

MAY 8, 2019

**RULES COMMITTEE PRINT 116–14**  
**TEXT OF H.R. 987, STRENGTHENING HEALTH**  
**CARE AND LOWERING PRESCRIPTION DRUG**  
**COSTS ACT**

[Showing the text of H.R. 938, H.R. 1499, H.R. 965, H.R. 1385, H.R. 1386, H.R. 987, and H.R. 1010, as ordered reported by the Committee on Energy and Commerce, with modifications.]

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.

**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.
- Sec. 204. Short-term limited duration insurance rule prohibition.

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

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

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

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

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

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

22                             “(dd) No application for the drug  
23                             submitted by any first applicant is ap-  
24                             proved at the time the conditions  
25                             under items (aa), (bb), and (cc) are

1 all met, regardless of whether such an  
2 application is subsequently ap-  
3 proved.”.

## 4 **Subtitle B—Protecting Consumer** 5 **Access to Generic Drugs**

### 6 **SEC. 111. UNLAWFUL AGREEMENTS.**

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

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

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

24 (b) EXCLUSION.—It shall not be unlawful under sub-  
25 section (a) if a party to an agreement described in such

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

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

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

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

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

20 (2) A payment for reasonable litigation ex-  
21 penses not to exceed \$7,500,000 in the aggregate.

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

24 (d) ENFORCEMENT BY FEDERAL TRADE COMMIS-  
25 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) 3 times the value re-  
17 ceived 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) 3 times the value given  
23 to the subsequent filer (or to the  
24 other subsequent filer) reason-

1 ably attributable to the violation  
2 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 requested to purchase sufficient quan-  
10 tities of the covered product from the li-  
11 cense holder; and

12 (iv) that the license holder has not de-  
13 livered to the eligible product developer  
14 sufficient quantities of the covered product  
15 on commercially reasonable, market-based  
16 terms—

17 (I) for a covered product that is  
18 not subject to a REMS with ETASU,  
19 by the date that is 31 days after the  
20 date on which the license holder re-  
21 ceived the request for the covered  
22 product; and

23 (II) for a covered product that is  
24 subject to a REMS with ETASU, by  
25 31 days after the later of—

1 (aa) the date on which the  
2 license holder received the re-  
3 quest for the covered product; or

4 (bb) the date on which the  
5 license holder received a copy of  
6 the covered product authorization  
7 issued by the Secretary in ac-  
8 cordance with subparagraph (B).

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

11 (i) REQUEST.—An eligible product de-  
12 veloper may submit to the Secretary a  
13 written request for the eligible product de-  
14 veloper to be authorized to obtain suffi-  
15 cient quantities of an individual covered  
16 product subject to a REMS with ETASU.

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

1 (I) development and testing that  
2 does not involve human clinical trials,  
3 if the eligible product developer has  
4 agreed to comply with any conditions  
5 the Secretary determines necessary; or

6 (II) development and testing that  
7 involves human clinical trials, if the  
8 eligible product developer has—

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

17 (BB) otherwise satisfied the  
18 Secretary that such protections  
19 will be provided; and

20 (bb) met any other require-  
21 ments the Secretary may estab-  
22 lish.

23 (iii) NOTICE.—A covered product au-  
24 thorization issued under this subparagraph  
25 shall state that the provision of the covered

1 product by the license holder under the  
2 terms of the authorization will not be a  
3 violation of the REMS for the covered  
4 product.

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

9 (A) that, on the date on which the eligible  
10 product developer requested to purchase suffi-  
11 cient quantities of the covered product from the  
12 license holder—

13 (i) neither the license holder nor any  
14 of its agents, wholesalers, or distributors  
15 was engaged in the manufacturing or com-  
16 mercial marketing of the covered product;  
17 and

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

24 (B) that—

1 (i) the license holder sells the covered  
2 product through agents, distributors, or  
3 wholesalers;

4 (ii) the license holder has placed no  
5 restrictions, explicit or implicit, on its  
6 agents, distributors, or wholesalers to sell  
7 covered products to eligible product devel-  
8 opers; and

9 (iii) the covered product can be pur-  
10 chased by the eligible product developer in  
11 sufficient quantities on commercially rea-  
12 sonable, market-based terms from the  
13 agents, distributors, or wholesalers of the  
14 license holder; or

15 (C) that the license holder made an offer  
16 to sell sufficient quantities of the covered prod-  
17 uct to the eligible product developer at commer-  
18 cially reasonable market-based terms—

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



1 date on which the eligible product devel-  
2 oper received such offer from the license  
3 holder; or

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

13 (4) METHODS FOR TRANSMISSION OF RE-  
14 QUESTS FOR COVERED PRODUCTS.—A written re-  
15 quest for a covered product, offer to sell a covered  
16 product, or acceptance of such an offer between the  
17 eligible product developer and the license holder  
18 shall be made by—

19 (A) certified or registered mail with return  
20 receipt requested;

21 (B) personal delivery; or

22 (C) electronic means.

