

116TH CONGRESS
1ST SESSION

H. R. 3947

To lower the cost of prescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 24, 2019

Mr. MEADOWS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, the Judiciary, Armed Services, and Oversight and Reform, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To lower the cost of prescription drugs, and for other purposes.

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Competition Prescription Act of 2019”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—ELIMINATING DELAYS OF GENERIC DRUGS AND
BIOSIMILAR PRODUCTS

- Sec. 101. Actions for delays of generic drugs and biosimilar biological products.
 Sec. 102. REMS approval process for subsequent filers.

TITLE II—INCREASING ACCESS TO DRUGS AND BIOSIMILAR PRODUCTS

- Sec. 201. Expedited development and priority review for generic complex drug products.
 Sec. 202. Increasing pharmaceutical options to treat an unmet medical need.
 Sec. 203. Preemption of State barriers to the substitution of biosimilar products.
 Sec. 204. Expedited process for biological products authorized for marketing in European Union.

TITLE III—PRESCRIPTION DRUG PRICING AND COMPETITION

- Sec. 301. Medicare drug coverage.
 Sec. 302. Fee transparency between pharmacies and PBMs.
 Sec. 303. Sunset of limit on maximum rebate amount for single source drugs and innovator multiple source drugs.
 Sec. 304. Regulation of manufacturer-sponsored copay contributions.

TITLE IV—PATENT DISCLOSURE REQUIREMENTS

- Sec. 401. Patent disclosure and transparency requirements.
 Sec. 402. Antitrust exemption for health insurance issuers to negotiate wholesale acquisition prices of prescription drugs purchased from drug manufacturers.
 Sec. 403. Fair treatment of Medicare part B billing codes for the prescribing of biosimilars.

TITLE V—FIXING GLOBAL FREELOADING

- Sec. 501. Chief Pharmaceutical Negotiator in the Office of the United States Trade Representative.

TITLE I—ELIMINATING DELAYS OF GENERIC DRUGS AND BIOSIMILAR PRODUCTS

SEC. 101. ACTIONS FOR DELAYS OF GENERIC DRUGS AND BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) DEFINITIONS.—In this section—

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

(A) a nondiscriminatory price for the sale of the covered product at or below, but not

greater than, the most recent wholesale acquisition cost for the drug, as defined in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B));

(B) a schedule for delivery that results in the transfer of the covered product to the eligible product developer consistent with the timing under subsection (b)(2)(A)(iv); and

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

(2) the term “covered product”—

(A) means—

(i) any drug approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);

(ii) any combination of a drug or biological product described in clause (i); or

(iii) when reasonably necessary to support approval of an application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), or sec-

tion 351 of the Public Health Service Act (42 U.S.C. 262), as applicable, or otherwise meet the requirements for approval under either such section, any product, including any device, that is marketed or intended for use with such a drug or biological product; and

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

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

(ii) the Secretary determines that inclusion of the drug or biological product as a covered product is likely to contribute to alleviating or preventing a shortage;

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

(4) the term “eligible product developer” means a person that seeks to develop a product for ap-

1 proval pursuant to an application for approval under
2 subsection (b)(2) or (j) of section 505 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
4 for licensing pursuant to an application under sec-
5 tion 351(k) of the Public Health Service Act (42
6 U.S.C. 262(k));

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

14 (6) the term “REMS” means a risk evaluation
15 and mitigation strategy under section 505–1 of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 355–1);

18 (7) the term “REMS with ETASU” means a
19 REMS that contains elements to assure safe use
20 under section 505–1(f) of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 355–1(f));

22 (8) the term “Secretary” means the Secretary
23 of Health and Human Services;

24 (9) the term “single, shared system of elements
25 to assure safe use” means a single, shared system

1 of elements to assure safe use under section 505–
2 1(f) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 355–1(f)); and

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

7 (A) conduct testing to support an applica-
8 tion under—

9 (i) subsection (b)(2) or (j) of section
10 505 of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355); or

12 (ii) section 351(k) of the Public
13 Health Service Act (42 U.S.C. 262(k));
14 and

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

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

19 (1) IN GENERAL.—An eligible product developer
20 may bring a civil action against the license holder
21 for a covered product seeking relief under this sub-
22 section in an appropriate district court of the United
23 States alleging that the license holder has declined
24 to provide sufficient quantities of the covered prod-

1 uct to the eligible product developer on commercially
2 reasonable, market-based terms.

