Calendar No. 113

118TH CONGRESS
1ST SESSION

S. 1339

To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.

IN THE SENATE OF THE UNITED STATES

APRIL 27, 2023

Mr. SANDERS (for himself, Mr. CASSIDY, Mrs. MURRAY, Mr. MARSHALL, and Mr. BRAUN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JUNE 22, 2023

Reported by Mr. SANDERS, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.

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 Benefit Manager Reform Act".~~

SEC. 2. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT 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 ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT 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 providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an applicable entity that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity providing pharmacy benefit 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, an entity providing pharmacy benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such

covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format and, as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may determine, other formats. Each such report shall include, with respect to the covered group health plan—

"(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;

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

"(i) the brand name, generic or nonproprietary name, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom the drug was billed during the reporting period, the total num-

ber of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the reporting period;

"(iii) for each claim or dosage unit described in clause (ii), the type of dispensing channel used, such as retail, mail order, or specialty pharmacy;

"(iv) the wholesale acquisition cost, listed as cost per days supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

"(v) the total out-of-pocket spending by participants and beneficiaries on such drug after application of any benefits under the plan or coverage, including participant and beneficiary spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted to the plan or coverage; and

"(vi) for any drug for which gross spending by the plan exceeded $10,000 and that is one of the 50 prescription drugs for which the group health plan spent the most on prescription drug benefits during the reporting period—

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

"(II) if applicable, the rationale for preferred formulary placement of such drug in that therapeutic class, selected from a list of standard rationales established by the Secretary;

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

"(i) total gross spending by the plan, before rebates, fees, alternative discounts, or other remuneration;

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

"(iii) if applicable to that class, a description of the formulary tiers and utilization management mechanisms (such as prior authorization or step therapy) employed for drugs in that 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 class under which 3 or more drugs are included on the formulary of such plan—

"(I) the amount received, or expected to be received, by such entity, from an applicable entity, in rebates, fees, alternative discounts, or other remuneration that—

‘‘(aa) has been paid, or will be paid, by such an applicable entity for claims incurred during the reporting period, or

‘‘(bb) is related to utilization of drugs or drug spending;

‘‘(II) the total net spending by the health plan on that class of drugs; and

‘‘(III) the net price per typical course of treatment or 30-day supply incurred by the health plan and its participants and beneficiaries, after rebates, fees, alternative discounts, or other remuneration provided by an applicable entity, for drugs dispensed within such therapeutic class during the reporting period;

‘‘(D) total gross spending on prescription drugs by the plan during the reporting period, before rebates, fees, alternative discounts, or other remuneration provided by an applicable entity;

‘‘(E) the total amount received, or expected to be received, by the health plan, from

an applicable entity, in rebates, fees, alternative discounts, and other remuneration received from any such entities, 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;

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act of 1974) to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's business to the pharmacy benefit manager; and

''(H) a summary document that includes such information described in subparagraphs (A) through (G) as the Secretary determines useful for plan sponsors for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.

''(2) SUPPLEMENTARY REPORTING FOR INTRA-COMPANY PRESCRIPTION DRUG TRANSACTIONS.—

''(A) IN GENERAL.—A health insurance issuer offering covered group health insurance coverage or an entity providing pharmacy benefit management services under a covered group health plan or covered group health insurance coverage shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes—

''(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries 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 providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and copayment incentives funded by an entity providing pharmacy benefit management services;

"(ii) the percentage of total prescriptions charged to the plan, coverage, or participants and beneficiaries in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are wholly or partially-owned by the issuer or entity providing pharmacy benefit management services; and

"(iii) a list of all drugs dispensed by such wholly or partially-owned pharmacy and charged to the plan or coverage, or participants and beneficiaries of the plan or coverage, during the applicable quarter, and, with respect to each drug—

"(I) the amounts charged, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, with respect to participants and beneficiaries in the plan or coverage, including amounts charged to the plan or coverage and amounts charged to the participants and beneficiaries;

"(II) the median amount charged to the plan or coverage, per dosage

unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

"(III) the interquartile range of the costs, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

"(IV) the lowest cost, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan or issuer and par-

ticipants and beneficiaries, that is available from any pharmacy included in the network of the plan or coverage;

"(V) the net acquisition cost per dosage unit and for a 30 day-supply, and the acquisition cost per typical course of treatment, if the drug is subject to a maximum price discount; and

"(VI) other information with respect to the cost of the drug, as determined by the Secretary, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit, per typical course of treatment, or per 30-day supply, for such drug, including amounts charged to the plan or issuer and participants and beneficiaries among all pharmacies included in the network of the plan or coverage.

"(B) PLANS AND COVERAGE OFFERED BY SMALL EMPLOYERS.—A health insurance issuer offering covered group health insurance cov-

erage that is not covered group health insurance coverage or an entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan or under group health insurance coverage that is not covered group health insurance coverage that conducts transactions with a wholly or partially-owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

''(3) PRIVACY REQUIREMENTS.—

''(A) RELATIONSHIP TO HIPAA REGULATIONS.—Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the privacy, security, breach notification, and enforcement regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

''(B) REQUIREMENT.—A report submitted under paragraph (1) or (2) shall contain only

summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

"(C) CLARIFICATION REGARDING CERTAIN DISCLOSURES OF INFORMATION.—

"(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage from placing reasonable restrictions on the public disclosure of the information contained in a report under paragraph (1) or (2).

