I

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

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A BILL

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

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Competition Prescription Act of 2019''.

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

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-

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

(5) the term ''license holder'' means the holder of an application approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or the holder of a license under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) for a covered product;

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

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

(8) the term ''Secretary'' means the Secretary of Health and Human Services;

(9) the term ''single, shared system of elements to assure safe use'' means a single, shared system

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

(10) the term ''sufficient quantities'' means an amount of a covered product that the eligible product developer determines allows it to—

(A) conduct testing to support an application under—

(i) subsection (b)(2) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); or

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

(B) fulfill any regulatory requirements relating to approval of such an application.

(b) CIVIL ACTION FOR FAILURE TO PROVIDE SUFFICIENT QUANTITIES OF A COVERED PRODUCT.—

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

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

(2) ELEMENTS.—

(A) IN GENERAL.—To prevail in a civil action brought under paragraph (1), an eligible product developer shall prove, by a preponderance of the evidence—

(i) that—

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

(II) if the covered product is subject to a REMS with ETASU—

(aa) the eligible product developer has obtained a covered product authorization from the Secretary in accordance with subparagraph (B); and

(bb) the eligible product developer has provided a copy of the covered product authorization to the license holder;

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

the covered product on commercially reasonable, market-based terms;

(iii) that the eligible product developer has requested to purchase sufficient quantities of the covered product from the license holder; and

(iv) that the license holder has not delivered to the eligible product developer sufficient quantities of the covered product on commercially reasonable, market-based terms—

(I) for a covered product that is not subject to a REMS with ETASU, by the date that is 31 days after the date on which the license holder received the request for the covered product; and

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

(aa) the date on which the license holder received the request for the covered product; or

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

the covered product authorization issued by the Secretary in accordance with subparagraph (B).

(B) AUTHORIZATION FOR COVERED PRODUCT SUBJECT TO A REMS WITH ETASU.—

(i) REQUEST.—An eligible product developer may submit to the Secretary a written request for the eligible product developer to be authorized to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU.

(ii) AUTHORIZATION.—Not later than 120 days after the date on which a request under clause (i) is received, the Secretary shall, by written notice, authorize the eligible product developer to obtain sufficient quantities of an individual covered product subject to a REMS with ETASU for purposes of—

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

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

(aa)(AA) submitted protocols, informed consent documents, and informational materials for testing that include protections that provide safety protections comparable to those provided by the REMS for the covered product; or

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

(bb) met any other requirements the Secretary may establish.

(iii) NOTICE.—A covered product authorization issued under this subparagraph shall state that the provision of the covered product by the license holder under the terms of the authorization will not be a violation of the REMS for the covered product.

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

(A) that, on the date on which the eligible product developer requested to purchase sufficient quantities of the covered product from the license holder—

(i) neither the license holder nor any of its agents, wholesalers, or distributors was engaged in the manufacturing or commercial marketing of the covered product; and

(ii) neither the license holder nor any of its agents, wholesalers, or distributors otherwise had access to inventory of the covered product to supply to the eligible product developer on commercially reasonable, market-based terms;

(B) that—

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

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

agents, distributors, or wholesalers to sell covered products to eligible product developers; and

(iii) the covered product can be purchased by the eligible product developer in sufficient quantities on commercially reasonable, market-based terms from the agents, distributors, or wholesalers of the license holder; or

(C) that the license holder made an offer to sell sufficient quantities of the covered product to the eligible product developer at commercially reasonable market-based terms—

(i) for a covered product that is not subject to a REMS with ETASU, by the date that is 14 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 7 days after the date on which the eligible product developer received such offer from the license holder; or

(ii) for a covered product that is subject to a REMS with ETASU, by the date

that is 20 days after the date on which the license holder received the request for the covered product, and the eligible product developer did not accept such offer by the date that is 10 days after the date on which the eligible product developer received such offer from the license holder.

(4) METHODS FOR TRANSMISSION OF REQUESTS FOR COVERED PRODUCTS.—A written request for a covered product, offer to sell a covered product, or acceptance of such an offer between the eligible product developer and the license holder shall be made by—

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

(B) personal delivery; or

(C) electronic means.

