

118TH CONGRESS
1ST SESSION

H. R. 3285

To establish patient protections with respect to highly rebated drugs.

IN THE HOUSE OF REPRESENTATIVES

MAY 15, 2023

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and the Workforce, and Ways and Means, 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 establish patient protections with respect to highly rebated drugs.

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.**

4 This Act may be cited as the “Fairness for Patient
5 Medications Act”.

1 **SEC. 2. REQUIREMENTS WITH RESPECT TO COST-SHARING**
2 **FOR HIGHLY REBATED DRUGS.**

3 (a) PHSA.—Part D of title XXVII of the Public
4 Health Service Act (42 U.S.C. 300gg–111 et seq.) is
5 amended by adding at the end the following:

6 **“SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-**
7 **SHARING FOR HIGHLY REBATED DRUGS.**

8 “(a) IN GENERAL.—No later than April 1, 2024, and
9 annually thereafter, the Secretary shall certify (or recer-
10 tify, if applicable) as a ‘highly rebated drug’ any drug
11 identified in reports submitted under sections 2799A–10,
12 725 of the Employee Retirement Income Security Act, and
13 9825 of the Internal Revenue Code of 1986 for which total
14 rebates, reductions in price, and other forms of remunera-
15 tion in the previous year aggregated across all commercial
16 markets exceeded 50 percent of total annual spending on
17 such drug in such year.

18 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS
19 FOR CERTIFIED DRUGS.—For plan years that begin on
20 or after January 1, 2025, a group health plan or a health
21 insurance issuer offering group or individual health insur-
22 ance coverage (or entity that provides pharmacy benefits
23 management services on behalf of such a plan or issuer)
24 that provides coverage of any highly rebated drug shall
25 not impose cost-sharing in excess of, per 30-day supply,
26 the quotient of the annual net price paid by such group

1 health plan or health insurance issuer (or entity that pro-
2 vides pharmacy benefits management services on behalf
3 of such a plan or issuer), in the most recent calendar year
4 for which a final net price has been calculated by such
5 plan or coverage (or entity that provides pharmacy benefit
6 management services on behalf of such plan or issuer),
7 per 30-day supply of such specific highly rebated drug,
8 divided by 12.

9 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT
10 TO FORMULARY EXCLUSION.—Beginning on January 1,
11 2025, in the case of a specific highly rebated drug covered
12 by a group health plan or health insurance issuer offering
13 group or individual health insurance coverage (or entity
14 that provides pharmacy benefits management services on
15 behalf of such plan or issuer) that provides coverage of
16 a specific highly rebated drug that was not covered in the
17 previous year, such group health plan or health insurance
18 issuer shall not receive from a drug manufacturer a reduc-
19 tion in price or other remuneration with respect to such
20 specific highly rebated drug received by an enrollee in the
21 plan or coverage and covered by the plan or coverage, un-
22 less—

23 “(1) any such reduction in price is reflected at
24 the point of sale to the enrollee; and

1 “(2) any such other remuneration is a flat fee-
2 based service fee not contingent on total volume of
3 sales that a manufacturer of prescription drugs pays
4 to an entity that provides pharmacy benefits man-
5 agement services.

6 “(d) DEFINITIONS.—In this section:

7 “(1) ENTITY THAT PROVIDES PHARMACY BENE-
8 FITS MANAGEMENT SERVICES.—The term ‘entity
9 that provides pharmacy benefits management serv-
10 ices’ means—

11 “(A) any entity that, pursuant to a written
12 agreement with a group health plan or a health
13 insurance issuer offering group or individual
14 health insurance coverage, directly or through
15 an intermediary—

16 “(i) acts as a price negotiator on be-
17 half of the plan or coverage; or

18 “(ii) manages the prescription drug
19 benefits provided by the plan or coverage,
20 which may include the processing and pay-
21 ment of claims for prescription drugs, the
22 performance of drug utilization review, the
23 processing of drug prior authorization re-
24 quests, the adjudication of appeals or
25 grievances related to the prescription drug

1 benefit, contracting with network phar-
2 macies, controlling the cost of covered pre-
3 scription drugs, or the provision of related
4 services; or

5 “(B) any entity that is owned, affiliated, or
6 related under a common ownership structure
7 with an entity described in subparagraph (A).

8 “(2) NET PRICE.—The term ‘net price’, with
9 respect to a prescription drug, means the final price
10 paid by a group health plan or health insurance
11 issuer offering group or individual health insurance
12 coverage (or entity that provides pharmacy benefits
13 management services on behalf of such a plan or
14 issuer) after applying any rebates and other remun-
15 eration under the plan or coverage from drug man-
16 ufacturers during the plan year.