3 (2) ELEMENTS.—

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

8 (i) that—

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

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

13 (aa) the eligible product de-
14 veloper has obtained a covered
15 product authorization from the
16 Secretary in accordance with sub-
17 paragraph (B); and

18 (bb) the eligible product de-
19 veloper has provided a copy of
20 the covered product authorization
21 to the license holder;

22 (ii) that, as of the date on which the
23 civil action is filed, the product developer
24 has not obtained sufficient quantities of

1 the covered product on commercially rea-
2 sonable, market-based terms;

3 (iii) that the eligible product developer
4 has requested to purchase sufficient quan-
5 tities of the covered product from the li-
6 cense holder; and

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

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

18 (II) for a covered product that is
19 subject to a REMS with ETASU, by
20 31 days after the later of—

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

24 (bb) the date on which the
25 license holder received a copy of

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

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

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

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

20 (I) development and testing that
21 does not involve human clinical trials,
22 if the eligible product developer has
23 agreed to comply with any conditions
24 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 sell sufficient quantities of the covered prod-
12 uct to the eligible product developer at commer-
13 cially reasonable market-based terms—

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

24 (ii) for a covered product that is sub-
25 ject to a REMS with ETASU, by the date

1 that is 20 days after the date on which the
2 license holder received the request for the
3 covered product, and the eligible product
4 developer did not accept such offer by the
5 date that is 10 days after the date on
6 which the eligible product developer re-
7 ceived such offer from the license holder.

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

14 (A) certified or registered mail with return
15 receipt requested;

16 (B) personal delivery; or

17 (C) electronic means.

18 (5) REMEDIES.—

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

22 (i) order the license holder to provide
23 to the eligible product developer without
24 delay sufficient quantities of the covered

1 product on commercially reasonable, mar-
2 ket-based terms;

3 (ii) award to the eligible product de-
4 veloper reasonable attorney's fees and costs
5 of the civil action; and

6 (iii) award to the eligible product de-
7 veloper a monetary amount sufficient to
8 deter the license holder from failing to pro-
9 vide eligible product developers with suffi-
10 cient quantities of a covered product on
11 commercially reasonable, market-based
12 terms, if the court finds, by a preponder-
13 ance of the evidence—

14 (I) that the license holder delayed
15 providing sufficient quantities of the
16 covered product to the eligible product
17 developer without a legitimate busi-
18 ness justification; or

19 (II) that the license holder failed
20 to comply with an order issued under
21 clause (i).

22 (B) MAXIMUM MONETARY AMOUNT.—A
23 monetary amount awarded under subparagraph
24 (A)(iii) shall not be greater than the revenue

1 that the license holder earned on the covered
2 product during the period—

3 (i) beginning on—

4 (I) for a covered product that is
5 not subject to a REMS with ETASU,
6 the date that is 31 days after the date
7 on which the license holder received
8 the request; or

9 (II) for a covered product that is
10 subject to a REMS with ETASU, the
11 date that is 31 days after the later
12 of—

13 (aa) the date on which the
14 license holder received the re-
15 quest; or

16 (bb) the date on which the
17 license holder received a copy of
18 the covered product authorization
19 issued by the Secretary in ac-
20 cordance with paragraph (2)(B);
21 and

22 (ii) ending on the date on which the
23 eligible product developer received suffi-
24 cient quantities of the covered product.

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

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

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

20 “(l) PROVISION OF SAMPLES NOT A VIOLATION OF
21 STRATEGY.—The provision of samples of a covered prod-
22 uct to an eligible product developer (as those terms are
23 defined in section 2(a) of the Creating and Restoring
24 Equal Access to Equivalent Samples Act of 2019) shall
25 not be considered a violation of the requirements of any

1 risk evaluation and mitigation strategy that may be in
2 place under this section for such drug.”.

3 (e) RULE OF CONSTRUCTION.—

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

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

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

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

16 **SEC. 102. REMS APPROVAL PROCESS FOR SUBSEQUENT**
17 **FILERS.**

18 Section 505–1 of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 355–1), as amended by section 101,
20 is further amended—

21 (1) in subsection (g)(4)(B)—

22 (A) in clause (i) by striking “or” after the
23 semicolon;

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

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

2 “(iii) accommodate different, com-
3 parable aspects of the elements to assure
4 safe use for a drug that is the subject of
5 an application under section 505(j), and
6 the applicable listed drug.”;

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

9 “(C)(i) Elements to assure safe use, if re-
10 quired under subsection (f) for the listed drug,
11 which, subject to clause (ii), for a drug that is
12 the subject of an application under section
13 505(j) may use—

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

16 “(II) a different, comparable aspect of
17 the elements to assure safe use under sub-
18 section (f).