"(ii) LIMITATIONS.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or any other Federal agency re-

sponsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the United States in accordance with paragraph (6).

"(4) USE AND DISCLOSURE BY PLAN SPONSORS.—

"(A) PROHIBITION.—A plan sponsor may not—

"(i) fail or refuse to hire, or discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph (1) or (2) attributed to the employee or a dependent of the employee; or

"(ii) limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of infor-

mation submitted under paragraph (1) or (2) attributed to the employee or a dependent of the employee.

"(B) DISCLOSURE AND REDISCLOSURE.—A plan sponsor shall not disclose the information received under paragraph (1) or (2) except—

"(i) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations (or successor regulations);

"(ii) in response to an order of a court, except that the plan sponsor may disclose only the information expressly authorized by such order;

"(iii) to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

"(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, to

abide by the same use and disclosure restrictions as the plan sponsor.

''(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

''(D) ENFORCEMENT.—

''(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Nondiscrimination Act to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

"(5) ADDITIONAL REPORTING.—

"(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable for-

mat, and such other formats as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may determine. Each such report shall include, with respect to the applicable group health plan, the information described in subparagraphs (A), (D), (E), (F), (G), and (H) of paragraph (1).

"(B) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE.—

"(i) IN GENERAL.—A plan sponsor may, on an annual basis, beginning with plan years beginning on or after January 1, 2025, elect to require a health insurance issuer offering group health insurance coverage to submit to such plan sponsor a report in accordance with this subsection.

"(ii) CONTENTS OF REPORTS.—

"(I) COVERED GROUP HEALTH INSURANCE COVERAGE.—In the case of an issuer that offers covered group health insurance coverage, a report provided pursuant to clause (i) shall include, with respect to the applicable covered group health insurance coverage, the information required under

paragraph (1) for covered group health plans.

''(II) OTHER GROUP HEALTH INSURANCE COVERAGE.—In the case of an issuer that offers group health insurance coverage that is not covered group health insurance, a report provided pursuant to clause (i) shall include, with respect to the applicable group health insurance coverage, the information described in subparagraphs (A), (D), (E), (F), and (G) of paragraph (1).

''(iii) APPLICATION.—For purposes of reports submitted in accordance with this subparagraph, paragraph (1) shall be applied by substituting 'group health insurance coverage' or 'health insurance issuer', as applicable, for 'group health plan', 'group plan', and 'plan' where such terms appear in such paragraph.

''(iv) REQUIRED REPORTING FOR ALL GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer of health insurance coverage shall annually submit the

information described in paragraph (1)(H), regardless of whether the plan sponsor made the election described in clause (i) for the applicable year.

"(6) SUBMISSIONS TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (5) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (3), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

"(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall specify, through rulemaking, standard formats for health insurance issuers and entities providing pharmacy benefit management services to submit reports required under this subsection.

"(B) LIMITED FORM OF REPORT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury shall define through rulemaking a limited form of the reports under paragraphs (1) and (2) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

"(c) LIMITATIONS ON SPREAD PRICING.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or health insurance issuer offering group or individual health insurance coverage shall not charge participants and beneficiaries, and an entity providing pharmacy benefit management services under such a plan or coverage shall not charge the plan, issuer, or participants and beneficiaries, a price for a prescription drug that exceeds the price paid to the pharmacy for such drug, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan, issuer, or entity.

"(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

"(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan, issuer, or entity.

"(B) A penalty paid if the original claim payment made by the plan, issuer, or entity to the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan, issuer, or entity.

"(C) A penalty paid if the pharmacist services billed to the plan, issuer, or entity were not rendered by the pharmacy.

"(d) FULL REBATE PASS-THROUGH TO PLAN.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services under such health plan or health insurance coverage shall—

"(A) remit 100 percent of rebates, fees, alternative discounts, and other remuneration received from any applicable entity that are re-

lated to utilization of drugs under such health plan or health insurance coverage, to the group health plan; and

"(B) ensure that any contract entered into by such third-party administrator, health insurance issuer, or entity providing pharmacy benefit management services with an applicable entity remit 100 percent of rebates, fees, alternative discounts, and other remuneration received to the third-party administrator, health insurance issuer, or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

"(A) remitted to the group health plan or group health insurance coverage in a timely fashion after the period for which such rebates, fees, alternative discounts, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

"(B) fully disclosed and enumerated to the group health plan sponsor, as described in paragraphs (1) and (4) of subsection (b);

"(C) available for audit by the plan sponsor, or a third-party designated by a plan sponsor not less than once per plan year; and

"(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by such issuer or entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan.

"(3) AUDIT OF REBATE CONTRACTS.—A third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services under such health plan or health insurance coverage shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by such plan sponsor or designated third-party, subject to confidentiality agreements to prevent re-disclosure of such contracts.

"(4) AUDITORS.—The applicable plan sponsor may select an auditor for purposes of carrying out audits under paragraphs (2)(C) and (3).