23 (5) REMEDIES.—

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

4 (i) order the license holder to provide  
5 to the eligible product developer without  
6 delay sufficient quantities of the covered  
7 product on commercially reasonable, mar-  
8 ket-based terms;

9 (ii) award to the eligible product de-  
10 veloper reasonable attorney’s fees and costs  
11 of the civil action; and

12 (iii) award to the eligible product de-  
13 veloper a monetary amount sufficient to  
14 deter the license holder from failing to pro-  
15 vide eligible product developers with suffi-  
16 cient quantities of a covered product on  
17 commercially reasonable, market-based  
18 terms, if the court finds, by a preponder-  
19 ance of the evidence—

20 (I) that the license holder delayed  
21 providing sufficient quantities of the  
22 covered product to the eligible product  
23 developer without a legitimate busi-  
24 ness justification; or

1 (II) that the license holder failed  
2 to comply with an order issued under  
3 clause (i).

4 (B) MAXIMUM MONETARY AMOUNT.—A  
5 monetary amount awarded under subparagraph  
6 (A)(iii) shall not be greater than the revenue  
7 that the license holder earned on the covered  
8 product during the period—

9 (i) beginning on—

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

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

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

22 (bb) the date on which the  
23 license holder received a copy of  
24 the covered product authorization  
25 issued by the Secretary in ac-

1 cordance with paragraph (2)(B);

2 and

3 (ii) ending on the date on which the  
4 eligible product developer received suffi-  
5 cient quantities of the covered product.

6 (C) AVOIDANCE OF DELAY.—The court  
7 may issue an order under subparagraph (A)(i)  
8 before conducting further proceedings that may  
9 be necessary to determine whether the eligible  
10 product developer is entitled to an award under  
11 clause (ii) or (iii) of subparagraph (A), or the  
12 amount of any such award.

13 (c) LIMITATION OF LIABILITY.—A license holder for  
14 a covered product shall not be liable for any claim under  
15 Federal, State, or local law arising out of the failure of  
16 an eligible product developer to follow adequate safeguards  
17 to assure safe use of the covered product during develop-  
18 ment or testing activities described in this section, includ-  
19 ing transportation, handling, use, or disposal of the cov-  
20 ered product by the eligible product developer.

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

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

9           (e) RULE OF CONSTRUCTION.—

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

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

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

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

1 **SEC. 122. REMS APPROVAL PROCESS FOR SUBSEQUENT**  
2 **FILERS.**

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

6 (1) in subsection (g)(4)(B)—

7 (A) in clause (i) by striking “or” after the  
8 semicolon;

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

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

12 “(iii) accommodate different, com-  
13 parable aspects of the elements to assure  
14 safe use for a drug that is the subject of  
15 an application under section 505(j), and  
16 the applicable listed drug.”;

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

19 “(C)(i) Elements to assure safe use, if re-  
20 quired under subsection (f) for the listed drug,  
21 which, subject to clause (ii), for a drug that is  
22 the subject of an application under section  
23 505(j) may use—

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

1                   “(II) a different, comparable aspect of  
2                   the elements to assure safe use under sub-  
3                   section (f).

4                   “(ii) The Secretary may require a drug  
5                   that is the subject of an application under sec-  
6                   tion 505(j) and the listed drug to use a single,  
7                   shared system under subsection (f), if the Sec-  
8                   retary determines that no different, comparable  
9                   aspect of the elements to assure safe use could  
10                  satisfy the requirements of subsection (f).”;

11                  (3) in subsection (i), by adding at the end the  
12                  following:

13                  “(3) SHARED REMS.—If the Secretary ap-  
14                  proves, in accordance with paragraph (1)(C)(i)(II), a  
15                  different, comparable aspect of the elements to as-  
16                  sure safe use under subsection (f) for a drug that  
17                  is the subject of an abbreviated new drug application  
18                  under section 505(j), the Secretary may require that  
19                  such different comparable aspect of the elements to  
20                  assure safe use can be used with respect to any  
21                  other drug that is the subject of an application  
22                  under section 505(j) or 505(b) that references the  
23                  same listed drug.”; and

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

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

12 **SEC. 123. RULE OF CONSTRUCTION.**

13           (a) IN GENERAL.—Nothing in this subtitle, the  
14 amendments made by this subtitle, or in section 505–1  
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16 355–1), shall be construed as—

17           (1) prohibiting a license holder from providing  
18 an eligible product developer access to a covered  
19 product in the absence of an authorization under  
20 this subtitle; or

21           (2) in any way negating the applicability of a  
22 REMS with ETASU, as otherwise required under  
23 such section 505–1, with respect to such covered  
24 product.



