

**AMENDMENT TO THE AMENDMENT IN THE  
NATURE OF A SUBSTITUTE TO H.R. 3561  
OFFERED BY M . \_\_\_\_\_**

Page 33, line 19 strike “companies” and insert “funds”.

Page 35, line 20 strike “company” and insert “fund”.

Page 35, line 21 strike “company” and insert “fund”.

Page 35, line 21 strike “fund” and all that follows and insert “fund has the meaning given such term in section 279.9 of title 17, Code of Federal Regulations”.

Page 36, line 6 strike “a hospital, a health plan, a private equity company, or a venture capital firm” and insert “any entity described in paragraph (2) of subsection (c)”.

Add at the end of title III the following new sections:

1 **SEC. 304. REQUIREMENTS WITH RESPECT TO COST-SHAR-**  
2 **ING 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.), as  
5 amended by section 107, is further amended by adding  
6 at the end the following:

7 **“SEC. 2799A–12. REQUIREMENTS WITH RESPECT TO COST-**  
8 **SHARING FOR HIGHLY REBATED DRUGS.**

9 “(a) IN GENERAL.—No later than December 31,  
10 2025, and annually thereafter, the Secretary shall—

11 “(1) aggregate the data from the reports sub-  
12 mitted under section 2799A–10, section 725 of the  
13 Employee Retirement Income Security Act, and sec-  
14 tion 9825 of the Internal Revenue Code of 1986, to  
15 determine the total spending and rebates, reductions  
16 in price, or other remuneration for each drug for  
17 which data is available, in the most recent calendar  
18 year for which such information is available; and

19 “(2) certify (or recertify, if applicable) and pub-  
20 licly list as a ‘highly rebated drug’ through the end  
21 of the succeeding plan year any drug identified in  
22 such reports for which total rebates, reductions in  
23 price, and other remuneration in the calendar year  
24 aggregated across all reports submitted pursuant to  
25 such sections exceeded 50 percent of total annual  
26 spending reported by group health plans and health

1 insurance issuers offering group or individual health  
2 coverage on such drug in such year.

3 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS  
4 FOR CERTIFIED DRUGS.—For plan years that begin on  
5 or after January 1, 2027, a group health plan or a health  
6 insurance issuer offering group or individual health insur-  
7 ance coverage (or entity that provides pharmacy benefits  
8 management services on behalf of such a plan or issuer)  
9 that provides coverage of any highly rebated drug shall  
10 not impose cost-sharing in excess of, the average net price  
11 paid by such group health plan or health insurance issuer  
12 (or entity that provides pharmacy benefits management  
13 services on behalf of such a plan or issuer), in the most  
14 recent calendar year for which a final net price has been  
15 calculated by such plan or coverage (or entity that pro-  
16 vides pharmacy benefit management services on behalf of  
17 such plan or issuer), for the equivalent quantity.

18 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT  
19 TO FORMULARY EXCLUSION.—For plan years beginning  
20 on January 1, 2027, in the case of a specific highly re-  
21 bated drug covered by a group health plan or health insur-  
22 ance issuer offering group or individual health insurance  
23 coverage (or entity that provides pharmacy benefits man-  
24 agement services on behalf of such plan or issuer) that  
25 provides coverage of a specific highly rebated drug that

1 was not covered in a previous year or has no net price  
2 for a recent previous year, as defined by the Secretary,  
3 such group health plan or health insurance issuer (or enti-  
4 ty that provides pharmacy benefit management services on  
5 behalf of such plan or issuer) shall not receive from a drug  
6 manufacturer a rebate, reduction in price or other remu-  
7 nation with respect to such specific highly rebated drug  
8 received by an enrollee in the plan or coverage and covered  
9 by the plan or coverage, unless—

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

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

17 “(d) DEFINITIONS.—In this section:

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

22 “(A) any entity that, pursuant to a written  
23 agreement with a group health plan or a health  
24 insurance issuer offering group or individual

1 health insurance coverage, directly or through  
2 an intermediary—

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

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

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

20 “(2) NET PRICE.—The term ‘net price’, with  
21 respect to a prescription drug, means the final price  
22 paid by a group health plan or health insurance  
23 issuer offering group or individual health insurance  
24 coverage (or entity that provides pharmacy benefits  
25 management services on behalf of such a plan or

1 issuer) after applying all rebates (including rebates  
2 retained by any entity that provides pharmacy bene-  
3 fits management services on behalf of such a plan or  
4 issuer), reductions in price, and other remuneration  
5 attributable to the plan or coverage (or entity that  
6 provides pharmacy benefit management services on  
7 behalf of such plan or issuer) from drug manufac-  
8 turers during the plan year.