17 “(e) SPECIFICATION.—A health insurance plan will
18 not fail to be treated as an HDHP for complying with
19 the cost-sharing cap in this section.”.

20 (b) ERISA.—

21 (1) IN GENERAL.—Subpart B of part 7 of sub-
22 title B of title I of the Employee Retirement Income
23 Security Act of 1974 (29 U.S.C. 1185 et seq.) is
24 amended by adding at the end the following:

1 **“SEC. 725. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
2 **ING FOR HIGHLY REBATED DRUGS.**

3 “(a) IN GENERAL.—No later than April 1, 2024, and
4 annually thereafter, the Secretary shall certify (or recer-
5 tify, if applicable) as a ‘highly rebated drug’ any drug
6 identified in reports submitted under sections 725,
7 2799A–10 of the Public Health Service Act, and 9825 of
8 the Internal Revenue Code of 1986 for which total rebates,
9 reductions in price, and other forms of remuneration in
10 the previous year aggregated across all commercial mar-
11 kets exceeded 50 percent of total annual spending on such
12 drug in such year.

13 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS
14 FOR CERTIFIED DRUGS.—For plan years that begin on
15 or after January 1, 2025, a group health plan or a health
16 insurance issuer offering group health insurance coverage
17 (or entity that provides pharmacy benefits management
18 services on behalf of such a plan or issuer) that provides
19 coverage of any highly rebated drug shall not impose cost-
20 sharing in excess of, per 30-day supply, the quotient of
21 the annual net price paid by such group health plan or
22 health insurance issuer (or entity that provides pharmacy
23 benefits management services on behalf of such a plan or
24 issuer), in the most recent calendar year for which a final
25 net price has been calculated by such plan or coverage (or
26 entity that provides pharmacy benefit management serv-

1 ices on behalf of such plan or issuer), per 30-day supply
2 of such specific highly rebated drug, divided by 12.

3 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT
4 TO FORMULARY EXCLUSION.—Beginning on January 1,
5 2025, in the case of a specific highly rebated drug covered
6 by a group health plan or health insurance issuer offering
7 group health insurance coverage (or entity that provides
8 pharmacy benefits management services on behalf of such
9 plan or issuer) that provides coverage of a specific highly
10 rebated drug that was not covered in the previous year,
11 such group health plan or health insurance issuer shall
12 not receive from a drug manufacturer a reduction in price
13 or other remuneration with respect to such specific highly
14 rebated drug received by an enrollee in the plan or cov-
15 erage and covered by the plan or coverage, unless—

16 “(1) any such reduction in price is reflected at
17 the point of sale to the enrollee; and

18 “(2) any such other remuneration is a flat fee-
19 based service fee not contingent on total volume of
20 sales that a manufacturer of prescription drugs pays
21 to an entity that provides pharmacy benefits man-
22 agement services.

23 “(d) DEFINITIONS.—In this section:

24 “(1) ENTITY THAT PROVIDES PHARMACY BENE-
25 FITS MANAGEMENT SERVICES.—The term ‘entity

1 that provides pharmacy benefits management serv-
2 ices’ means—

3 “(A) any entity that, pursuant to a written
4 agreement with a group health plan or a health
5 insurance issuer offering group health insur-
6 ance coverage, directly or through an inter-
7 mediary—

8 “(i) acts as a price negotiator on be-
9 half of the plan or coverage; or

10 “(ii) manages the prescription drug
11 benefits provided by the plan or coverage,
12 which may include the processing and pay-
13 ment of claims for prescription drugs, the
14 performance of drug utilization review, the
15 processing of drug prior authorization re-
16 quests, the adjudication of appeals or
17 grievances related to the prescription drug
18 benefit, contracting with network phar-
19 macies, controlling the cost of covered pre-
20 scription drugs, or the provision of related
21 services; or

22 “(B) any entity that is owned, affiliated, or
23 related under a common ownership structure
24 with an entity described in subparagraph (A).

1 “(2) NET PRICE.—The term ‘net price’, with
2 respect to a prescription drug, means the final price
3 paid by a group health plan or health insurance
4 issuer offering group health insurance coverage (or
5 entity that provides pharmacy benefits management
6 services on behalf of such a plan or issuer) after ap-
7 plying any rebates and other remuneration under
8 the plan or coverage from drug manufacturers dur-
9 ing the plan year.