"(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit payments to entities offering pharmacy benefit manage-

ment services for bona fide services using a fee structure not contemplated by this subsection, provided that such fees are transparent to group health plans and health insurance issuers.

''(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 benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services that violates subsection (d) 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, entity providing pharmacy benefit manage-

ment services, or drug manufacturer 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 subsections (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.

''(f) 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.~~

~~"(g) DEFINITIONS.—In this section—~~

~~"(1) the term 'applicable entity' means—~~

~~"(A) a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), group purchasing organization, or associated third party;~~

~~"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or~~

~~"(C) such other entity as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may specify through rulemaking;~~

~~"(2) the term 'covered group health insurance coverage' means health insurance coverage offered in connection with a group health plan maintained by a large employer;~~

~~"(3) the term 'covered group health plan' means a group health plan maintained by a large employer;~~

''(4) the term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

''(5) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;

''(6) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

''(7) the term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974;

''(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Labor, and the Secretary of the Treasury, through notice and comment rulemaking;

''(9) the term 'small employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 49 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year; and

''(10) 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 section 2799A–11)'' after ''part D''; and

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

(B) in subsection (b)—

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

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

(iii) in paragraph (2)(C)(ii), by inserting ''(other than 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 ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT 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 providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an applicable entity that limits the disclosure of information

to plan sponsors in such a manner that prevents the plan or issuer, or an entity providing pharmacy benefit 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, an entity providing pharmacy benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format and, as the Secretary may determine, other formats. Each such report shall include, with respect to the covered group health plan—

"(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;

"(B) a list of each drug covered by such plan or entity providing pharmacy benefit man-

agement services that was billed during the reporting period, including, with respect to each such drug during the reporting period—

"(i) the brand name, generic or non-proprietary name, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom the drug was billed during the reporting period, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the reporting period;

"(iii) for each claim or dosage unit described in clause (ii), the type of dispensing channel used, such as retail, mail order, or specialty pharmacy;

"(iv) the wholesale acquisition cost, listed as cost per days supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

"(v) the total out-of-pocket spending by participants and beneficiaries on such drug after application of any benefits

under the plan or coverage, including participant and beneficiary spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted to the plan or coverage; and

''(vi) for any drug for which gross spending by the plan exceeded $10,000 and that is one of the 50 prescription drugs for which the group health plan spent the most on prescription drug benefits during the reporting period—

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

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

selected from a list of standard rationales established by the Secretary;

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

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

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

''(iii) if applicable to that class, a description of the formulary tiers and utilization management mechanisms (such as prior authorization or step therapy) employed for drugs in that 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 class under which 3 or more drugs are included on the formulary of such plan—

"(I) the amount received, or expected to be received, by such entity, from an applicable entity, in rebates, fees, alternative discounts, or other remuneration that—

"(aa) has been paid, or will be paid, by such an applicable entity for claims incurred during the reporting period, or

"(bb) is related to utilization of drugs or drug spending;

"(II) the total net spending by the health plan on that class of drugs; and

"(III) the net price per typical course of treatment or 30-day supply incurred by the health plan and its participants and beneficiaries, after rebates, fees, alternative discounts, or other remuneration provided by an applicable entity, for drugs dispensed

within such therapeutic class during the reporting period;

"(D) total gross spending on prescription drugs by the plan during the reporting period, before rebates, fees, alternative discounts, or other remuneration provided by an applicable entity;

"(E) the total amount received, or expected to be received, by the health plan, from an applicable entity, in rebates, fees, alternative discounts, and other remuneration received from any such entities, 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;

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA)) to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's business to the pharmacy benefit manager; and

"(H) a summary document that includes such information described in subparagraphs (A) through (G) as the Secretary determines useful for plan sponsors for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.

"(2) SUPPLEMENTARY REPORTING FOR INTRA-COMPANY PRESCRIPTION DRUG TRANSACTIONS.—

"(A) IN GENERAL.—A health insurance issuer offering covered group health insurance coverage or an entity providing pharmacy benefit management services under a covered group health plan or covered group health insurance coverage shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes—

"(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries 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 providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and copayment incentives funded by an entity providing pharmacy benefit management services;

''(ii) the percentage of total prescriptions charged to the plan, coverage, or participants and beneficiaries in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are wholly or partially-owned by the issuer or entity providing pharmacy benefit management services; and

''(iii) a list of all drugs dispensed by such wholly or partially-owned pharmacy and charged to the plan or coverage, or participants and beneficiaries of the plan or coverage, during the applicable quarter, and, with respect to each drug—

''(I) the amounts charged, per dosage unit, per course of treatment, per 30-day supply, and per 90-day

supply, with respect to participants and beneficiaries in the plan or coverage, including amounts charged to the plan or coverage and amounts charged to the participants and beneficiaries;

"(II) the median amount charged to the plan or coverage, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

"(III) the interquartile range of the costs, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the

~~issuer or entity and that are included in the pharmacy network of that plan or coverage;~~

~~"(IV) the lowest cost, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan or issuer and participants and beneficiaries, that is available from any pharmacy included in the network of the plan or coverage;~~

~~"(V) the net acquisition cost per dosage unit and for a 30 day-supply, and the acquisition cost per typical course of treatment, if the drug is subject to a maximum price discount; and~~

~~"(VI) other information with respect to the cost of the drug, as determined by the Secretary, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit, per typical course of treatment, or per 30-day~~

supply, for such drug, including amounts charged to the plan or issuer and participants and beneficiaries among all pharmacies included in the network of the plan or coverage.

