generic drugs  
24       and biosimiliar biological products in place of cor-  
25       responding drugs products; and

1 (5) the impacts of generic drugs and biosimilar  
2 biological products on consumer costs.

### 3 **Subtitle F—Reports**

#### 4 **SEC. 151. EFFECTS OF INCREASES IN PRESCRIPTION DRUG** 5 **PRICE.**

6 Not later than 1 year after the date of enactment  
7 of this Act, the Secretary of Health and Human Services  
8 shall submit a report to the Congress on the extent to  
9 which increases in prescription drug prices may have  
10 caused Medicare beneficiaries to forego recommended  
11 treatment, including failing to fill prescriptions.

## 12 **TITLE II—HEALTH INSURANCE** 13 **MARKET STABILIZATION**

#### 14 **SEC. 201. PRESERVING STATE OPTION TO IMPLEMENT** 15 **HEALTH CARE MARKETPLACES.**

16 (a) IN GENERAL.—Section 1311 of the Patient Pro-  
17 tection and Affordable Care Act (42 U.S.C. 18031) is  
18 amended—

19 (1) in subsection (a)—

20 (A) in paragraph (4)(B), by striking  
21 “under this subsection” and inserting “under  
22 this paragraph or paragraph (1)”; and

23 (B) by adding at the end the following new  
24 paragraph:

1           “(6) ADDITIONAL PLANNING AND ESTABLISH-  
2           MENT GRANTS.—

3           “(A) IN GENERAL.—There shall be appro-  
4           priated to the Secretary, out of any moneys in  
5           the Treasury not otherwise appropriated, \$200  
6           million to award grants to eligible States for  
7           the uses described in paragraph (3).

8           “(B) DURATION AND RENEWABILITY.—A  
9           grant awarded under subparagraph (A) shall be  
10          for a period of 2 years and may not be renewed.

11          “(C) LIMITATION.—A grant may not be  
12          awarded under subparagraph (A) after Decem-  
13          ber 31, 2023.

14          “(D) ELIGIBLE STATE DEFINED.—For  
15          purposes of this paragraph, the term ‘eligible  
16          State’ means a State that, as of the date of the  
17          enactment of this paragraph, is not operating  
18          an Exchange (other than an Exchange de-  
19          scribed in section 155.200(f) of title 45, Code  
20          of Federal Regulations).”; and

21          (2) in subsection (d)(5)(A)—

22                 (A) by striking “OPERATIONS.—In estab-  
23                 lishing an Exchange under this section” and in-  
24                 serting “OPERATIONS.—

1           “(i) IN GENERAL.—In establishing an  
2           Exchange under this section (other than in  
3           establishing an Exchange pursuant to a  
4           grant awarded under subsection (a)(6))”;  
5           and  
6           (B) by adding at the end the following:

7           “(ii) ADDITIONAL PLANNING AND ES-  
8           TABLISHMENT GRANTS.—In establishing  
9           an Exchange pursuant to a grant awarded  
10          under subsection (a)(6), the State shall en-  
11          sure that such Exchange is self-sustaining  
12          beginning on January 1, 2025, including  
13          allowing the Exchange to charge assess-  
14          ments or user fees to participating health  
15          insurance issuers, or to otherwise generate  
16          funding, to support its operations.”.

17          (b) CLARIFICATION REGARDING FAILURE TO ESTAB-  
18          LISH EXCHANGE OR IMPLEMENT REQUIREMENTS.—Sec-  
19          tion 1321(c) of the Patient Protection and Affordable  
20          Care Act (42 U.S.C. 18041(c)) is amended—

21                 (1) in paragraph (1), by striking “If” and in-  
22                 serting “Subject to paragraph (3), if”; and

23                 (2) by adding at the end the following new  
24                 paragraph:

1           “(3) CLARIFICATION.—This subsection shall  
2           not apply in the case of a State that elects to apply  
3           the requirements described in subsection (a) and  
4           satisfies the requirement described in subsection (b)  
5           on or after January 1, 2014.”.