10 “(e) SPECIFICATION.—A health insurance plan will
11 not fail to be treated as an HDHP for complying with
12 the cost-sharing cap in this section.”.

13 (2) CLERICAL AMENMDNET.—The table of con-
14 tents in section 1 of the Employee Retirement In-
15 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
16 is amended by inserting after the item related to
17 section 725 the following:

 “Sec. 725. Requirements with respect to cost-sharing for highly rebated
 drugs.”.

18 (c) IRC.—

19 (1) IN GENERAL.—Subchapter B of chapter
20 100 of the Internal Revenue Code of 1986 is amend-
21 ed by adding at the end the following new section:

1 **“SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
2 **ING FOR HIGHLY REBATED DRUGS.**

3 “(a) IN GENERAL.—No later than April 1, 2024, and
4 annually thereafter, the Secretary shall certify (or recer-
5 tify, if applicable) as a ‘highly rebated drug’ any drug
6 identified in reports submitted under sections 9825,
7 2799A–10 of the Public Health Service Act, and 725 of
8 the Employee Retirement Income Security Act for which
9 total rebates, reductions in price, and other forms of remu-
10 neration in the previous year aggregated across all com-
11 mercial markets exceeded 50 percent of total annual
12 spending on such drug in such year.

13 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS
14 FOR CERTIFIED DRUGS.—For plan years that begin on
15 or after January 1, 2025, a group health plan (or entity
16 that provides pharmacy benefits management services on
17 behalf of such a plan) that provides coverage of any highly
18 rebated drug shall not impose cost-sharing in excess of,
19 per 30-day supply, the quotient of the annual net price
20 paid by such group health plan (or entity that provides
21 pharmacy benefits management services on behalf of such
22 a plan), in the most recent calendar year for which a final
23 net price has been calculated by such plan (or entity that
24 provides pharmacy benefit management services on behalf
25 of such plan), per 30-day supply of such specific highly
26 rebated drug, divided by 12.

1 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT
2 TO FORMULARY EXCLUSION.—Beginning on January 1,
3 2025, in the case of a specific highly rebated drug covered
4 by a group health plan (or entity that provides pharmacy
5 benefits management services on behalf of such plan) that
6 provides coverage of a specific highly rebated drug that
7 was not covered in the previous year, such group health
8 plan shall not receive from a drug manufacturer a reduc-
9 tion in price or other remuneration with respect to such
10 specific highly rebated drug received by an enrollee in the
11 plan and covered by the plan, unless—

12 “(1) any such reduction in price is reflected at
13 the point of sale to the enrollee; and

14 “(2) any such other remuneration is a flat fee-
15 based service fee not contingent on total volume of
16 sales that a manufacturer of prescription drugs pays
17 to an entity that provides pharmacy benefits man-
18 agement services.

19 “(d) DEFINITIONS.—In this section:

20 “(1) ENTITY THAT PROVIDES PHARMACY BENE-
21 FITS MANAGEMENT SERVICES.—The term ‘entity
22 that provides pharmacy benefits management serv-
23 ices’ means—

1 “(A) any entity that, pursuant to a written
2 agreement with a group health plan, directly or
3 through an intermediary—

4 “(i) acts as a price negotiator on be-
5 half of the plan; or

6 “(ii) manages the prescription drug
7 benefits provided by the plan, which may
8 include the processing and payment of
9 claims for prescription drugs, the perform-
10 ance of drug utilization review, the proc-
11 essing of drug prior authorization requests,
12 the adjudication of appeals or grievances
13 related to the prescription drug benefit,
14 contracting with network pharmacies, con-
15 trolling the cost of covered prescription
16 drugs, or the provision of related services;
17 or

18 “(B) any entity that is owned, affiliated, or
19 related under a common ownership structure
20 with an entity described in subparagraph (A).

21 “(2) NET PRICE.—The term ‘net price’, with
22 respect to a prescription drug, means the final price
23 paid by a group health plan (or entity that provides
24 pharmacy benefits management services on behalf of
25 such a plan) after applying any rebates and other

1 remuneration under the plan from drug manufactur-
2 ers during the plan year.

3 “(e) SPECIFICATION.—A health insurance plan will
4 not fail to be treated as an HDHP for complying with
5 the cost-sharing cap in this section.”.

6 (2) CLERICAL AMENDMENT.—The table of sec-
7 tions for subchapter B of chapter 100 of such Code
8 is amended by adding at the end the following new
9 item:

“Sec. 9826. Requirements with respect to cost-sharing for highly rebated
drugs.”.

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