"(B) PLANS AND COVERAGE OFFERED BY SMALL EMPLOYERS.—A health insurance issuer offering covered group health insurance coverage that is not covered group health insurance coverage or an entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan or under group health insurance coverage that is not covered group health insurance coverage that conducts transactions with a wholly or partially-owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

"(3) PRIVACY REQUIREMENTS.—

"(A) RELATIONSHIP TO HIPAA REGULATIONS.—Nothing in this section shall be construed to modify the requirements for the cre-

ation, receipt, maintenance, or transmission of protected health information under the privacy, security, breach notification, and enforcement regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

''(B) REQUIREMENT.—A report submitted under paragraph (1) or (2) shall contain only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(C) CLARIFICATION REGARDING CERTAIN DISCLOSURES OF INFORMATION.—

''(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage from placing reasonable restrictions on the public disclosure of the information contained in a report under paragraph (1) or (2).

''(ii) LIMITATIONS.—A health insurance issuer offering group health insurance

coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or any other Federal agency responsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the United States in accordance with paragraph (6).

"(4) USE AND DISCLOSURE BY PLAN SPONSORS.—

"(A) PROHIBITION.—A plan sponsor may not—

"(i) fail or refuse to hire, or discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph (1) or (2) attrib-

uted to the employee or a dependent of the employee; or

''(ii) limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of information submitted under paragraph (1) or (2) attributed to the employee or a dependent of the employee.

''(B) DISCLOSURE AND REDISCLOSURE.—A plan sponsor shall not disclose the information received under paragraph (1) or (2) except—

''(i) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations (or successor regulations);

''(ii) in response to an order of a court, except that the plan sponsor may disclose only the information expressly authorized by such order;

"(iii) to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

"(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, to abide by the same use and disclosure restrictions as the plan sponsor.

"(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2), subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

"(D) ENFORCEMENT.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Nondiscrimination Act (42 U.S.C. 2000ff–6) to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

"(5) ADDITIONAL REPORTING.—

"(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format, and such other formats as the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor may determine. Each such report shall include, with respect to the applicable group health plan, the information described in subparagraphs (A), (D), (E), (F), (G), and (H) of paragraph (1).

"(B) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE.—

"(i) IN GENERAL.—A plan sponsor may, on an annual basis, beginning with plan years beginning on or after January 1, 2025, elect to require a health insurance issuer offering group health insurance cov-

erage to submit to such plan sponsor a report in accordance with this subsection.

"(ii) CONTENTS OF REPORTS.—

"(I) COVERED GROUP HEALTH INSURANCE COVERAGE.—In the case of an issuer that offers covered group health insurance coverage, a report provided pursuant to clause (i) shall include, with respect to the applicable covered group health insurance coverage, the information required under paragraph (1) for covered group health plans.

"(II) OTHER GROUP HEALTH INSURANCE COVERAGE.—In the case of an issuer that offers group health insurance coverage that is not covered group health insurance, a report provided pursuant to clause (i) shall include, with respect to the applicable group health insurance coverage, the information described in subparagraphs (A), (D), (E), (F), and (G) of paragraph (1).

"(iii) APPLICATION.—For purposes of reports submitted in accordance with this subparagraph, paragraph (1) shall be applied by substituting 'group health insurance coverage' or 'health insurance issuer', as applicable, for 'group health plan', 'group plan', and 'plan' where such terms appear in such paragraph.

"(iv) REQUIRED REPORTING FOR ALL GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer of health insurance coverage shall annually submit the information described in paragraph (1)(H), regardless of whether the plan sponsor made the election described in clause (i) for the applicable year.

"(6) SUBMISSIONS TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (5) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy

requirements under paragraph (3), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

"(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall specify, through rulemaking, standard formats for health insurance issuers and entities providing pharmacy benefit management services to submit reports required under this subsection.

"(B) LIMITED FORM OF REPORT.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall define through rulemaking a limited form of the reports under paragraphs (1) and (2) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in order to prevent anticompetitive behavior.

"(c) LIMITATIONS ON SPREAD PRICING.—

"(1) 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 shall not charge participants and beneficiaries, and an entity providing pharmacy benefit management services under such a plan or coverage shall not charge the plan, issuer, or participants and beneficiaries, a price for a prescription drug that exceeds the price paid to the pharmacy for such drug, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan, issuer, or entity.

"(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

"(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan, issuer, or entity.

"(B) A penalty paid if the original claim payment made by the plan, issuer, or entity to the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan, issuer, or entity.

"(C) A penalty paid if the pharmacist services billed to the plan, issuer, or entity were not rendered by the pharmacy.