6 **SEC. 202. PROVIDING FOR ADDITIONAL REQUIREMENTS**  
7                           **WITH RESPECT TO THE NAVIGATOR PRO-**  
8                           **GRAM.**

9           (a) IN GENERAL.—Section 1311(i) of the Patient  
10          Protection and Affordable Care Act (42 U.S.C. 18031(i))  
11          is amended—

12                   (1) in paragraph (2), by adding at the end the  
13          following new subparagraph:

14                           “(C) SELECTION OF RECIPIENTS.—In the  
15                           case of an Exchange established and operated  
16                           by the Secretary within a State pursuant to sec-  
17                           tion 1321(c), in awarding grants under para-  
18                           graph (1), the Exchange shall—

19                                   “(i) select entities to receive such  
20                                   grants based on an entity’s demonstrated  
21                                   capacity to carry out each of the duties  
22                                   specified in paragraph (3);

23                                   “(ii) not take into account whether or  
24                                   not the entity has demonstrated how the  
25                                   entity will provide information to individ-



1 uals relating to group health plans offered  
2 by a group or association of employers de-  
3 scribed in section 2510.3–5(b) of title 29,  
4 Code of Federal Regulations (or any suc-  
5 cessor regulation), or short-term limited  
6 duration insurance (as defined by the Sec-  
7 retary for purposes of section 2791(b)(5)  
8 of the Public Health Service Act); and

9 “(iii) ensure that, each year, the Ex-  
10 change awards such a grant to—

11 “(I) at least one entity described  
12 in this paragraph that is a community  
13 and consumer-focused nonprofit  
14 group; and

15 “(II) at least one entity described  
16 in subparagraph (B), which may in-  
17 clude another community and con-  
18 sumer-focused nonprofit group in ad-  
19 dition to any such group awarded a  
20 grant pursuant to subclause (I).

21 In awarding such grants, an Exchange may  
22 consider an entity’s record with respect to  
23 waste, fraud, and abuse for purposes of main-  
24 taining the integrity of such Exchange.”.

25 (2) in paragraph (3)—

1 (A) by amending subparagraph (C) to read  
2 as follows:

3 “(C) facilitate enrollment, including with  
4 respect to individuals with limited English pro-  
5 ficiency and individuals with chronic illnesses,  
6 in qualified health plans, State medicaid plans  
7 under title XIX of the Social Security Act, and  
8 State child health plans under title XXI of such  
9 Act;”;

10 (B) in subparagraph (D), by striking  
11 “and” at the end;

12 (C) in subparagraph (E), by striking the  
13 period at the end and inserting a semicolon;

14 (D) by inserting after subparagraph (E)  
15 the following:

16 “(F) conduct public education activities in  
17 plain language to raise awareness of the re-  
18 quirements of and the protections provided  
19 under—

20 “(i) the essential health benefits pack-  
21 age (as defined in section 1302(a)); and

22 “(ii) section 2726 of the Public  
23 Health Service Act (relating to parity in  
24 mental health and substance use disorder  
25 benefits); and”;

1 (E) by inserting after subparagraph (F)  
2 (as added by subparagraph (D)) the following  
3 new subparagraph:

4 “(G) provide referrals to community-based  
5 organizations that address social needs related  
6 to health outcomes.”; and

7 (F) by adding at the end the following  
8 flush left sentence:

9 “The duties specified in the preceding sentences may  
10 be carried out by such a navigator at any time dur-  
11 ing a year.”;

12 (3) in paragraph (4)(A)—

13 (A) in the matter preceding clause (i), by  
14 striking “not”;

15 (B) in clause (i)—

16 (i) by inserting “not” before “be”;

17 and

18 (ii) by striking “; or” and inserting a  
19 semicolon;

20 (C) in clause (ii)—

21 (i) by inserting “not” before “re-  
22 ceive”; and

23 (ii) by striking the period and insert-  
24 ing a semicolon; and

1 (D) by adding at the end the following new  
2 clauses:

3 “(iii) maintain physical presence in  
4 the State of the Exchange so as to allow  
5 in-person assistance to consumers;

6 “(iv) receive training on how to assist  
7 individuals with enrolling for medical as-  
8 sistance under State plans under the Med-  
9 icaid program under title XIX of the Social  
10 Security Act or for child health assistance  
11 under State child health plans under title  
12 XXI of such Act; and

