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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act, the Employee Retirement Income Security Act, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefits manager services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. KUSTER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefits manager services, 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.

This Act may be cited as the ''Pharmacy Benefits Manager Accountability Act''.

SEC. 2. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

(a) PHSA.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) in part D (42 U.S.C. 300gg–111 et seq.), by adding at the end the following new section:

"SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or health insurance issuer offering group health insurance coverage or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, a health insurance issuer offering group health insurance coverage or an entity pro-

viding pharmacy benefits management services on behalf of a group health plan or an issuer providing group health insurance coverage shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan or health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) as applicable, information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, issuer, or entity providing pharmacy benefits management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of participants and beneficiaries who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers

and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions,

alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, re-

lated to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

''(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's or health insurance issuer's business to the pharmacy benefits manager.

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manu-

facturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 2(d) of the Pharmacy Benefits Manager Accountability Act.

''(5) STANDARD FORMAT.—Not later than June 1, 2023, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty

or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Health and Human Services to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such issuer, plan, or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

(2) in section 2723 (42 U.S.C. 300gg–22)—

(A) in subsection (a)—

(i) in paragraph (1), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''; and

(ii) in paragraph (2), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''; and

(B) in subsection (b)—

(i) in paragraph (1), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D'';

(ii) in paragraph (2)(A), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''; and

(iii) in paragraph (2)(C)(ii), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''.

(b) ERISA.—

(1) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021 et seq.) is amended—

(A) in subpart B of part 7 (29 U.S.C. 1185 et seq.), by adding at the end the following:

''SEC. 726. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage

in connection with such a plan) or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan or an issuer providing group health insurance coverage shall submit to the plan sponsor (as defined in section 3(16)(B)) of such group health plan or group health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) as applicable, information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, issuer, or entity providing pharmacy benefits management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of participants and beneficiaries who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are in-

cluded on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants and

beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

''(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health

plan's or health insurance issuer's business to the pharmacy benefits manager.

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management

services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested,

in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 2(d) of the Pharmacy Benefits Manager Accountability Act.

''(5) STANDARD FORMAT.—Not later than June 1, 2023, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Labor to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such issuer, plan, or entity.

''(d) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

(B) in section 502 (29 U.S.C. 1132)—

(i) in subsection (a)—

(I) in paragraph (6), by striking ''or (9)'' and inserting ''(9), or (13)'';

(II) in paragraph (10), by striking at the end ''or'';

(III) in paragraph (11), at the end by striking the period and inserting ''; or''; and

(IV) by adding at the end the following new paragraph:

''(12) by the Secretary, in consultation with the Secretary of Health and Human Services, and the Secretary of the Treasury, to enforce section 726.'';

(ii) in subsection (b)(3), by inserting ''and subsections (a)(12) and (c)(13)'' before '', the Secretary is not''; and

(iii) in subsection (c), by adding at the end the following new paragraph:

''(13) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.—

''(A) FAILURE TO PROVIDE TIMELY INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against any health insurance issuer or

entity providing pharmacy benefits management services that violates section 726(a) or fails to provide information required under section 726(b) in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(B) FALSE INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against a health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under section 726 in an amount not to exceed $100,000 for each item of false information. Such penalty shall be in addition to other penalties as may be prescribed by law.

''(C) WAIVERS.—The Secretary may waive penalties under subparagraph (A), or extend the period of time for compliance with a requirement of section 726, for an entity in violation of such section that has made a good-faith effort to comply with such section.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement In-

come Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new item:

''Sec. 726. Oversight of pharmacy benefits manager services.''.

(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:

''SEC. 9826. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefits management services on behalf of a group health

plan shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan—

''(A) as applicable, information collected from drug manufacturers by such entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan;

''(B) a list of each drug covered by such plan or entity providing pharmacy benefits management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of

prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of participants and beneficiaries who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan and its participants and beneficiaries, after manufacturer

rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan during the reporting period;

''(F) the total net spending on prescription drugs by the health plan during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's business to the pharmacy benefits manager.

''(2) PRIVACY REQUIREMENTS.—Entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such entity may not re-

strict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—An entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under sec-

tion 2(d) of the Pharmacy Benefits Manager Accountability Act.

''(5) STANDARD FORMAT.—Not later than June 1, 2023, the Secretary shall specify through rulemaking standards for entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Health and Human Services, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—An entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—An entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of

false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a group health plan or other entity to restrict disclosure to, or otherwise limit the access of, the Department of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such plan or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''.

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 9826. Oversight of pharmacy benefits manager services.''.

(d) GAO STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on—

(A) pharmacy networks of group health plans, health insurance issuers, and entities providing pharmacy benefits management services under such group health plan or group or individual health insurance coverage, including networks that have pharmacies that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefits management services or pharmacy benefits administrative services under group health plan or group or individual health insurance coverage;

(B) as it relates to pharmacy networks that include pharmacies under common ownership described in subparagraph (A)—

(i) whether such networks are designed to encourage enrollees of a plan or coverage to use such pharmacies over other network pharmacies for specific services or drugs, and if so, the reasons the networks give for encouraging use of such pharmacies; and

(ii) whether such pharmacies are used by enrollees disproportionately more in the aggregate or for specific services or drugs compared to other network pharmacies;

(C) whether group health plans and health insurance issuers offering group or individual health insurance coverage have options to elect different network pricing arrangements in the marketplace with entities that provide pharmacy benefits management services, the prevalence of electing such different network pricing arrangements;

(D) pharmacy network design parameters that encourage enrollees in the plan or coverage to fill prescriptions at mail order, specialty, or

retail pharmacies that are wholly or partially-owned by that issuer or entity; and

(E) the degree to which mail order, specialty, or retail pharmacies that dispense prescription drugs to an enrollee in a group health plan or health insurance coverage that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefits management services or pharmacy benefits administrative services under group health plan or group or individual health insurance coverage receive reimbursement that is greater than the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to enrollees in the plan or coverage by other pharmacies included in the pharmacy network of that plan, issuer, or entity that are not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefits management services.

(2) REQUIREMENT.—The Comptroller General of the United States shall ensure that the report under paragraph (1) does not contain information that would allow a reader to identify a specific plan

or entity providing pharmacy benefits management services or otherwise contain commercial or financial information that is privileged or confidential.

(3) DEFINITIONS.—In this subsection, the terms ''group health plan'', ''health insurance coverage'', and ''health insurance issuer'' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91).