.....

(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To establish patient protections with respect to highly rebated drugs.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on _____

A BILL

To establish patient protections with respect to highly rebated drugs.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Fairness for Patient Medications Act".

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

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

"SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

''(a) IN GENERAL.—No later than April 1, 2024, and annually thereafter, the Secretary shall certify (or recertify, if applicable) as a 'highly rebated drug' any drug identified in reports submitted under sections 2799A–10, 725 of the Employee Retirement Income Security Act, and 9825 of the Internal Revenue Code of 1986 for which total rebates, reductions in price, and other forms of remuneration in the previous year aggregated across all commercial markets exceeded 50 percent of total annual spending on such drug in such year.

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

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

''(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—Beginning on January 1, 2025, in the case of a specific highly rebated drug covered by a group health plan or health insurance issuer offering group or individual health insurance coverage (or entity that provides pharmacy benefits management services on behalf of such plan or issuer) that provides coverage of a specific highly rebated drug that was not covered in the previous year, such group health plan or health insurance issuer shall not receive from a drug manufacturer a reduction in price or other remuneration with respect to such specific highly rebated drug received by an enrollee in the plan or coverage and covered by the plan or coverage, unless—

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

''(2) any such other remuneration is a flat fee-based service fee not contingent on total volume of sales that a manufacturer of prescription drugs pays to an entity that provides pharmacy benefits management services.

''(d) DEFINITIONS.—In this section:

''(1) ENTITY THAT PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES.—The term 'entity that provides pharmacy benefits management services' means—

''(A) any entity that, pursuant to a written agreement with a group health plan or a health insurance issuer offering group or individual health insurance coverage, directly or through an intermediary—

''(i) acts as a price negotiator on behalf of the plan or coverage; or

''(ii) manages the prescription drug benefits provided by the plan or coverage, which may include the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug

benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of related services; or

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

''(2) NET PRICE.—The term 'net price', with respect to a prescription drug, means the final price paid by a group health plan or health insurance issuer offering group or individual health insurance coverage (or entity that provides pharmacy benefits management services on behalf of such a plan or issuer) after applying any rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year.

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

(b) ERISA.—

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

"SEC. 725. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

"(a) IN GENERAL.—No later than April 1, 2024, and annually thereafter, the Secretary shall certify (or recertify, if applicable) as a 'highly rebated drug' any drug identified in reports submitted under sections 725, 2799A–10 of the Public Health Service Act, and 9825 of the Internal Revenue Code of 1986 for which total rebates, reductions in price, and other forms of remuneration in the previous year aggregated across all commercial markets exceeded 50 percent of total annual spending on such drug in such year.

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

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

''(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—Beginning on January 1, 2025, in the case of a specific highly rebated drug covered by a group health plan or health insurance issuer offering group health insurance coverage (or entity that provides pharmacy benefits management services on behalf of such plan or issuer) that provides coverage of a specific highly rebated drug that was not covered in the previous year, such group health plan or health insurance issuer shall not receive from a drug manufacturer a reduction in price or other remuneration with respect to such specific highly rebated drug received by an enrollee in the plan or coverage and covered by the plan or coverage, unless—

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

''(2) any such other remuneration is a flat fee-based service fee not contingent on total volume of sales that a manufacturer of prescription drugs pays to an entity that provides pharmacy benefits management services.

''(d) DEFINITIONS.—In this section:

''(1) ENTITY THAT PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES.—The term 'entity

that provides pharmacy benefits management services' means—

''(A) any entity that, pursuant to a written agreement with a group health plan or a health insurance issuer offering group health insurance coverage, directly or through an intermediary—

''(i) acts as a price negotiator on behalf of the plan or coverage; or

''(ii) manages the prescription drug benefits provided by the plan or coverage, which may include the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of related services; or

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

''(2) NET PRICE.—The term 'net price', with respect to a prescription drug, means the final price paid by a group health plan or health insurance issuer offering group health insurance coverage (or entity that provides pharmacy benefits management services on behalf of such a plan or issuer) after applying any rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year.

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

(2) CLERICAL AMENMDNET.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item related to section 725 the following:

''Sec. 726. Requirements with respect to cost-sharing for highly rebated drugs.''.

(c) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

"SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

"(a) IN GENERAL.—No later than April 1, 2024, and annually thereafter, the Secretary shall certify (or recertify, if applicable) as a 'highly rebated drug' any drug identified in reports submitted under sections 9825, 2799A–10 of the Public Health Service Act, and 725 of the Employee Retirement Income Security Act for which total rebates, reductions in price, and other forms of remuneration in the previous year aggregated across all commercial markets exceeded 50 percent of total annual spending on such drug in such year.

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

''(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—Beginning on January 1, 2025, in the case of a specific highly rebated drug covered by a group health plan (or entity that provides pharmacy benefits management services on behalf of such plan) that provides coverage of a specific highly rebated drug that was not covered in the previous year, such group health plan shall not receive from a drug manufacturer a reduction in price or other remuneration with respect to such specific highly rebated drug received by an enrollee in the plan and covered by the plan, unless—

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

''(2) any such other remuneration is a flat fee-based service fee not contingent on total volume of sales that a manufacturer of prescription drugs pays to an entity that provides pharmacy benefits management services.

''(d) DEFINITIONS.—In this section:

''(1) ENTITY THAT PROVIDES PHARMACY BENEFITS MANAGEMENT SERVICES.—The term 'entity that provides pharmacy benefits management services' means—

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

''(i) acts as a price negotiator on behalf of the plan; or

''(ii) manages the prescription drug benefits provided by the plan, which may include the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of related services; or

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

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

remuneration under the plan from drug manufacturers during the plan year.

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

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code is amended by adding at the end the following new item:

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