13 “(v) receive opioid specific education  
14 and training that ensures the navigator  
15 can best educate individuals on qualified  
16 health plans offered through an Exchange,  
17 specifically coverage under such plans for  
18 opioid health care treatment.”; and

19 (4) in paragraph (6)—

20 (A) by striking “FUNDING.—Grants  
21 under” and inserting “FUNDING.—

22 “(A) STATE EXCHANGES.—Subject to sub-  
23 paragraph (C), grants under”; and

24 (B) by adding at the end the following new  
25 subparagraphs:

1           “(B) FEDERAL EXCHANGES.—For pur-  
2           poses of carrying out this subsection, with re-  
3           spect to an Exchange established and operated  
4           by the Secretary within a State pursuant to sec-  
5           tion 1321(c), the Secretary shall obligate \$100  
6           million out of amounts collected through the  
7           user fees on participating health insurance  
8           issuers pursuant to section 156.50 of title 45,  
9           Code of Federal Regulations (or any successor  
10          regulations) for fiscal year 2020 and each sub-  
11          sequent fiscal year. Such amount for a fiscal  
12          year shall remain available until expended.

13          “(C) STATE EXCHANGES.—For the pur-  
14          poses of carrying out this subsection, with re-  
15          spect to an Exchange operated by a State pur-  
16          suant to this section, there is authorized to be  
17          appropriated \$25 million for fiscal year 2020  
18          and each subsequent fiscal year. Each State re-  
19          ceiving a grant pursuant to this subparagraph  
20          shall receive a grant in an amount that is not  
21          less than \$1 million.”.

22          (b) STUDY ON EFFECTS OF FUNDING CUTS.—Not  
23          later than 1 year after the date of the enactment of this  
24          Act, the Comptroller General of the United States shall  
25          study the effects of funding cuts made for plan year 2019

1 with respect to the navigator program (as described in sec-  
2 tion 1311(i) of the Patient Protection and Affordable Care  
3 Act (42 U.S.C. 18031(i))) and other education and out-  
4 reach activities carried out with respect to Exchanges es-  
5 tablished by the Secretary of Health and Human Services  
6 pursuant to section 1321(c) of such Act. Such study shall  
7 describe the following:

8           (1) How such funding cuts negatively impacted  
9           the ability of entities under such program to conduct  
10           outreach activities and fulfill duties required under  
11           such section 1311(i).

12           (2) The overall effect on—

13                   (A) the number of individuals enrolled in  
14                   health insurance coverage offered in the indi-  
15                   vidual market for plan year 2019; and

16                   (B) the costs of health insurance coverage  
17                   offered in the individual market.

18           (c) PROMOTE TRANSPARENCY AND ACCOUNTABILITY  
19 IN THE ADMINISTRATION'S EXPENDITURES OF EX-  
20 CHANGE USER FEES.—For plan year 2020 and each sub-  
21 sequent plan year, not later than the date that is 3 months  
22 after the end of such plan year, the Secretary of Health  
23 and Human Services shall submit to the appropriate com-  
24 mittees of Congress and make available to the public an  
25 annual report on the expenditures by the Department of

1 Health and Human Services of user fees collected pursu-  
2 ant to section 156.50 of title 45, Code of Federal Regula-  
3 tions (or any successor regulations). Each such report for  
4 a plan year shall include a detailed accounting of the  
5 amount of such user fees collected during such plan year  
6 and of the amount of such expenditures used during such  
7 plan year for the federally facilitated Exchange operated  
8 pursuant to section 1321(c) of the Patient Protection and  
9 Affordable Care Act (42 U.S.C. 18041(c)) on outreach  
10 and enrollment activities, navigators, maintenance of  
11 Healthcare.gov, and operation of call centers.

12 (d) EFFECTIVE DATE.—The amendments made by  
13 this section shall apply with respect to plan years begin-  
14 ning on or after January 1, 2020.