(5) REMEDIES.—

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

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

product on commercially reasonable, market-based terms;

(ii) award to the eligible product developer reasonable attorney's fees and costs of the civil action; and

(iii) award to the eligible product developer a monetary amount sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms, if the court finds, by a preponderance of the evidence—

(I) that the license holder delayed providing sufficient quantities of the covered product to the eligible product developer without a legitimate business justification; or

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

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

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

(i) beginning on—

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

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

(aa) the date on which the license holder received the request; or

(bb) the date on which the license holder received a copy of the covered product authorization issued by the Secretary in accordance with paragraph (2)(B); and

(ii) ending on the date on which the eligible product developer received sufficient quantities of the covered product.

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

(c) LIMITATION OF LIABILITY.—A license holder for a covered product shall not be liable for any claim under Federal, State, or local law arising out of the failure of an eligible product developer to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in this section, including transportation, handling, use, or disposal of the covered product by the eligible product developer.

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

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

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

(e) RULE OF CONSTRUCTION.—

(1) DEFINITION.—In this subsection, the term ''antitrust laws''—

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

(B) includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that such section applies to unfair methods of competition.

(2) ANTITRUST LAWS.—Nothing in this section shall be construed to limit the operation of any provision of the antitrust laws.

SEC. 102. REMS APPROVAL PROCESS FOR SUBSEQUENT FILERS.

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

(1) in subsection (g)(4)(B)—

(A) in clause (i) by striking ''or'' after the semicolon;

(B) in clause (ii) by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(iii) accommodate different, comparable aspects of the elements to assure safe use for a drug that is the subject of an application under section 505(j), and the applicable listed drug.'';

(2) in subsection (i)(1), by striking subparagraph (C) and inserting the following:

''(C)(i) Elements to assure safe use, if required under subsection (f) for the listed drug, which, subject to clause (ii), for a drug that is the subject of an application under section 505(j) may use—

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

''(II) a different, comparable aspect of the elements to assure safe use under subsection (f).

''(ii) The Secretary may require a drug that is the subject of an application under section 505(j) and the listed drug to use a single, shared system under subsection (f), if the Secretary determines that no different, comparable aspect of the elements to assure safe use could satisfy the requirements of subsection (f).'';

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

''(3) SHARED REMS.—If the Secretary approves, in accordance with paragraph (1)(C)(i)(II), a different, comparable aspect of the elements to assure safe use under subsection (f) for a drug that is the subject of an abbreviated new drug application under section 505(j), the Secretary may require that such different comparable aspect of the elements to assure safe use can be used with respect to any other drug that is the subject of an application under section 505(j) or 505(b) that references the same listed drug.''; and

(4) by adding at the end the following:

''(m) SEPARATE REMS.—When used in this section, the terms 'different, comparable aspect of the elements to assure safe use' or 'different, comparable approved risk evaluation and mitigation strategies' means a risk evaluation and mitigation strategy for a drug that is the subject of an application under section 505(j) that uses different methods or operational means than the strategy required under subsection (a) for the applicable listed drug, or other application under section 505(j) with the same such listed drug, but achieves the same level of safety as such strategy.''.

TITLE II—INCREASING ACCESS TO DRUGS AND BIOSIMILAR PRODUCTS

SEC. 201. EXPEDITED DEVELOPMENT AND PRIORITY REVIEW FOR GENERIC COMPLEX DRUG PRODUCTS.

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

"SEC. 524B. EXPEDITED DEVELOPMENT AND PRIORITY REVIEW FOR GENERIC COMPLEX DRUG PRODUCTS.

''(a) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide priority review under section 505(j) for, generic complex drug products.

''(b) REQUEST FOR DESIGNATION.—A sponsor of a generic complex drug product may request that the Secretary designate such product for expedited development and priority review under this section.

''(c) DESIGNATION PROCESS.—

''(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the product that is the subject of the request meets the cri-

teria under subsection (e) to be considered a generic complex drug product. If the Secretary determines that the product meets the criteria, the Secretary shall designate the product for expedited development and priority review.