19 “(ii) The Secretary may require a drug
20 that is the subject of an application under sec-
21 tion 505(j) and the listed drug to use a single,
22 shared system under subsection (f), if the Sec-
23 retary determines that no different, comparable
24 aspect of the elements to assure safe use could
25 satisfy the requirements of subsection (f).”;

1 (3) in subsection (i), by adding at the end the
2 following:

3 “(3) SHARED REMS.—If the Secretary ap-
4 proves, in accordance with paragraph (1)(C)(i)(II), a
5 different, comparable aspect of the elements to as-
6 sure safe use under subsection (f) for a drug that
7 is the subject of an abbreviated new drug application
8 under section 505(j), the Secretary may require that
9 such different comparable aspect of the elements to
10 assure safe use can be used with respect to any
11 other drug that is the subject of an application
12 under section 505(j) or 505(b) that references the
13 same listed drug.”; and

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

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

1 **TITLE II—INCREASING ACCESS**
2 **TO DRUGS AND BIOSIMILAR**
3 **PRODUCTS**

4 **SEC. 201. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
5 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
6 **UCTS.**

7 Subchapter A of chapter V of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
9 ed by adding at the end the following:

10 **“SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY RE-**
11 **VIEW FOR GENERIC COMPLEX DRUG PROD-**
12 **UCTS.**

13 “(a) ESTABLISHMENT OF PROGRAM.—The Secretary
14 shall establish a program to expedite the development of,
15 and provide priority review under section 505(j) for, ge-
16 neric complex drug products.

17 “(b) REQUEST FOR DESIGNATION.—A sponsor of a
18 generic complex drug product may request that the Sec-
19 retary designate such product for expedited development
20 and priority review under this section.

21 “(c) DESIGNATION PROCESS.—

22 “(1) IN GENERAL.—Not later than 60 calendar
23 days after the receipt of a request under subsection
24 (c), the Secretary shall determine whether the prod-
25 uct that is the subject of the request meets the cri-

1 teria under subsection (e) to be considered a generic
2 complex drug product. If the Secretary determines
3 that the product meets the criteria, the Secretary
4 shall designate the product for expedited develop-
5 ment and priority review.

6 “(2) REVIEW.—Review of a request under sub-
7 section (b) shall be undertaken by a team that is
8 composed of experienced staff and senior managers
9 of the Food and Drug Administration.

10 “(3) WITHDRAWAL.—The Secretary may not
11 withdraw a designation granted under this section
12 on the basis of the criteria under subsection (e) no
13 longer applying because of the subsequent clearance
14 or approval of any other product.

15 “(d) EXPEDITED DEVELOPMENT AND PRIORITY RE-
16 VIEW GUIDANCE.—

17 “(1) CONTENT.—Not later than December 31,
18 2021, the Secretary shall issue guidance on the im-
19 plementation of this section. Such guidance shall—

20 “(A) set forth the process by which a per-
21 son may seek a designation under subsection
22 (c);

23 “(B) provide a template for requests under
24 subsection (b);

1 “(C) identify the criteria the Secretary will
2 use in evaluating a request for designation
3 under this section; and

4 “(D) identify the criteria and processes the
5 Secretary will use to expedite the development
6 and review of products designated under this
7 section.

8 “(2) PROCESS.—Prior to finalizing the guid-
9 ance under paragraph (1), the Secretary shall seek
10 public comment on a draft version of that guidance.

11 “(e) GENERIC COMPLEX DRUG PRODUCT DE-
12 FINED.—In this section, the term ‘generic complex drug
13 product’ means a product that represents a complex ther-
14 apy that consists of or includes a drug for approval under
15 section 505(j) and that—

16 “(1)(A) contains complex active ingredients
17 (such as peptides, polymeric compounds, complex
18 mixtures of active ingredients, and naturally sourced
19 ingredients);

20 “(B) is composed of complex formulations (such
21 as liposomes or colloids);

22 “(C) requires a complex route of delivery (such
23 as locally acting drugs such as dermatological prod-
24 ucts and complex ophthalmological products and otic

1 dosage forms that are formulated as suspensions,
2 emulsions, or gels); or

3 “(D) involves a complex dosage form (such as
4 transdermals, metered dose inhalers, or extended re-
5 lease injectables);

6 “(2) presents as a complex drug-device com-
7 bination product (such as auto injectors or metered
8 dose inhalers); or

9 “(3) is a product that would benefit from early
10 scientific engagement due to complexity or uncer-
11 tainty concerning the approval pathway under sec-
12 tion 505(j).”.

13 **SEC. 202. INCREASING PHARMACEUTICAL OPTIONS TO**
14 **TREAT AN UNMET MEDICAL NEED.**

15 Subsection (b) of section 506 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 356) is amended by
17 adding at the end the following:

18 “(4) UNMET MEDICAL NEED.—For purposes of
19 paragraph (1), a drug shall be deemed to address an
20 unmet medical need for a disease or condition if
21 fewer than 3 available drugs exist for the treatment
22 of such disease or condition.”.