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

12 (b) ERISA.—

13 (1) IN GENERAL.—Subpart B of part 7 of sub-  
14 title B of title I of the Employee Retirement Income  
15 Security Act of 1974 (29 U.S.C. 1185 et seq.), as  
16 amended by section 107, is further amended by add-  
17 ing at the end the following:

18 **“SEC. 727. REQUIREMENTS WITH RESPECT TO COST-SHAR-**  
19 **ING FOR HIGHLY REBATED DRUGS.**

20 “(a) IN GENERAL.—No later than December 31,  
21 2025, and annually thereafter, the Secretary shall—

22 “(1) aggregate the data from the reports sub-  
23 mitted under section 725, section 2799A–10 of the  
24 Public Health Service Act, and section 9825 of the  
25 Internal Revenue Code of 1986, to determine the

1 total spending and rebates, reductions in price, or  
2 other remuneration for each drug for which data is  
3 available, in the most recent calendar year for which  
4 such information is available; and

5 “(2) certify (or recertify, if applicable) and pub-  
6 licly list as a ‘highly rebated drug’ through the end  
7 of the succeeding plan year any drug identified in  
8 such reports for which total rebates, reductions in  
9 price, and other remuneration in the calendar year  
10 aggregated across all reports submitted pursuant to  
11 such sections exceeded 50 percent of total annual  
12 spending reported by group health plans and health  
13 insurance issuers offering group health coverage on  
14 such drug in such year.

15 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS  
16 FOR CERTIFIED DRUGS.—For plan years that begin on  
17 or after January 1, 2027, a group health plan or a health  
18 insurance issuer offering group health insurance coverage  
19 (or entity that provides pharmacy benefits management  
20 services on behalf of such a plan or issuer) that provides  
21 coverage of any highly rebated drug shall not impose cost-  
22 sharing in excess of, the average net price paid by such  
23 group health plan or health insurance issuer (or entity  
24 that provides pharmacy benefits management services on  
25 behalf of such a plan or issuer), in the most recent cal-

1 endar year for which a final net price has been calculated  
2 by such plan or coverage (or entity that provides pharmacy  
3 benefit management services on behalf of such plan or  
4 issuer), for the equivalent quantity of such specific highly  
5 rebated drug.

6 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT  
7 TO FORMULARY EXCLUSION.—For plan years beginning  
8 on January 1, 2027, in the case of a specific highly re-  
9 bated drug covered by a group health plan or health insur-  
10 ance issuer offering group health insurance coverage (or  
11 entity that provides pharmacy benefits management serv-  
12 ices on behalf of such plan or issuer) that provides cov-  
13 erage of a specific highly rebated drug that was not cov-  
14 ered in a previous year or has no net price for a recent  
15 previous year, as defined by the Secretary, such group  
16 health plan or health insurance issuer (or entity that pro-  
17 vides pharmacy benefit management services on behalf of  
18 such plan or issuer) shall not receive from a drug manu-  
19 facturer a rebate, reduction in price or other remuneration  
20 with respect to such specific highly rebated drug received  
21 by an enrollee in the plan or coverage and covered by the  
22 plan or coverage, unless—

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 health insur-  
14          ance coverage, directly or through an inter-  
15          mediary—

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 health insurance coverage (or  
12 entity that provides pharmacy benefits management  
13 services on behalf of such a plan or issuer) after ap-  
14 plying all rebates (including rebates retained by any  
15 entity that provides pharmacy benefits management  
16 services on behalf of such a plan or issuer), reduc-  
17 tions in price, and other remuneration attributable  
18 to the plan or coverage (or entity that provides phar-  
19 macy benefit management services on behalf of such  
20 plan or issuer) from drug manufacturers during the  
21 plan year.

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

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

          “Sec. 727. Requirements with respect to cost-sharing for highly rebated  
          drugs.”.

6           (c) IRC.—

7           (1) IN GENERAL.—Subchapter B of chapter  
8           100 of the Internal Revenue Code of 1986 is amend-  
9           ed by adding at the end the following new section:

10       **“SEC. 9827. REQUIREMENTS WITH RESPECT TO COST-SHAR-**  
11                               **ING FOR HIGHLY REBATED DRUGS.**

12       “(a) IN GENERAL.—No later than December 31,  
13       2025, and annually thereafter, the Secretary shall—

14           “(1) aggregate the data from the reports sub-  
15           mitted under section 9825, section 2799A–10 of the  
16           Public Health Service Act, and section 725 of the  
17           Employee Retirement Income Security Act, to deter-  
18           mine the total spending and rebates, reductions in  
19           price, or other remuneration for each drug for which  
20           data is available, in the most recent calendar year  
21           for which such information is available; and

22           “(2) certify (or recertify, if applicable) and pub-  
23           licly list as a ‘highly rebated drug’ through the end  
24           of the succeeding plan year any drug identified in

1 such reports for which total rebates, reductions in  
2 price, and other remuneration in the calendar year  
3 aggregated across all reports submitted pursuant to  
4 such sections exceeded 50 percent of total annual  
5 spending reported by group health plans on such  
6 drug in such year.