''(2) REVIEW.—Review of a request under subsection (b) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

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

''(d) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW GUIDANCE.—

''(1) CONTENT.—Not later than December 31, 2021, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

''(A) set forth the process by which a person may seek a designation under subsection (c);

''(B) provide a template for requests under subsection (b);

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

''(D) identify the criteria and processes the Secretary will use to expedite the development and review of products designated under this section.

''(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a draft version of that guidance.

''(e) GENERIC COMPLEX DRUG PRODUCT DEFINED.—In this section, the term 'generic complex drug product' means a product that represents a complex therapy that consists of or includes a drug for approval under section 505(j) and that—

''(1)(A) contains complex active ingredients (such as peptides, polymeric compounds, complex mixtures of active ingredients, and naturally sourced ingredients);

''(B) is composed of complex formulations (such as liposomes or colloids);

''(C) requires a complex route of delivery (such as locally acting drugs such as dermatological products and complex ophthalmological products and otic

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

''(D) involves a complex dosage form (such as transdermals, metered dose inhalers, or extended release injectables);

''(2) presents as a complex drug-device combination product (such as auto injectors or metered dose inhalers); or

''(3) is a product that would benefit from early scientific engagement due to complexity or uncertainty concerning the approval pathway under section 505(j).''.

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

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

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

SEC. 203. PREEMPTION OF STATE BARRIERS TO THE SUBSTITUTION OF BIOSIMILAR PRODUCTS.

No State, or any political subdivision thereof, may prohibit a pharmacy or pharmacist from dispensing, in place of a biological reference product, any product that, pursuant to section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), has been determined by the Secretary of Health and Human Services to be interchangeable with the reference product in accordance with subsections (a) and (k)(4) of such Act (42 U.S.C. 262(a), (k)(4)).

SEC. 204. EXPEDITED PROCESS FOR BIOLOGICAL PRODUCTS AUTHORIZED FOR MARKETING IN EUROPEAN UNION.

Section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) is amended by adding at the end the following new paragraph:

''(4) PRODUCTS AUTHORIZED FOR MARKETING IN EUROPEAN UNION.—In considering whether to license a biological product under this subsection or subsection (k), the Secretary may expedite the licensing process if the biological product has been authorized for marketing by the European Medicines Agency and such authorization remains in effect.''.

TITLE III—PRESCRIPTION DRUG PRICING AND COMPETITION

SEC. 301. MEDICARE DRUG COVERAGE.

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

SEC. 302. FEE TRANSPARENCY BETWEEN PHARMACIES AND PBMS.

(a) PROHIBITING MEDICARE PDP SPONSORS AND MA–PD ORGANIZATIONS FROM RETROACTIVELY REDUCING PAYMENT ON CLEAN CLAIMS SUBMITTED BY PHARMACIES.—

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

"(iv) PROHIBITING RETROACTIVE REDUCTIONS IN PAYMENTS ON CLEAN CLAIMS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered

by such sponsor shall provide that after the date of receipt of a clean claim submitted by a pharmacy, the PDP sponsor (or an agent of the PDP sponsor) may not retroactively reduce payment on such claim directly or indirectly through aggregated effective rate or otherwise except in the case such claim is found to not be a clean claim (such as in the case of a claim lacking required substantiating documentation) during the course of a routine audit as permitted pursuant to written agreement between the PDP sponsor (or such an agent) and such pharmacy. The previous sentence shall not prohibit any retroactive increase in payment to a pharmacy pursuant to a written agreement between a PDP sponsor (or an agent of such sponsor) and such pharmacy.''.

(2) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to contracts entered into on or after January 1, 2021.

(b) ELIMINATION OF DIR FEES.—

(1) PHARMACY BENEFITS MANAGER STANDARDS UNDER THE MEDICARE PROGRAM FOR PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—

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

''(7) PHARMACY BENEFITS MANAGER TRANSPARENCY REQUIREMENTS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor or with an MA organization offering an MA–PD plan under part C shall provide that the sponsor or organization, respectively, may not enter into a contract with any pharmacy benefits manager (referred to in this paragraph as a 'PBM') to manage the prescription drug coverage provided under such plan, or to control the costs of the prescription drug coverage under such plan, unless the PBM adheres to the following criteria when handling personally identifiable utilization and claims data or other sensitive patient data:

''(A) The PBM may not transmit any personally identifiable utilization, protected health information, or claims data, with respect to a

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

''(B) The PBM may not require that a plan enrollee use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM, or provide an incentive to a plan enrollee to encourage the enrollee to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM, if the incentive is applicable only to such pharmacies.''.