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

5 **TITLE II—HEALTH INSURANCE**  
6 **MARKET STABILIZATION**

7 **SEC. 201. PRESERVING STATE OPTION TO IMPLEMENT**  
8 **HEALTH CARE MARKETPLACES.**

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

12 (1) in subsection (a)—

13 (A) in paragraph (4)(B), by striking  
14 “under this subsection” and inserting “under  
15 this paragraph or paragraph (1)”; and

16 (B) by adding at the end the following new  
17 paragraph:

18 “(6) ADDITIONAL PLANNING AND ESTABLISH-  
19 MENT GRANTS.—

20 “(A) IN GENERAL.—There shall be appro-  
21 priated to the Secretary, out of any moneys in  
22 the Treasury not otherwise appropriated,  
23 \$200,000,000 to award grants to eligible States  
24 for the uses described in paragraph (3).

1           “(B) DURATION AND RENEWABILITY.—A  
2 grant awarded under subparagraph (A) shall be  
3 for a period of two years and may not be re-  
4 newed.

5           “(C) LIMITATION.—A grant may not be  
6 awarded under subparagraph (A) after Decem-  
7 ber 31, 2022.

8           “(D) ELIGIBLE STATE DEFINED.—For  
9 purposes of this paragraph, the term ‘eligible  
10 State’ means a State that, as of the date of the  
11 enactment of this paragraph, is not operating  
12 an Exchange (other than an Exchange de-  
13 scribed in section 155.200(f) of title 45, Code  
14 of Federal Regulations).”; and  
15 (2) in subsection (d)(5)(A)—

16           (A) by striking “OPERATIONS.—In estab-  
17 lishing an Exchange under this section” and in-  
18 serting “OPERATIONS.—

19           “(i) IN GENERAL.—In establishing an  
20 Exchange under this section (other than in  
21 establishing an Exchange pursuant to a  
22 grant awarded under subsection (a)(6))”;  
23 and

24           (B) by adding at the end the following:

1           “(ii) ADDITIONAL PLANNING AND ES-  
2           TABLISHMENT GRANTS.—In establishing  
3           an Exchange pursuant to a grant awarded  
4           under subsection (a)(6), the State shall en-  
5           sure that such Exchange is self-sustaining  
6           beginning on January 1, 2024, including  
7           allowing the Exchange to charge assess-  
8           ments or user fees to participating health  
9           insurance issuers, or to otherwise generate  
10          funding, to support its operations.”.

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

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

17                 (2) by adding at the end the following new  
18                 paragraph:

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

1 **SEC. 202. PROVIDING FOR ADDITIONAL REQUIREMENTS**  
2 **WITH RESPECT TO THE NAVIGATOR PRO-**  
3 **GRAM.**

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

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

9 “(C) SELECTION OF RECIPIENTS.—In the  
10 case of an Exchange established and operated  
11 by the Secretary within a State pursuant to sec-  
12 tion 1321(c), in awarding grants under para-  
13 graph (1), the Exchange shall—

14 “(i) select entities to receive such  
15 grants based on an entity’s demonstrated  
16 capacity to carry out each of the duties  
17 specified in paragraph (3);

18 “(ii) not take into account whether or  
19 not the entity has demonstrated how the  
20 entity will provide information to individ-  
21 uals relating to group health plans offered  
22 by a group or association of employers de-  
23 scribed in section 2510.3–5(b) of title 29,  
24 Code of Federal Regulations (or any suc-  
25 cessor regulation), or short-term limited  
26 duration insurance (as defined by the Sec-

1           retary for purposes of section 2791(b)(5)  
2           of the Public Health Service Act); and

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

5                   “(I) at least one entity described  
6                   in this paragraph that is a community  
7                   and consumer-focused nonprofit  
8                   group; and

9                   “(II) at least one entity described  
10                  in subparagraph (B), which may in-  
11                  clude another community and con-  
12                  sumer-focused nonprofit group in ad-  
13                  dition to any such group awarded a  
14                  grant pursuant to subclause (I).

15           In awarding such grants, an Exchange may  
16           consider an entity’s record with respect to  
17           waste, fraud, and abuse for purposes of main-  
18           taining the integrity of such Exchange.”.