"(d) FULL REBATE PASS-THROUGH TO PLAN.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services under such health plan or health insurance coverage shall—

"(A) remit 100 percent of rebates, fees, alternative discounts, and other applicable remuneration received from any applicable entity that are related to utilization of drugs under such health plan or health insurance coverage, to the group health plan; and

"(B) ensure that any contract entered into by such third-party administrator, health insurance issuer, or entity providing pharmacy benefit management services with an applicable entity remit 100 percent of rebates, fees, alternative discounts, and other remuneration received to the third-party administrator, health

insurance issuer, or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

"(A) remitted to the group health plan or group health insurance coverage in a timely fashion after the period for which such rebates, fees, alternative discounts, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

"(B) fully disclosed and enumerated to the group health plan sponsor, as described in paragraphs (1) and (4) of subsection (b);

"(C) available for audit by the plan sponsor, or a third-party designated by a plan sponsor not less than once per plan year; and

"(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by such issuer or entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan.

"(3) AUDIT OF REBATE CONTRACTS.—A third-party administrator of a group health plan, a health

insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services under such health plan or health insurance coverage shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by such plan sponsor or designated third-party, subject to confidentiality agreements to prevent re-disclosure of such contracts.

''(4) AUDITORS.—The applicable plan sponsor may select an auditor for purposes of carrying out audits under paragraphs (2)(C) and (3).

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not contemplated by this subsection, provided that such fees are transparent to group health plans and health insurance issuers.

''(e) ENFORCEMENT.—

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

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity pro-

viding pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services that violates subsection (d) 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, entity providing pharmacy benefit management services, or drug manufacturer 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 subsections (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.

''(f) 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.

''(g) DEFINITIONS.—In this section—

''(1) the term 'applicable entity' means—

''(A) a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), group purchasing organization, or associated third party;

"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

"(C) such other entity as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may specify through rulemaking;

"(2) the term 'covered group health insurance coverage' means health insurance coverage offered in connection with a group health plan maintained by a large employer;

"(3) the term 'covered group health plan' means a group health plan maintained by a large employer;

"(4) the term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

''(5) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;

''(6) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

''(7) the term 'plan sponsor' has the meaning given such term in section 3(16)(B);

''(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, through notice and comment rulemaking;

''(9) the term 'small employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than

49 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year; and

''(10) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).''; and

(B) in section 502(b)(3) (29 U.S.C. 1132(b)(3)), by inserting ''(other than section 726)'' after ''part 7''.

(2) CLERICAL AMENDMENT.—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 relating to section 725 the following new item:

''Sec. 726. Oversight of entities that provide pharmacy benefit management services.''.

(c) INTERNAL REVENUE CODE.—

(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 ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity providing pharmacy benefit management services on be-

half of such a plan shall not enter into a contract with an applicable entity that limits the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity providing pharmacy benefit 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 benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format and, as the Secretary may determine, other formats. Each such report shall include, with respect to the covered 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 benefit management services that was billed during the reporting period, including, with respect to each such drug during the reporting period—

"(i) the brand name, generic or nonproprietary name, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom the drug was billed during the reporting period, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the reporting period;

"(iii) for each claim or dosage unit described in clause (ii), the type of dispensing channel used, such as retail, mail order, or specialty pharmacy;

"(iv) the wholesale acquisition cost, listed as cost per days supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

"(v) the total out-of-pocket spending by participants and beneficiaries on such drug after application of any benefits under the plan, including participant and beneficiary spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or for which no claim is submitted to the plan; and

"(vi) for any drug for which gross spending by the plan exceeded $10,000 and that is one of the 50 prescription drugs for which the group health plan spent the most on prescription drug benefits during the reporting period—

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

"(II) if applicable, the rationale for preferred formulary placement of

such drug in that therapeutic class, selected from a list of standard rationales established by the Secretary;

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

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

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

''(iii) if applicable to that class, a description of the formulary tiers and utilization management mechanisms (such as prior authorization or step therapy) employed for drugs in that 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 class under which 3 or more drugs are included on the formulary of such plan—

"(I) the amount received, or expected to be received, by such entity, from an applicable entity, in rebates, fees, alternative discounts, or other remuneration that—

"(aa) has been paid, or will be paid, by such an applicable entity for claims incurred during the reporting period, or

"(bb) is related to utilization of drugs or drug spending;

"(II) the total net spending by the health plan on that class of drugs; and

"(III) the net price per typical course of treatment or 30-day supply incurred by the health plan and its participants and beneficiaries, after rebates, fees, alternative discounts, or other remuneration provided by an applicable entity, for drugs dispensed

within such therapeutic class during the reporting period;

"(D) total gross spending on prescription drugs by the plan during the reporting period, before rebates, fees, alternative discounts, or other remuneration provided by an applicable entity;

"(E) the total amount received, or expected to be received, by the health plan, from an applicable entity, in rebates, fees, alternative discounts, and other remuneration received from any such entities, 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;

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(dd)(A))) to brokers, consultants, advisors, or any other individual or firm

who referred the group health plan's business to the pharmacy benefit manager; and

"(H) a summary document that includes such information described in subparagraphs (A) through (G) as the Secretary determines useful for plan sponsors for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.