1 **SEC. 203. PREEMPTION OF STATE BARRIERS TO THE SUB-**
2 **STITUTION OF BIOSIMILAR PRODUCTS.**

3 No State, or any political subdivision thereof, may
4 prohibit a pharmacy or pharmacist from dispensing, in
5 place of a biological reference product, any product that,
6 pursuant to section 351(k) of the Public Health Service
7 Act (42 U.S.C. 262(k)), has been determined by the Sec-
8 retary of Health and Human Services to be interchange-
9 able with the reference product in accordance with sub-
10 sections (a) and (k)(4) of such Act (42 U.S.C. 262(a),
11 (k)(4)).

12 **SEC. 204. EXPEDITED PROCESS FOR BIOLOGICAL PROD-**
13 **UCTS AUTHORIZED FOR MARKETING IN EU-**
14 **ROPEAN UNION.**

15 Section 351(a) of the Public Health Service Act (42
16 U.S.C. 262(a)) is amended by adding at the end the fol-
17 lowing new paragraph:

18 “(4) PRODUCTS AUTHORIZED FOR MARKETING
19 IN EUROPEAN UNION.—In considering whether to li-
20 cense a biological product under this subsection or
21 subsection (k), the Secretary may expedite the li-
22 censing process if the biological product has been
23 authorized for marketing by the European Medicines
24 Agency and such authorization remains in effect.”.

1 **TITLE III—PRESCRIPTION DRUG**
2 **PRICING AND COMPETITION**

3 **SEC. 301. MEDICARE DRUG COVERAGE.**

4 Notwithstanding any other provision of law, the Sec-
5 retary of Health and Human Services may alter payments
6 for prescription drugs, including biologicals, provided
7 through the Medicare part B program by paying at rates
8 that, based on the average sales price plus 6 percent in
9 the year of implementation of this Act, grow at the con-
10 sumer price index (CPI Prescription Drugs).

11 **SEC. 302. FEE TRANSPARENCY BETWEEN PHARMACIES AND**
12 **PBMS.**

13 (a) PROHIBITING MEDICARE PDP SPONSORS AND
14 MA–PD ORGANIZATIONS FROM RETROACTIVELY REDUC-
15 ING PAYMENT ON CLEAN CLAIMS SUBMITTED BY PHAR-
16 MACIES.—

17 (1) IN GENERAL.—Section 1860D–12(b)(4)(A)
18 of the Social Security Act (42 U.S.C. 1395w–
19 112(b)(4)(A)) is amended by adding at the end the
20 following new clause:

21 “(iv) PROHIBITING RETROACTIVE RE-
22 Ductions in payments on clean
23 claims.—Each contract entered into with
24 a PDP sponsor under this part with re-
25 spect to a prescription drug plan offered

1 by such sponsor shall provide that after
2 the date of receipt of a clean claim sub-
3 mitted by a pharmacy, the PDP sponsor
4 (or an agent of the PDP sponsor) may not
5 retroactively reduce payment on such claim
6 directly or indirectly through aggregated
7 effective rate or otherwise except in the
8 case such claim is found to not be a clean
9 claim (such as in the case of a claim lack-
10 ing required substantiating documentation)
11 during the course of a routine audit as
12 permitted pursuant to written agreement
13 between the PDP sponsor (or such an
14 agent) and such pharmacy. The previous
15 sentence shall not prohibit any retroactive
16 increase in payment to a pharmacy pursu-
17 ant to a written agreement between a PDP
18 sponsor (or an agent of such sponsor) and
19 such pharmacy.”.

20 (2) EFFECTIVE DATE.—The amendment made
21 by subsection (a) shall apply with respect to con-
22 tracts entered into on or after January 1, 2021.

23 (b) ELIMINATION OF DIR FEES.—

1 (1) PHARMACY BENEFITS MANAGER STAND-
2 ARDS UNDER THE MEDICARE PROGRAM FOR PRE-
3 SCRIPTION DRUG PLANS AND MA–PD PLANS.—

4 (A) IN GENERAL.—Section 1860D–12(b)
5 of the Social Security Act (42 U.S.C. 1395w–
6 112(b)) is amended by adding at the end the
7 following new paragraph:

8 “(7) PHARMACY BENEFITS MANAGER TRANS-
9 PARENCY REQUIREMENTS.—Each contract entered
10 into with a PDP sponsor under this part with re-
11 spect to a prescription drug plan offered by such
12 sponsor or with an MA organization offering an
13 MA–PD plan under part C shall provide that the
14 sponsor or organization, respectively, may not enter
15 into a contract with any pharmacy benefits manager
16 (referred to in this paragraph as a ‘PBM’) to man-
17 age the prescription drug coverage provided under
18 such plan, or to control the costs of the prescription
19 drug coverage under such plan, unless the PBM ad-
20 heres to the following criteria when handling person-
21 ally identifiable utilization and claims data or other
22 sensitive patient data:

23 “(A) The PBM may not transmit any per-
24 sonally identifiable utilization, protected health
25 information, or claims data, with respect to a

1 plan enrollee, to a pharmacy owned by a PBM
2 if the plan enrollee has not voluntarily elected
3 in writing or via secure electronic means to fill
4 that particular prescription at the PBM-owned
5 pharmacy.

6 “(B) The PBM may not require that a
7 plan enrollee use a retail pharmacy, mail order
8 pharmacy, specialty pharmacy, or other phar-
9 macy entity providing pharmacy services in
10 which the PBM has an ownership interest or
11 that has an ownership interest in the PBM, or
12 provide an incentive to a plan enrollee to en-
13 courage the enrollee to use a retail pharmacy,
14 mail order pharmacy, specialty pharmacy, or
15 other pharmacy entity providing pharmacy serv-
16 ices in which the PBM has an ownership inter-
17 est or that has an ownership interest in the
18 PBM, if the incentive is applicable only to such
19 pharmacies.”.

20 (B) REGULAR UPDATE OF PRESCRIPTION
21 DRUG PRICING STANDARD.—Paragraph (6) of
22 section 1860D–12(b) of the Social Security Act
23 (42 U.S.C. 1395w–112(b)) is amended to read
24 as follows:

1 “(6) REGULAR UPDATE OF PRESCRIPTION
2 DRUG PRICING STANDARD.—

3 “(A) IN GENERAL.—If the PDP sponsor of
4 a prescription drug plan (or MA organization
5 offering an MA–PD plan) uses a standard for
6 reimbursement (as described in subparagraph
7 (B)) of pharmacies based on the cost of a drug,
8 each contract entered into with such sponsor
9 under this part (or organization under part C)
10 with respect to the plan shall provide that the
11 sponsor (or organization) shall—

12 “(i) update such standard not less fre-
13 quently than once every 7 days, beginning
14 with an initial update on January 1 of
15 each year, to accurately reflect the market
16 price of acquiring the drug;

17 “(ii) disclose to applicable pharmacies
18 and the contracting entities of such phar-
19 macies the sources used for making any
20 such update immediately without require-
21 ment of request;

22 “(iii) if the source for such a standard
23 for reimbursement is not publicly available,
24 disclose to the applicable pharmacies and
25 the respective contracting entities of such

1 pharmacies all individual drug prices to be
2 so updated in advance of the use of such
3 prices for the reimbursement of claims;

4 “(iv) establish a process to appeal, in-
5 vestigate, and resolve disputes regarding
6 individual drug prices that are less than
7 the pharmacy acquisition price for such
8 drug, which must be adjudicated within 7
9 days of the pharmacy filing its appeal; and

10 “(v) provide all such pricing data in
11 an .xml spreadsheet format or a com-
12 parable easily accessible and complete
13 spreadsheet format.

14 “(B) PRESCRIPTION DRUG PRICING
15 STANDARD DEFINED.—For purposes of sub-
16 paragraph (A), a standard for reimbursement
17 of a pharmacy is any methodology or formula
18 for varying the pricing of a drug or drugs dur-
19 ing the term of the pharmacy reimbursement
20 contract that is based on the cost of the drug
21 involved, including drug pricing references and
22 amounts that are based upon average wholesale
23 price, wholesale average cost, average manufac-
24 turer price, average sales price, maximum al-

1 lowable cost (MAC), or other costs, whether
2 publicly available or not.”.

3 (C) EFFECTIVE DATE.—The amendments
4 made by this section shall apply to plan years
5 beginning on or after January 1, 2020.

6 (2) REGULAR UPDATE OF PRESCRIPTION DRUG
7 PRICING STANDARD UNDER TRICARE RETAIL PHAR-
8 MACY PROGRAM.—Section 1074g(d) of title 10,
9 United States Code, is amended by adding at the
10 end the following new paragraph:

11 “(3) To the extent practicable, with respect to the
12 TRICARE retail pharmacy program described in sub-
13 section (a)(2)(E)(ii), the Secretary shall ensure that a con-
14 tract entered into with a TRICARE managed care support
15 contractor includes requirements described in section
16 1860D–12(b)(6) of the Social Security Act (42 U.S.C.
17 1395w–112(b)(6)) to ensure the provision of information
18 regarding the pricing standard for prescription drugs.”.