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

"(6) REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—

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

"(i) update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug;

"(ii) disclose to applicable pharmacies and the contracting entities of such pharmacies the sources used for making any such update immediately without requirement of request;

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

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

''(iv) establish a process to appeal, investigate, and resolve disputes regarding individual drug prices that are less than the pharmacy acquisition price for such drug, which must be adjudicated within 7 days of the pharmacy filing its appeal; and

''(v) provide all such pricing data in an .xml spreadsheet format or a comparable easily accessible and complete spreadsheet format.

''(B) PRESCRIPTION DRUG PRICING STANDARD DEFINED.—For purposes of subparagraph (A), a standard for reimbursement of a pharmacy is any methodology or formula for varying the pricing of a drug or drugs during the term of the pharmacy reimbursement contract that is based on the cost of the drug involved, including drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum al-

lowable cost (MAC), or other costs, whether publicly available or not.''.

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

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

''(3) To the extent practicable, with respect to the TRICARE retail pharmacy program described in subsection (a)(2)(E)(ii), the Secretary shall ensure that a contract entered into with a TRICARE managed care support contractor includes requirements described in section 1860D–12(b)(6) of the Social Security Act (42 U.S.C. 1395w–112(b)(6)) to ensure the provision of information regarding the pricing standard for prescription drugs.''.

(3) PRESCRIPTION DRUG TRANSPARENCY IN THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.—

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

''(p) A contract may not be made or a plan approved under this chapter under which a carrier has an agreement with a pharmacy benefits manager (in this subsection referred to as a 'PBM') to manage prescription drug coverage or to control the costs of the prescription drug coverage unless the carrier and PBM adhere to the following criteria:

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

''(2) The PBM may not require that an individual enrolled under such contract or plan use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an ownership interest in the PBM or provide an incentive to a plan enrollee to encourage the enrollee to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or that has an own-

ership interest in the PBM, if the incentive is applicable only to such pharmacies.

''(q)(1) If a contract made or plan approved under this chapter provides for a standard for reimbursement (as described in paragraph (2)) with respect to a prescription drug plan, such contract or plan shall provide that the applicable carrier—

''(A) update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug;

''(B) disclose to applicable pharmacies and the contracting entities of such pharmacies the sources used for making any such update immediately without requirement of request;

''(C) if the source for such a standard for reimbursement is not publicly available, disclose to the applicable pharmacies and contracting entities of such pharmacies all individual drug prices to be so updated in advance of the use of such prices for the reimbursement of claims;

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

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

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

''(2) For purposes of paragraph (1), a standard for reimbursement of a pharmacy is any methodology or formula for varying the pricing of a drug or drugs during the term of the pharmacy reimbursement contract that is based on the cost of the drug involved, including drug pricing references and amounts that are based upon average wholesale price, wholesale average cost, average manufacturer price, average sales price, maximum allowable cost, or other costs, whether publicly available or not.''.

(B) APPLICATION.—The amendment made by subparagraph (A) shall apply to any contract entered into under section 8902 of title 5, United States Code, on or after the date of enactment of this section.

SEC. 303. SUNSET OF LIMIT ON MAXIMUM REBATE AMOUNT FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.

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

''December 31, 2009,'' the following: ''and before December 31, 2024,''.

SEC. 304. REGULATION OF MANUFACTURER-SPONSORED COPAY CONTRIBUTIONS.

Notwithstanding any other provision of law, the Secretary of Health and Human Services may establish a mechanism prohibiting drug manufacturers from contributing financially to patient copays, and establish a system of penalizing such behavior.