15 **SEC. 203. FEDERAL EXCHANGE OUTREACH AND EDU-**  
16 **CATIONAL ACTIVITIES AND ANNUAL ENROLL-**  
17 **MENT TARGETS.**

18 (a) IN GENERAL.—Section 1321(c) of the Patient  
19 Protection and Affordable Care Act (42 U.S.C. 18041(c)),  
20 as amended by section 201(b)(2), is further amended by  
21 adding at the end the following new paragraphs:

22 “(4) OUTREACH AND EDUCATIONAL ACTIVI-  
23 TIES.—

24 “(A) IN GENERAL.—In the case of an Ex-  
25 change established or operated by the Secretary

1 within a State pursuant to this subsection, the  
2 Secretary shall carry out outreach and edu-  
3 cational activities for purposes of informing in-  
4 dividuals about qualified health plans offered  
5 through the Exchange, including by informing  
6 such individuals of the availability of coverage  
7 under such plans and financial assistance for  
8 coverage under such plans. Such outreach and  
9 educational activities shall be provided in a  
10 manner that is culturally and linguistically ap-  
11 propriate to the needs of the populations being  
12 served by the Exchange (including hard-to-  
13 reach populations, such as racial and sexual mi-  
14 norities, limited English proficient populations,  
15 individuals residing in areas where the unem-  
16 ployment rates exceeds the national average un-  
17 employment rate, individuals in rural areas, vet-  
18 erans, and young adults) and shall be provided  
19 to populations residing in high health disparity  
20 areas (as defined in subparagraph (E)) served  
21 by the Exchange, in addition to other popu-  
22 lations served by the Exchange.

23 “(B) LIMITATION ON USE OF FUNDS.—No  
24 funds appropriated under this paragraph shall



1 be used for expenditures for promoting non-  
2 ACA compliant health insurance coverage.

3 “(C) NON-ACA COMPLIANT HEALTH INSUR-  
4 ANCE COVERAGE.—For purposes of subpara-  
5 graph (B):

6 “(i) The term ‘non-ACA compliant  
7 health insurance coverage’ means health  
8 insurance coverage, or a group health plan,  
9 that is not a qualified health plan.

10 “(ii) Such term includes the following:

11 “(I) An association health plan.

12 “(II) Short-term limited duration  
13 insurance.

14 “(D) FUNDING.—Out of any funds in the  
15 Treasury not otherwise appropriated, there are  
16 hereby appropriated for fiscal year 2020 and  
17 each subsequent fiscal year, \$100 million to  
18 carry out this paragraph. Funds appropriated  
19 under this subparagraph shall remain available  
20 until expended.

21 “(E) HIGH HEALTH DISPARITY AREA DE-  
22 FINED.—For purposes of subparagraph (A), the  
23 term ‘high health disparity area’ means a con-  
24 tiguous geographic area that—

1 “(i) is located in one census tract or  
2 ZIP code;

3 “(ii) has measurable and documented  
4 racial, ethnic, or geographic health dispari-  
5 ties;

6 “(iii) has a low-income population, as  
7 demonstrated by—

8 “(I) average income below 138  
9 percent of the Federal poverty line; or

10 “(II) a rate of participation in  
11 the special supplemental nutrition  
12 program under section 17 of the Child  
13 Nutrition Act of 1966 (42 U.S.C.  
14 1786) that is higher than the national  
15 average rate of participation in such  
16 program;

17 “(iv) has poor health outcomes, as  
18 demonstrated by—

19 “(I) lower life expectancy than  
20 the national average; or

21 “(II) a higher percentage of in-  
22 stances of low birth weight than the  
23 national average; and

1                   “(v) is part of a Metropolitan Statis-  
2                   tical Area identified by the Office of Man-  
3                   agement and Budget.

4                   “(5) ANNUAL ENROLLMENT TARGETS.—For  
5                   plan year 2020 and each subsequent plan year, in  
6                   the case of an Exchange established or operated by  
7                   the Secretary within a State pursuant to this sub-  
8                   section, the Secretary shall establish annual enroll-  
9                   ment targets for such Exchange for such year.”.

10                  (b) STUDY AND REPORT.—Not later than 30 days  
11 after the date of the enactment of this Act, the Secretary  
12 of Health and Human Services shall release to Congress  
13 all aggregated documents relating to studies and data sets  
14 that were created on or after January 1, 2014, and related  
15 to marketing and outreach with respect to qualified health  
16 plans offered through Exchanges under title I of the Pa-  
17 tient Protection and Affordable Care Act.