19 (3) PRESCRIPTION DRUG TRANSPARENCY IN
20 THE FEDERAL EMPLOYEES HEALTH BENEFITS PRO-
21 GRAM.—

22 (A) IN GENERAL.—Section 8902 of title 5,
23 United States Code, is amended by adding at
24 the end the following new subsections:

1 “(p) A contract may not be made or a plan approved
2 under this chapter under which a carrier has an agree-
3 ment with a pharmacy benefits manager (in this sub-
4 section referred to as a ‘PBM’) to manage prescription
5 drug coverage or to control the costs of the prescription
6 drug coverage unless the carrier and PBM adhere to the
7 following criteria:

8 “(1) The PBM may not transmit any personally
9 identifiable utilization, protected health information,
10 or claims data with respect to an individual enrolled
11 under such contract or plan to a pharmacy owned by
12 the PBM if the individual has not voluntarily elected
13 in writing or via secure electronic means to fill that
14 particular prescription at such a pharmacy.

15 “(2) The PBM may not require that an indi-
16 vidual enrolled under such contract or plan use a re-
17 tail pharmacy, mail order pharmacy, specialty phar-
18 macy, or other pharmacy entity providing pharmacy
19 services in which the PBM has an ownership interest
20 or that has an ownership interest in the PBM or
21 provide an incentive to a plan enrollee to encourage
22 the enrollee to use a retail pharmacy, mail order
23 pharmacy, specialty pharmacy, or other pharmacy
24 entity providing pharmacy services in which the
25 PBM has an ownership interest or that has an own-

1 ership interest in the PBM, if the incentive is appli-
2 cable only to such pharmacies.

3 “(q)(1) If a contract made or plan approved under
4 this chapter provides for a standard for reimbursement
5 (as described in paragraph (2)) with respect to a prescrip-
6 tion drug plan, such contract or plan shall provide that
7 the applicable carrier—

8 “(A) update such standard not less frequently
9 than once every 7 days, beginning with an initial up-
10 date on January 1 of each year, to accurately reflect
11 the market price of acquiring the drug;

12 “(B) disclose to applicable pharmacies and the
13 contracting entities of such pharmacies the sources
14 used for making any such update immediately with-
15 out requirement of request;

16 “(C) if the source for such a standard for reim-
17 bursement is not publicly available, disclose to the
18 applicable pharmacies and contracting entities of
19 such pharmacies all individual drug prices to be so
20 updated in advance of the use of such prices for the
21 reimbursement of claims;

22 “(D) establish a process to appeal, investigate,
23 and resolve disputes regarding individual drug prices
24 that are less than the pharmacy acquisition price for

1 such drug, which must be adjudicated within 7 days
2 of the pharmacy filing its appeal; and

3 “(E) provide all such pricing data in an .xml
4 spreadsheet format or a comparable easily accessible
5 and complete spreadsheet format.

6 “(2) For purposes of paragraph (1), a standard for
7 reimbursement of a pharmacy is any methodology or for-
8 mula for varying the pricing of a drug or drugs during
9 the term of the pharmacy reimbursement contract that is
10 based on the cost of the drug involved, including drug pric-
11 ing references and amounts that are based upon average
12 wholesale price, wholesale average cost, average manufac-
13 turer price, average sales price, maximum allowable cost,
14 or other costs, whether publicly available or not.”.

15 (B) APPLICATION.—The amendment made
16 by subparagraph (A) shall apply to any contract
17 entered into under section 8902 of title 5,
18 United States Code, on or after the date of en-
19 actment of this section.

20 **SEC. 303. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT**
21 **FOR SINGLE SOURCE DRUGS AND INNO-**
22 **VATOR MULTIPLE SOURCE DRUGS.**

23 Section 1927(c)(2)(D) of the Social Security Act (42
24 U.S.C. 1396r-8(c)(2)(D)) is amended by inserting after

1 “December 31, 2009,” the following: “and before Decem-
 2 ber 31, 2024,”.

3 **SEC. 304. REGULATION OF MANUFACTURER-SPONSORED**
 4 **COPAY CONTRIBUTIONS.**

5 Notwithstanding any other provision of law, the Sec-
 6 retary of Health and Human Services may establish a
 7 mechanism prohibiting drug manufacturers from contrib-
 8 uting financially to patient copays, and establish a system
 9 of penalizing such behavior.

