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 ins 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:

SEC. 304. 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.), as amended by section 107, is further amended by adding at the end the following:

"SEC. 2799A–12. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

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

''(1) aggregate the data from the reports submitted under section 2799A–10, section 725 of the Employee Retirement Income Security Act, and section 9825 of the Internal Revenue Code of 1986, to determine the total spending and rebates, reductions in price, or other remuneration for each drug for which data is available, in the most recent calendar year for which such information is available; and

''(2) certify (or recertify, if applicable) and publicly list as a 'highly rebated drug' through the end of the succeeding plan year any drug identified in such reports for which total rebates, reductions in price, and other remuneration in the calendar year aggregated across all reports submitted pursuant to such sections exceeded 50 percent of total annual spending reported by group health plans and health

insurance issuers offering group or individual health coverage 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, 2027, 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, the average 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), for the equivalent quantity.

''(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—For plan years beginning on January 1, 2027, 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 a previous year or has no net price for a recent previous year, as defined by the Secretary, such group health plan or health insurance issuer (or entity that provides pharmacy benefit management services on behalf of such plan or issuer) shall not receive from a drug manufacturer a rebate, 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 all rebates (including rebates retained by any entity that provides pharmacy benefits management services on behalf of such a plan or issuer), reductions in price, and other remuneration attributable to the plan or coverage (or entity that provides pharmacy benefit management services on behalf of such plan or issuer) 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.), as amended by section 107, is further amended by adding at the end the following:

''SEC. 727. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

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

''(1) aggregate the data from the reports submitted under section 725, section 2799A–10 of the Public Health Service Act, and section 9825 of the Internal Revenue Code of 1986, to determine the

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

''(2) certify (or recertify, if applicable) and publicly list as a 'highly rebated drug' through the end of the succeeding plan year any drug identified in such reports for which total rebates, reductions in price, and other remuneration in the calendar year aggregated across all reports submitted pursuant to such sections exceeded 50 percent of total annual spending reported by group health plans and health insurance issuers offering group health coverage 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, 2027, 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, the average 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 cal-

endar 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), for the equivalent quantity of such specific highly rebated drug.

''(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—For plan years beginning on January 1, 2027, 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 a previous year or has no net price for a recent previous year, as defined by the Secretary, such group health plan or health insurance issuer (or entity that provides pharmacy benefit management services on behalf of such plan or issuer) shall not receive from a drug manufacturer a rebate, 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 all rebates (including rebates retained by any entity that provides pharmacy benefits management services on behalf of such a plan or issuer), reductions in price, and other remuneration attributable to the plan or coverage (or entity that provides pharmacy benefit management services on behalf of such plan or issuer) 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. 727. 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. 9827. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR HIGHLY REBATED DRUGS.

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

''(1) aggregate the data from the reports submitted under section 9825, section 2799A–10 of the Public Health Service Act, and section 725 of the Employee Retirement Income Security Act, to determine the total spending and rebates, reductions in price, or other remuneration for each drug for which data is available, in the most recent calendar year for which such information is available; and

''(2) certify (or recertify, if applicable) and publicly list as a 'highly rebated drug' through the end of the succeeding plan year any drug identified in

such reports for which total rebates, reductions in price, and other remuneration in the calendar year aggregated across all reports submitted pursuant to such sections exceeded 50 percent of total annual spending reported by group health plans 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, 2027, 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, the average 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), for the equivalent quantity.

''(c) HIGHLY REBATED DRUG PREVIOUSLY SUBJECT TO FORMULARY EXCLUSION.—For plan years beginning on January 1, 2027, 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 high-

ly rebated drug that was not covered in a previous year or has no net price for a recent previous year, as defined by the Secretary, such group health plan (or entity that provides pharmacy benefit management services on behalf of such 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 all rebates (including rebates retained by any entity that provides pharmacy benefits management services on behalf of such a plan), reductions in price, and other remuneration attributable to the plan (or entity that provides pharmacy benefit management services on behalf of

such 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, as amended by section 107, is further amended by adding at the end the following new item:

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

SEC. 305. PBM REPORTING AND INCREASED FLEXIBILITY.

(a) PHSA.—Section 2799A–10(a) of the Public Health Service Act (42 U.S.C. 300gg–111(a)) is amended—

(1) in the matter preceding paragraph (1), by striking '', a group health plan or health insurance issuer offering group or individual health insurance coverage (except for a church plan)'' and inserting ''(or at such time as specified by the Secretary), a group health plan or health insurance issuer offering group or individual health insurance coverage (except for a church plan), or an entity providing pharmacy benefits management services on behalf of such plan or coverage,''; and

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

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

(1) in the matter preceding paragraph (1), by striking '', a group health plan (or health insurance coverage offered in connection with such a plan)'' and inserting ''(or at such time as specified by the Secretary), a group health plan (or health insurance coverage offered in connection with such a plan), or an entity providing pharmacy benefits management services on behalf of such plan or coverage,''; and

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

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

(1) in the matter preceding paragraph (1), by striking '', a group health plan'' and inserting ''(or at such time as specified by the Secretary), a group health plan, or an entity providing pharmacy benefits management services on behalf of such plan,''; and

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

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