18 **SEC. 204. SHORT-TERM LIMITED DURATION INSURANCE**

19                   **RULE PROHIBITION.**

20                  (a) FINDINGS.—Congress finds the following:

21                   (1) On August 3, 2018, the Administration  
22                   issued a final rule entitled “Short-Term, Limited-  
23                   Duration Insurance” (83 Fed. Reg. 38212).

24                   (2) The final rule dramatically expands the sale  
25                   and marketing of insurance that—

1 (A) may discriminate against individuals  
2 living with preexisting health conditions, includ-  
3 ing children with complex medical needs and  
4 disabilities and their families;

5 (B) lacks important financial protections  
6 provided by the Patient Protection and Afford-  
7 able Care Act (Public Law 111–148), including  
8 the prohibition of annual and lifetime coverage  
9 limits and annual out-of-pocket limits, that may  
10 increase the cost of treatment and cause finan-  
11 cial hardship to those requiring medical care,  
12 including children with complex medical needs  
13 and disabilities and their families; and

14 (C) excludes coverage of essential health  
15 benefits including hospitalization, prescription  
16 drugs, and other lifesaving care.

17 (3) The implementation and enforcement of the  
18 final rule weakens critical protections for up to 130  
19 million Americans living with preexisting health con-  
20 ditions and may place a large financial burden on  
21 those who enroll in short-term limited-duration in-  
22 surance, which jeopardizes Americans' access to  
23 quality, affordable health insurance.

24 (b) PROHIBITION.—The Secretary of Health and  
25 Human Services, the Secretary of the Treasury, and the

1 Secretary of Labor may not take any action to implement,  
2 enforce, or otherwise give effect to the rule entitled  
3 “Short-Term, Limited Duration Insurance” (83 Fed. Reg.  
4 38212 (August 3, 2018)), and the Secretaries may not  
5 promulgate any substantially similar rule.

6 **SEC. 205. PROTECTION OF HEALTH INSURANCE COVERAGE**  
7 **IN CERTAIN EXCHANGES.**

8 In the case of an Exchange that the Secretary of  
9 Health and Human Services operates pursuant to section  
10 1321(c)(1) of the Patient Protection and Affordable Care  
11 Act (42 U.S.C. 18041(c)(1)), the Secretary may not im-  
12 plement any process that would terminate the health in-  
13 surance coverage of an enrollee solely because such en-  
14 rollee did not actively enroll during the most recent open  
15 enrollment period.

16 **SEC. 206. SENSE OF CONGRESS RELATING TO THE PRAC-**  
17 **TICE OF SILVER LOADING.**

18 It is the sense of Congress that the Secretary of  
19 Health and Human Services should not take any action  
20 to prohibit or otherwise restrict the practice commonly  
21 known as “silver loading” (as described in the rule entitled  
22 “Patient Protection and Affordable Care Act; HHS Notice  
23 of Benefit and Payment Parameters for 2020” published  
24 on April 25, 2019 (84 Fed. Reg. 17533)).

1 **SEC. 207. CONSUMER OUTREACH, EDUCATION, AND ASSIST-**  
2 **ANCE.**

3 (a) OPEN ENROLLMENT REPORTS.—For plan year  
4 2020 and each subsequent year, the Secretary of Health  
5 and Human Services (referred to in this section as the  
6 “Secretary”), in coordination with the Secretary of the  
7 Treasury and the Secretary of Labor, shall issue biweekly  
8 public reports during the annual open enrollment period  
9 on the performance of the Federal Exchange. Each such  
10 report shall include a summary, including information on  
11 a State-by-State basis where available, of—

12 (1) the number of unique website visits;

13 (2) the number of individuals who create an ac-  
14 count;

15 (3) the number of calls to the call center;

16 (4) the average wait time for callers contacting  
17 the call center;

18 (5) the number of individuals who enroll in a  
19 qualified health plan; and

20 (6) the percentage of individuals who enroll in  
21 a qualified health plan through each of—

22 (A) the website;

23 (B) the call center;

24 (C) navigators;

25 (D) agents and brokers;

26 (E) the enrollment assistant program;

1 (F) directly from issuers or web brokers;

2 and

3 (G) other means.