10 **TITLE IV—PATENT DISCLOSURE**
 11 **REQUIREMENTS**

12 **SEC. 401. PATENT DISCLOSURE AND TRANSPARENCY RE-**
 13 **QUIREMENTS.**

14 (a) IN GENERAL.—

15 (1) IN GENERAL.—Section 351 of the Public
 16 Health Service Act (42 U.S.C. 262) is amended by
 17 adding at the end the following:

18 “(o) ADDITIONAL REQUIREMENTS WITH RESPECT
 19 TO PATENTS.—

20 “(1) PUBLICATION OF INFORMATION.—

21 “(A) IN GENERAL.—Within 1 year of the
 22 date of enactment of the Biologic Patent Trans-
 23 parency Act, the Secretary shall publish and
 24 make available to the public a single, easily
 25 searchable list that includes—

1 “(i) the proper and proprietary name
2 of each biological product licensed or
3 deemed to be licensed under subsection (a)
4 or (k);

5 “(ii) the date of approval and applica-
6 tion number for each such biological prod-
7 uct;

8 “(iii) the marketing status, dosage
9 form, route of administration, strength,
10 and, if applicable, reference product, for
11 each such biological product;

12 “(iv) the licensure status for each
13 such biological product, including whether
14 the license at the time of listing is ap-
15 proved, withdrawn, or revoked;

16 “(v) for each such biological product
17 that is a reference product for which an
18 exclusivity period applies, and for which
19 the Secretary has determined the dates of
20 such exclusivity period, under subsection
21 (k)(7)(A) or subsection (k)(7)(B) of this
22 section or under section 527 of the Federal
23 Food, Drug, and Cosmetic Act, including
24 any extension of such exclusivity period in
25 accordance with subsection (m) of this sec-

tion, the date on which such exclusivity period expires;

“(vi) any determination of biosimilarity or interchangeability for each such biological product; and

“(vii) information regarding approved indications for each such biological product, in such manner as the Secretary determines appropriate.

“(B) UPDATES.—Every 30 days after the publication of the first list under subparagraph (A), the Secretary shall revise the list to include—

“(i)(I) each biological product licensed under subsection (a) or (k) during the 30-day period; and

“(II) with respect to each biological product described in subclause (I), the information described in clauses (i) through (vii) of subparagraph (A); and

“(ii) any updates to information previously published in accordance with subparagraph (A).”.

(2) PUBLIC LISTING OF PATENT INFORMATION.—

1 (A) IN GENERAL.—The Secretary of
2 Health and Human Services shall include in the
3 recommendations transmitted to Congress
4 under section 744I(f) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 379j–53(f))
6 recommendations with respect to the collection
7 and publication of patent information in the list
8 described in section 351(o) of the Public Health
9 Service Act (42 U.S.C. 262), as added by para-
10 graph (1).

11 (B) DEVELOPMENT.—In developing rec-
12 ommendations under subparagraph (A), the
13 Secretary of Health and Human Services may
14 consult with the Federal Trade Commission,
15 the Director of the United States Patent and
16 Trademark Office, and the Federal Trade Com-
17 mission, in addition to the entities listed in sec-
18 tion 744I(f)(1) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 379j–53(f)(1)).

20 (b) RULE OF CONSTRUCTION.—Nothing in this sec-
21 tion, including the amendment made by this section, shall
22 be construed to require or allow the Secretary of Health
23 and Human Services to delay the review or approval of
24 a biologic license application under section 351 of the Pub-
25 lic Health Service Act (42 U.S.C. 262).

1 **SEC. 402. ANTITRUST EXEMPTION FOR HEALTH INSURANCE**
2 **ISSUERS TO NEGOTIATE WHOLESALE ACQUI-**
3 **SITION PRICES OF PRESCRIPTION DRUGS**
4 **PURCHASED FROM DRUG MANUFACTURERS.**

5 (a) EXEMPTION.—It shall not be a violation of the
6 antitrust laws for one or more health insurance issuers
7 or their designated agents to jointly negotiate wholesale
8 acquisition prices of a prescription drug with a manufac-
9 turer of a prescription drug with regards to the reimburse-
10 ment policies of the insurers of the manufacturer’s drugs
11 so long as no single wholesale acquisition price is jointly
12 determined between the insurance issuers or their des-
13 ignated agents.

14 (b) DEFINITIONS.—For purposes of this section:

15 (1) ANTITRUST LAWS.—The term “antitrust
16 laws” has the meaning given it in subsection (a) of
17 the 1st section of the Clayton Act (15 U.S.C. 12(a)),
18 except that such term includes section 5 of the Fed-
19 eral Trade Commission Act (15 U.S.C. 45) to the
20 extent such section 5 applies to unfair methods of
21 competition.