TITLE IV—PATENT DISCLOSURE REQUIREMENTS

SEC. 401. PATENT DISCLOSURE AND TRANSPARENCY REQUIREMENTS.

(a) IN GENERAL.—

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

''(o) ADDITIONAL REQUIREMENTS WITH RESPECT TO PATENTS.—

''(1) PUBLICATION OF INFORMATION.—

''(A) IN GENERAL.—Within 1 year of the date of enactment of the Biologic Patent Transparency Act, the Secretary shall publish and make available to the public a single, easily searchable list that includes—

''(i) the proper and proprietary name of each biological product licensed or deemed to be licensed under subsection (a) or (k);

''(ii) the date of approval and application number for each such biological product;

''(iii) the marketing status, dosage form, route of administration, strength, and, if applicable, reference product, for each such biological product;

''(iv) the licensure status for each such biological product, including whether the license at the time of listing is approved, withdrawn, or revoked;

''(v) for each such biological product that is a reference product for which an exclusivity period applies, and for which the Secretary has determined the dates of such exclusivity period, under subsection (k)(7)(A) or subsection (k)(7)(B) of this section or under section 527 of the Federal Food, Drug, and Cosmetic Act, including any extension of such exclusivity period in 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.—

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

(B) DEVELOPMENT.—In developing recommendations under subparagraph (A), the Secretary of Health and Human Services may consult with the Federal Trade Commission, the Director of the United States Patent and Trademark Office, and the Federal Trade Commission, in addition to the entities listed in section 744I(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(f)(1)).

(b) RULE OF CONSTRUCTION.—Nothing in this section, including the amendment made by this section, shall be construed to require or allow the Secretary of Health and Human Services to delay the review or approval of a biologic license application under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 402. ANTITRUST EXEMPTION FOR HEALTH INSURANCE ISSUERS TO NEGOTIATE WHOLESALE ACQUISITION PRICES OF PRESCRIPTION DRUGS PURCHASED FROM DRUG MANUFACTURERS.

(a) EXEMPTION.—It shall not be a violation of the antitrust laws for one or more health insurance issuers or their designated agents to jointly negotiate wholesale acquisition prices of a prescription drug with a manufacturer of a prescription drug with regards to the reimbursement policies of the insurers of the manufacturer's drugs so long as no single wholesale acquisition price is jointly determined between the insurance issuers or their designated agents.

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

(1) ANTITRUST LAWS.—The term ''antitrust laws'' has the meaning given it in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)), except that such term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent such section 5 applies to unfair methods of competition.

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

(3) HEALTH MAINTENANCE ORGANIZATION.—The term ''health maintenance organization'' means—

(A) a federally qualified health maintenance organization (as defined in section 300e(a) of title 42 of the Code of Federal Regulations),

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

(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(4) MANUFACTURER.—The term ''manufacturer'' means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(5) PRESCRIPTION DRUG.—The term ''prescription drug'' means a drug for human use subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

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

SEC. 403. FAIR TREATMENT OF MEDICARE PART B BILLING CODES FOR THE PRESCRIBING OF BIOSIMILARS.

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

''(h) USE OF CERTAIN CODES.—Notwithstanding any previous provision of this section, for purposes of payment of biological biosimilar product the Secretary of Health and Human Services shall assign a uniform Common Procedure System code to describe all such products that share a common reference product.''.

TITLE V—FIXING GLOBAL FREELOADING

SEC. 501. CHIEF PHARMACEUTICAL NEGOTIATOR IN THE OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE.

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

(1) in subsection (b)(2)—

(A) by striking ''and one Chief Innovation and Intellectual Property Negotiator'' and inserting ''one Chief Innovation and Intellectual Property Negotiator, and one Chief Pharmaceutical 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

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

''Chief Innovation and Intellectual Property Negotiator, Office of the United States Trade Representative.

''Chief Pharmaceutical Negotiator, Office of the United States Trade Representative.''.

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

(1) enforcement actions taken by the Trade Representative during the one-year period preceding the submission of the report to ensure the protection of United States pharmaceutical products and services; and

(2) other actions taken by the Trade Representative to advance United States pharmaceutical products and services.

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