7 “(b) DEDUCTIBLE AND COST-SHARING LIMITATIONS  
8 FOR CERTIFIED DRUGS.—For plan years that begin on  
9 or after January 1, 2027, a group health plan (or entity  
10 that provides pharmacy benefits management services on  
11 behalf of such a plan) that provides coverage of any highly  
12 rebated drug shall not impose cost-sharing in excess of,  
13 the average net price paid by such group health plan (or  
14 entity that provides pharmacy benefits management serv-  
15 ices on behalf of such a plan), in the most recent calendar  
16 year for which a final net price has been calculated by  
17 such plan (or entity that provides pharmacy benefit man-  
18 agement services on behalf of such plan), for the equiva-  
19 lent quantity.

20 “(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT  
21 TO FORMULARY EXCLUSION.—For plan years beginning  
22 on January 1, 2027, in the case of a specific highly re-  
23 bated drug covered by a group health plan (or entity that  
24 provides pharmacy benefits management services on be-  
25 half of such plan) that provides coverage of a specific high-

1 ly rebated drug that was not covered in a previous year  
2 or has no net price for a recent previous year, as defined  
3 by the Secretary, such group health plan (or entity that  
4 provides pharmacy benefit management services on behalf  
5 of such plan) shall not receive from a drug manufacturer  
6 a reduction in price or other remuneration with respect  
7 to such specific highly rebated drug received by an enrollee  
8 in the plan and covered by the plan, unless—

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

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

16           “(d) DEFINITIONS.—In this section:

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

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

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

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

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

16                  “(2) NET PRICE.—The term ‘net price’, with  
17                  respect to a prescription drug, means the final price  
18                  paid by a group health plan (or entity that provides  
19                  pharmacy benefits management services on behalf of  
20                  such a plan) after applying all rebates (including re-  
21                  bates retained by any entity that provides pharmacy  
22                  benefits management services on behalf of such a  
23                  plan), reductions in price, and other remuneration  
24                  attributable to the plan (or entity that provides  
25                  pharmacy benefit management services on behalf of

1 such plan) from drug manufacturers during the plan  
2 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 as amended by section 107, is further amended by  
9 adding at the end the following new item:

“Sec. 9827. Requirements with respect to cost-sharing for highly rebated  
drugs.”.

10 **SEC. 305. PBM REPORTING AND INCREASED FLEXIBILITY.**

11 (a) PHSA.—Section 2799A–10(a) of the Public  
12 Health Service Act (42 U.S.C. 300gg–111(a)) is amend-  
13 ed—

14 (1) in the matter preceding paragraph (1), by  
15 striking “, a group health plan or health insurance  
16 issuer offering group or individual health insurance  
17 coverage (except for a church plan)” and inserting  
18 “(or at such time as specified by the Secretary), a  
19 group health plan or health insurance issuer offering  
20 group or individual health insurance coverage (ex-  
21 cept for a church plan), or an entity providing phar-  
22 macy benefits management services on behalf of  
23 such plan or coverage,”; and

1           (2) in paragraph (9)(B), by inserting “by the  
2           plan or coverage, and by the participant, beneficiary,  
3           or enrollee,” after “the amounts so paid”.

4           (b) ERISA.—Section 725(a) of the Employee Retirement  
5           Income Security Act (29 U.S.C. 1195n(a)) is amended—  
6           ed—

7           (1) in the matter preceding paragraph (1), by  
8           striking “, a group health plan (or health insurance  
9           coverage offered in connection with such a plan)”  
10          and inserting “(or at such time as specified by the  
11          Secretary), a group health plan (or health insurance  
12          coverage offered in connection with such a plan), or  
13          an entity providing pharmacy benefits management  
14          services on behalf of such plan or coverage,”; and

15          (2) in paragraph (9)(B), by inserting “by the  
16          plan or coverage, and by the participant, beneficiary,  
17          or enrollee,” after “the amounts so paid”.

18          (c) IRC.—Section 9825(a) of the Internal Revenue  
19          Code of 1986 is amended—

20          (1) in the matter preceding paragraph (1), by  
21          striking “, a group health plan” and inserting “(or  
22          at such time as specified by the Secretary), a group  
23          health plan, or an entity providing pharmacy bene-  
24          fits management services on behalf of such plan,”;  
25          and



1           (2) in paragraph (9)(B), by inserting “by the  
2           plan or coverage, and by the participant, beneficiary,  
3           or enrollee,” after “the amounts so paid”.