"(2) SUPPLEMENTARY REPORTING FOR INTRA-COMPANY PRESCRIPTION DRUG TRANSACTIONS.—

"(A) IN GENERAL.—An entity providing pharmacy benefit management services under a covered group health plan shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes—

"(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that entity providing

pharmacy benefit management services under such plan, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and co-payment incentives funded by an entity providing pharmacy benefit management services;

"(ii) the percentage of total prescriptions charged to the plan or participants and beneficiaries in the plan, that were dispensed by mail order, specialty, or retail pharmacies that are wholly or partially-owned by the entity providing pharmacy benefit management services; and

"(iii) a list of all drugs dispensed by such wholly or partially-owned pharmacy and charged to the plan, or participants and beneficiaries of the plan, during the applicable quarter, and, with respect to each drug—

"(I) the amounts charged, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, with respect to participants and beneficiaries in the plan, includ-

ing amounts charged to the plan and amounts charged to the participants and beneficiaries;

"(II) the median amount charged to the plan, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the entity and that are included in the pharmacy network of that plan;

"(III) the interquartile range of the costs, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the entity and that are included in the pharmacy network of that plan;

"(IV) the lowest cost, per dosage unit, per course of treatment, per 30-

day supply, and per 90-day supply, for such drug, including amounts charged to the plan and participants and beneficiaries, that is available from any pharmacy included in the network of the plan;

"(V) the net acquisition cost per dosage unit and for a 30 day-supply, and the acquisition cost per typical course of treatment, if the drug is subject to a maximum price discount; and

"(VI) other information with respect to the cost of the drug, as determined by the Secretary, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit, per typical course of treatment, or per 30-day supply, for such drug, including amounts charged to the plan and participants and beneficiaries among all pharmacies included in the network of the plan.

"(B) PLANS OFFERED BY SMALL EMPLOYERS.—An entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan that conducts transactions with a wholly or partially-owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

"(3) PRIVACY REQUIREMENTS.—

"(A) RELATIONSHIP TO HIPAA REGULATIONS.—Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the privacy, security, breach notification, and enforcement regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

"(B) REQUIREMENT.—A report submitted under paragraph (1) or (2) shall contain only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

"(C) CLARIFICATION REGARDING CERTAIN DISCLOSURES OF INFORMATION.—

"(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents an entity providing pharmacy benefit management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report under paragraph (1) or (2).

"(ii) LIMITATIONS.—An entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or any other Federal agency responsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the United States in accordance with paragraph (6).

‘‘(4) USE AND DISCLOSURE BY PLAN SPONSORS.—

‘‘(A) PROHIBITION.—A plan sponsor may not—

‘‘(i) fail or refuse to hire, or discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph (1) or (2) attributed to the employee or a dependent of the employee; or

‘‘(ii) limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of information submitted under paragraph (1) or (2) attributed to the employee or a dependent of the employee.

‘‘(B) DISCLOSURE AND REDISCLOSURE.—A plan sponsor shall not disclose the informa-

tion received under paragraph (1) or (2) except—

"(i) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations (or successor regulations);

"(ii) in response to an order of a court, except that the plan sponsor may disclose only the information expressly authorized by such order;

"(iii) to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

"(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, to abide by the same use and disclosure restrictions as the plan sponsor.

"(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to the regulations promulgated by the Secretary of Health and

Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2), subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

"(D) ENFORCEMENT.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Nondiscrimination Act (42 U.S.C. 2000ff–6) to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such indi-

vidual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

''(5) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, 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, the information described in subparagraphs (A), (D), (E), (F), (G), and (H) of paragraph (1).

"(6) SUBMISSIONS TO GAO.—An entity providing pharmacy benefit management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (5) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (3), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

"(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall specify, through rulemaking, standard formats for health insurance issuers and entities providing pharmacy benefit management services to submit reports required under this subsection.

"(B) LIMITED FORM OF REPORT.—The Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall define through rulemaking a limited form of the

reports under paragraphs (1) and (2) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(c) LIMITATIONS ON SPREAD PRICING.—

''(1) IN GENERAL.—A group health plan shall not charge participants and beneficiaries, and an entity providing pharmacy benefit management services under such a plan shall not charge the plan or participants and beneficiaries, a price for a prescription drug that exceeds the price paid to the pharmacy for such drug, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan or entity.

''(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

''(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan or entity.

''(B) A penalty paid if the original claim payment made by the plan, issuer, or entity to

the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan or entity.

''(C) A penalty paid if the pharmacist services billed to the plan or entity were not rendered by the pharmacy.

''(d) FULL REBATE PASS-THROUGH TO PLAN.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, a third-party administrator of a group health plan or an entity providing pharmacy benefit management services under such health plan shall—

''(A) remit 100 percent of rebates, fees, alternative discounts, and other remuneration received from any applicable entity that are related to utilization of drugs under such health plan, to the group health plan; and

''(B) ensure that any contract entered into by such third-party administrator or entity providing pharmacy benefit management services with an applicable entity remit 100 percent of rebates, fees, alternative discounts, and other remuneration received to the third-party administrator or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

"(A) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, alternative discounts, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

"(B) fully disclosed and enumerated to the group health plan sponsor, as described in paragraphs (1) and (4) of subsection (b);

"(C) available for audit by the plan sponsor, or a third-party designated by a plan sponsor not less than once per plan year; and

"(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by such entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan.