22 (2) HEALTH INSURANCE ISSUER.—The term
23 “health insurance issuer” has the meaning given
24 that term in section 2791(b) of the Public Health
25 Service Act (42 U.S.C. 300gg–91(b)).

1 (3) HEALTH MAINTENANCE ORGANIZATION.—

2 The term “health maintenance organization”
3 means—

4 (A) a federally qualified health mainte-
5 nance organization (as defined in section
6 300e(a) of title 42 of the Code of Federal Reg-
7 ulations),

8 (B) an organization recognized under State
9 law as a health maintenance organization, or

10 (C) a similar organization regulated under
11 State law for solvency in the same manner and
12 to the same extent as such a health mainte-
13 nance organization.

14 (4) MANUFACTURER.—The term “manufac-
15 turer” means anyone who is engaged in manufac-
16 turing, preparing, propagating, compounding, proc-
17 essing, packaging, repackaging, or labeling of a pre-
18 scription drug.

19 (5) PRESCRIPTION DRUG.—The term “prescrip-
20 tion drug” means a drug for human use subject to
21 section 503(b)(1) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 353(b)(1)).

23 (c) EFFECTIVE DATE.—This section shall take effect
24 on the date of the enactment of this Act but shall not
25 apply with respect to conduct that occurs before such date.

1 **SEC. 403. FAIR TREATMENT OF MEDICARE PART B BILLING**
2 **CODES FOR THE PRESCRIBING OF**
3 **BIOSIMILARS.**

4 Section 1847A of the Social Security Act (42 U.S.C.
5 1395w–3a) is amended by adding at the end the following
6 new subsection:

7 “(h) USE OF CERTAIN CODES.—Notwithstanding
8 any previous provision of this section, for purposes of pay-
9 ment of biological biosimilar product the Secretary of
10 Health and Human Services shall assign a uniform Com-
11 mon Procedure System code to describe all such products
12 that share a common reference product.”.

13 **TITLE V—FIXING GLOBAL**
14 **FREELOADING**

15 **SEC. 501. CHIEF PHARMACEUTICAL NEGOTIATOR IN THE**
16 **OFFICE OF THE UNITED STATES TRADE REP-**
17 **RESENTATIVE.**

18 (a) IN GENERAL.—Section 141 of the Trade Act of
19 1974 (19 U.S.C. 2171) is amended—

20 (1) in subsection (b)(2)—

21 (A) by striking “and one Chief Innovation
22 and Intellectual Property Negotiator” and in-
23 serting “one Chief Innovation and Intellectual
24 Property Negotiator, and one Chief Pharma-
25 ceutical Negotiator”;

(B) by striking “or the Chief Innovation and Intellectual Property Negotiator” and inserting “the Chief Innovation and Intellectual Property Negotiator, or the Chief Pharmaceutical Negotiator”; and

(C) by striking “and the Chief Innovation and Intellectual Property Negotiator” and inserting “the Chief Innovation and Intellectual Property Negotiator, and the Chief Pharmaceutical Negotiator”; and

(2) in subsection (c), by adding at the end the following new paragraph:

“(7) The principal function of the Chief Pharmaceutical Negotiator shall be to conduct trade negotiations and to enforce trade agreements relating to United States pharmaceutical products and services. The Chief Pharmaceutical Negotiator shall be a vigorous advocate on behalf of United States pharmaceutical interests, including patients and United States pharmaceutical workers. The Chief Pharmaceutical Negotiator shall perform such other functions as the United States Trade Representative may direct.”.

(b) COMPENSATION.—Section 5314 of title 5, United States Code is amended by striking “Chief Innovation and

1 Intellectual Property Negotiator, Office of the United
2 States Trade Representative.” and inserting the following:

3 “Chief Innovation and Intellectual Property Nego-
4 tiator, Office of the United States Trade Representative.

5 “Chief Pharmaceutical Negotiator, Office of the
6 United States Trade Representative.”.

7 (c) REPORT REQUIRED.—Not later than one year
8 after the appointment of the first Chief Pharmaceutical
9 Negotiator pursuant to paragraph (2) of section 141(b)
10 of the Trade Act of 1974, as amended by subsection (a),
11 and annually thereafter, the United States Trade Rep-
12 resentative shall submit to the Committee on Finance of
13 the Senate and the Committee on Ways and Means of the
14 House of Representatives a report describing in detail—

15 (1) enforcement actions taken by the Trade
16 Representative during the one-year period preceding
17 the submission of the report to ensure the protection
18 of United States pharmaceutical products and serv-
19 ices; and

20 (2) other actions taken by the Trade Represent-
21 ative to advance United States pharmaceutical prod-
22 ucts and services.

○