4 (b) OPEN ENROLLMENT AFTER ACTION REPORT.—

5 For plan year 2020 and each subsequent year, the Sec-  
6 retary, in coordination with the Secretary of the Treasury  
7 and the Secretary of Labor, shall publish an after action  
8 report not later than 3 months after the completion of the  
9 annual open enrollment period regarding the performance  
10 of the Federal Exchange for the applicable plan year.

11 Each such report shall include a summary, including in-  
12 formation on a State-by-State basis where available, of—

13 (1) the open enrollment data reported under  
14 subsection (a) for the entirety of the enrollment pe-  
15 riod; and

16 (2) activities related to patient navigators de-  
17 scribed in section 1311(i) of the Patient Protection  
18 and Affordable Care Act (42 U.S.C. 18031(i)), in-  
19 cluding—

20 (A) the performance objectives established  
21 by the Secretary for such patient navigators;

22 (B) the number of consumers enrolled by  
23 such a patient navigator;

24 (C) an assessment of how such patient  
25 navigators have met established performance

1 metrics, including a detailed list of all patient  
2 navigators, funding received by patient naviga-  
3 tors, and whether established performance ob-  
4 jectives of patient navigators were met; and

5 (D) with respect to the performance objec-  
6 tives described in subparagraph (A)—

7 (i) whether such objectives assess the  
8 full scope of patient navigator responsibil-  
9 ities, including general education, plan se-  
10 lection, and determination of eligibility for  
11 tax credits, cost-sharing reductions, or  
12 other coverage;

13 (ii) how the Secretary worked with pa-  
14 tient navigators to establish such objec-  
15 tives; and

16 (iii) how the Secretary adjusted such  
17 objectives for case complexity and other  
18 contextual factors.

19 (c) REPORT ON ADVERTISING AND CONSUMER OUT-  
20 REACH.—Not later than 3 months after the completion of  
21 the annual open enrollment period for the 2020 plan year,  
22 the Secretary shall issue a report on advertising and out-  
23 reach to consumers for the open enrollment period for the  
24 2020 plan year. Such report shall include a description  
25 of—



1           (1) the division of spending on individual adver-  
2           tising platforms, including television and radio ad-  
3           vertisements and digital media, to raise consumer  
4           awareness of open enrollment;

5           (2) the division of spending on individual out-  
6           reach platforms, including email and text messages,  
7           to raise consumer awareness of open enrollment; and

8           (3) whether the Secretary conducted targeted  
9           outreach to specific demographic groups and geo-  
10          graphic areas.

11 **SEC. 208. GAO REPORT.**

12          Not later than 1 year after the date of the enactment  
13 of this Act, the Comptroller General of the United States  
14 shall submit to Congress a study that analyzes the costs  
15 and benefits of the establishment of State-administered  
16 health insurance plans to be offered in the insurance mar-  
17 ket of such States that choose to administer and offer such  
18 a plan.

19 **SEC. 209. REPORT ON THE EFFECTS OF WEBSITE MAINTENANCE DURING OPEN ENROLLMENT.**

21          Not later than 1 year after the date of the enactment  
22 of this Act, the Comptroller General of the United States  
23 shall submit to Congress a report examining whether the  
24 Department of Health and Human Services has been con-  
25 ducting maintenance on the website commonly referred to

1 as “Healthcare.gov” during annual open enrollment peri-  
2 ods (as described in section 1311(c)(6)(B) of the Patient  
3 Protection and Affordable Care Act (42 U.S.C.  
4 18031(c)(6)(B)) in such a manner so as to minimize any  
5 disruption to the use of such website resulting from such  
6 maintenance.

## 7 **TITLE III—BUDGETARY EFFECTS**

### 8 **SEC. 301. DETERMINATION OF BUDGETARY EFFECTS.**

9 The budgetary effects of this Act, for the purpose of  
10 complying with the Statutory Pay-As-You-Go Act of 2010,  
11 shall be determined by reference to the latest statement  
12 titled “Budgetary Effects of PAYGO Legislation” for this  
13 Act, submitted for printing in the Congressional Record  
14 by the Chairman of the House Budget Committee, pro-  
15 vided that such statement has been submitted prior to the  
16 vote on passage.

Passed the House of Representatives May 16, 2019.

Attest:                      CHERYL L. JOHNSON,  
*Clerk.*