"(3) AUDIT OF REBATE CONTRACTS.—A third-party administrator of a group health plan or an entity providing pharmacy benefit management services under such health plan shall make rebate contracts with rebate aggregators or drug manufactur-

ers available for audit by such plan sponsor or designated third-party, subject to confidentiality agreements to prevent re-disclosure of such contracts.

''(4) AUDITORS.—The applicable plan sponsor may select an auditor for purposes of carrying out audits under paragraphs (2)(C) and (3).

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not contemplated by this subsection, provided that such fees are transparent to group health plans.

''(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.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan or entity providing pharmacy benefit management services that violates subsection (c); or a third-party

administrator of a group health plan or an entity providing pharmacy benefit management services that violates subsection (d) 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 benefit management services, or drug manufacturer 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 subsections (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 sec-

tion, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(f) 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.

''(g) DEFINITIONS.—In this section—

''(1) the term 'applicable entity' means—

''(A) a drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), group purchasing organization, or associated third party;

''(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

''(C) such other entity as the Secretary, the Secretary of Health and Human Services,

and the Secretary of Labor may specify through rulemaking;

''(2) the term 'covered group health insurance coverage' means health insurance coverage offered in connection with a group health plan maintained by a large employer;

''(3) the term 'covered group health plan' means a group health plan maintained by a large employer;

''(4) the term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

''(5) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;

''(6) the term 'net spending', with respect to prescription drug benefits under a group health plan

or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

''(7) the term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(B));

''(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, through notice and comment rulemaking;

''(9) the term 'small employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 49 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year; and

''(10) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).''.

(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 entities that provide pharmacy benefit management services.".

(d) FUNDING.—

(1) For purposes of carrying out the amendments made by subsection (a), there are appropriated to the Centers for Medicare & Medicaid Services, out of amounts in the Treasury not otherwise appropriated, $80,000,000 for fiscal year 2024.

(2) For purposes of carrying out the amendments made by subsection (b), there are appropriated to the Department of Labor, out of amounts in the Treasury not otherwise appropriated, $43,750,000 for fiscal year 2024.

(e) ASPE STUDY.—The Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services shall conduct or commission a study on how the United States health care market would be impacted by potential regulatory changes disallowing manufacturer rebates in the manner and to the extent allowed on the date of enactment of this Act, with a focus on the impact to stakeholders in the commercial insurance market, and, not later than 1 year after the date of enactment

of this Act, submit a report to Congress on the results of such study. Such study and report shall consider the following:

(1) The impact on the impact of making no such regulatory changes, as well as potential behavioral changes by plan sponsors, members, and pharmaceutical manufacturers, such as tighter formularies, changes to price concessions, changes in utilization, if such regulatory changes are made.

(2) The mechanics needed in the pharmaceutical supply chain (whether existing or not) to move a manufacturer rebate to the point of sale.

(3) The feasibility of a partial point-of-sale manufacturer rebate versus a full point-of-sale manufacturer rebate.

(4) The impact on patient out-of-pocket costs, premiums, and other cost-sharing.

(5) Possible behavioral changes by other third parties in the pharmaceutical supply chain including drug manufacturer, distributor, wholesaler, rebate aggregators, pharmacy services administrative organizations, or group purchasing organizations.

(6) Behavioral changes between entities that contract with pharmaceutical manufacturers and pharmaceutical supply chain.

(7) Alternative price negotiation mechanisms, including the impact of the Act of June 19, 1936 (commonly known as the ''Robinson-Patman Act''; 49 Stat. 1526, chapter 592; 15 U.S.C. 13a et seq.), and the amendments made by that Act, on drug pricing negotiations.

(8) The impact on pharmacies, including pharmacy rebates, pharmacy fees, and dispensing channels.

(f) GAO STUDY.—

(1) IN GENERAL.—Not later than January 1, 2029, the Comptroller General of the United States shall report to Congress on—

(A) pharmacy networks of group health plans, health insurance issuers, and entities providing pharmacy benefit 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 benefit management services or pharmacy benefit 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 participants and beneficiaries 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 participants and beneficiaries 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 benefit management services, the prevalence of electing such different network pricing arrangements;

(D) pharmacy network design parameters that encourage participants and beneficiaries 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 participants and beneficiaries 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 benefit management services or pharmacy benefit 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 participants and beneficiaries 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 benefit management services.

~~(2) REQUIREMENT.—In carrying out paragraph (1), the Comptroller General of the United States shall not disclose—~~

~~(A) information that would allow for identification of a specific individual, plan sponsor, health insurance issuer, plan, or entity providing pharmacy benefit management services; or~~

~~(B) 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).~~

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pharmacy Benefit Manager Reform Act".