19           (2) in paragraph (3)—

20                   (A) in subparagraph (C), by inserting after  
21                   “qualified health plans” the following: “, State  
22                   medicaid plans under title XIX of the Social  
23                   Security Act, and State child health plans  
24                   under title XXI of such Act”; and

1 (B) by adding at the end the following  
2 flush left sentence:

3 “The duties specified in the preceding sentence may  
4 be carried out by such a navigator at any time dur-  
5 ing a year.”;

6 (3) in paragraph (4)(A)—

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

9 (B) in clause (i)—

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

11 and

12 (ii) by striking “; or” and inserting  
13 “;”;

14 (C) in clause (ii)—

15 (i) by inserting “not” before “re-  
16 ceive”; and

17 (ii) by striking the period and insert-  
18 ing “; and”; and

19 (D) by adding at the end the following new  
20 clause:

21 “(iii) maintain physical presence in  
22 the State of the Exchange so as to allow  
23 in-person assistance to consumers.”; and

24 (4) in paragraph (6)—

1 (A) by striking “FUNDING.—Grants  
2 under” and inserting “FUNDING.—

3 “(A) STATE EXCHANGES.—Grants under”;  
4 and

5 (B) by adding at the end the following new  
6 subparagraph:

7 “(B) FEDERAL EXCHANGES.—For pur-  
8 poses of carrying out this subsection, with re-  
9 spect to an Exchange established and operated  
10 by the Secretary within a State pursuant to sec-  
11 tion 1321(c), the Secretary shall obligate  
12 \$100,000,000 out of amounts collected through  
13 the user fees on participating health insurance  
14 issuers pursuant to section 156.50 of title 45,  
15 Code of Federal Regulations (or any successor  
16 regulations) for fiscal year 2020 and each sub-  
17 sequent fiscal year. Such amount for a fiscal  
18 year shall remain available until expended.”.

19 (b) EFFECTIVE DATE.—The amendments made by  
20 subsection (a) shall apply with respect to plan years begin-  
21 ning on or after January 1, 2020.

22 **SEC. 203. FEDERAL EXCHANGE OUTREACH AND EDU-**  
23 **CATIONAL ACTIVITIES.**

24 Section 1321(c) of the Patient Protection and Afford-  
25 able Care Act (42 U.S.C. 18041(c)), as amended by sec-

1 tion 201(b)(2), is further amended by adding at the end  
2 the following new paragraph:

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

5 “(A) IN GENERAL.—In the case of an Ex-  
6 change established or operated by the Secretary  
7 within a State pursuant to this subsection, the  
8 Secretary shall carry out outreach and edu-  
9 cational activities for purposes of informing in-  
10 dividuals about qualified health plans offered  
11 through the Exchange, including by informing  
12 such individuals of the availability of coverage  
13 under such plans and financial assistance for  
14 coverage under such plans. Such outreach and  
15 educational activities shall be provided in a  
16 manner that is culturally and linguistically ap-  
17 propriate to the needs of the populations being  
18 served by the Exchange (including hard-to-  
19 reach populations, such as racial and sexual mi-  
20 norities, limited English proficient populations,  
21 and young adults).

22 “(B) LIMITATION ON USE OF FUNDS.—No  
23 funds appropriated under this paragraph shall  
24 be used for expenditures for promoting non-  
25 ACA compliant health insurance coverage.



1           “(C) NON-ACA COMPLIANT HEALTH IN-  
2           SURANCE COVERAGE.—For purposes of sub-  
3           paragraph (B):

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

8                   “(ii) Such term includes the following:

9                           “(I) An association health plan.

10                           “(II) Short-term limited duration  
11                   insurance.

12           “(D) FUNDING.—Out of any funds in the  
13           Treasury not otherwise appropriated, there are  
14           hereby appropriated for fiscal year 2020 and  
15           each subsequent fiscal year, \$100,000,000 to  
16           carry out this paragraph. Funds appropriated  
17           under this subparagraph shall remain available  
18           until expended.”.

19   **SEC. 204. SHORT-TERM LIMITED DURATION INSURANCE**  
20                   **RULE PROHIBITION.**

21           The Secretary of Health and Human Services, the  
22           Secretary of the Treasury, and the Secretary of Labor  
23           may not take any action to implement, enforce, or other-  
24           wise give effect to the rule entitled “Short-Term, Limited  
25           Duration Insurance” (83 Fed. Reg. 38212 (August 3,

1 2018)), and the Secretaries may not promulgate any sub-  
2 stantially similar rule.

### 3 **TITLE III—BUDGETARY EFFECTS**

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

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