SEC. 2. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

(a) PUBLIC HEALTH SERVICE ACT.—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 ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

"(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a group health plan or health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an applicable entity unless such applicable entity agrees to—

"(1) not limit the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity providing pharmacy benefit management services on behalf of a plan or issuer, from making the reports described in subsection (b); and

"(2) provide the group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of a plan or issuer, relevant information necessary to make the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of

enactment of the Pharmacy Benefit Manager Reform Act, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a covered group health plan or group health insurance coverage (regardless of whether such coverage is covered group health insurance coverage as defined in subsection (g)(3)) shall submit to the plan sponsor of such covered group health plan or issuer of such health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor or issuer in plain language, in a machine-readable format, and, as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may determine, other formats. Each such report shall include, with respect to the covered group health plan or health insurance coverage—

"(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 such drug manufacturers with respect to the participants and beneficiaries in such plan or coverage;

"(B) a list of each drug covered by the plan, coverage, or entity providing pharmacy benefit

management services for which a claim was filed during the reporting period, including, with respect to each such drug during the reporting period—

"(i) the brand name, generic or non-proprietary name, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom a claim for the drug was filed during the reporting period, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug for which a claim was filed across the reporting period;

"(iii) for each claim or dosage unit described in clause (ii), the type of dispensing channel used, such as retail, mail order, or specialty pharmacy;

"(iv) the wholesale acquisition cost, listed as cost per days' supply and cost per dosage unit;

"(v) the total out-of-pocket spending by participants and beneficiaries on such drug after application of any benefits under the plan or coverage—

"(I) including copayments, coinsurance, and deductibles; and

"(II) not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted to the plan or coverage; and

"(vi) for each of the 50 prescription drugs with the highest gross spending under the group health plan or health insurance coverage during the reporting period—

"(I) a list of all other drugs in the same therapeutic class (as defined by the Secretary, the Secretary of Labor, and the Secretary of the Treasury), including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic class as such drug;

"(II) if applicable, the rationale for preferred formulary placement of such drug in that therapeutic class, selected from a list of standard rationales established by the Secretary, the

Secretary of Labor, and the Secretary of the Treasury, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year;

"(C) a list of each therapeutic class of drugs for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class (as defined as described in subparagraph (B)(vi)(I)) of drugs, during the reporting period—

"(i) total gross spending by the plan or by the issuer offering such coverage;

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

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

"(iv) the total out-of-pocket spending by participants and beneficiaries on drugs

in such therapeutic class, after application of any benefits under the plan or coverage—

"(I) including copayments, coinsurance, and deductibles; and

"(II) not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted to the plan or issuer; and

"(v) for each therapeutic 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, by such entity, from applicable entities, in rebates, fees, alternative discounts, or other remuneration—

"(aa) for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs or drug spending;

"(II) the total net spending by the plan or by the issuer with respect to such coverage on that class of drugs; and

"(III) the average net spending per 30-day supply and per 90-day supply by the plan or by the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

"(D) total gross spending on prescription drugs by the plan or by the issuer with respect to such coverage during the reporting period;

"(E) the total amount received, or expected to be received, by the group health plan or health insurance issuer, from applicable entities, in rebates, fees, alternative discounts, and other remuneration received from such entities, related to utilization of drugs or drug spending under that group health plan or health insurance coverage during the reporting period;

"(F) the total net spending on prescription drugs by the group health plan or health insurance issuer with respect to the coverage during the reporting period;

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation

(as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act of 1974) to brokers, consultants, advisors, or any other individual or firm for—

"(i) referral of the group health plan's or health insurance issuer's business to the pharmacy benefit manager;

"(ii) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

"(iii) the retention of the entity by the group health plan or health insurance issuer;

"(H)(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services on behalf of such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost-sharing assistance incentives funded by

an entity providing pharmacy benefit management services;

"(ii) the percentage of total prescriptions charged to the plan, issuer, or participants and beneficiaries in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services; and

"(iii) a list of all drugs dispensed by such affiliated pharmacy or pharmacy under common ownership and charged to the plan, issuer, or participants and beneficiaries of the plan or coverage, during the applicable period, and, with respect to each drug—

"(I)(aa) the amount charged, per dosage unit, per 30-day supply, and per 90-day supply, with respect to participants and beneficiaries in the plan or coverage, to the plan or issuer; and

"(bb) the amount charged, per dosage unit, per 30-day supply, and per 90-day supply to participants and beneficiaries;

"(II) the median amount charged to the plan or issuer, per dosage unit, per 30-

day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of that plan or coverage;

"(III) the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of that plan or coverage;

"(IV) the lowest cost, per dosage unit, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan and participants and beneficiaries, that is available from any pharmacy included in the network of the plan or coverage;

"(V) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day

supply, if the drug is subject to a maximum price discount; and

"(VI) other information with respect to the cost of the drug, as determined by the Secretary, the Secretary of Labor, and the Secretary of the Treasury, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit or per 30-day supply, for such drug, including amounts charged to the plan or issuer and participants and beneficiaries among all pharmacies included in the network of the plan or coverage;

"(I) a summary document for plan sponsors or issuers that includes the information described in subparagraphs (A) through (H) that the Secretary, the Secretary of Labor, and the Secretary of the Treasury determine useful to plan sponsors and health insurance issuers for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary; and

"(J) a summary document for participants or beneficiaries, which shall be made available to participants or beneficiaries upon request to the plan sponsor, that contains the information described in subparagraphs (D) through (G) that the Secretary, the Secretary of Labor, and the Secretary of the Treasury determine useful to participants or beneficiaries in better understanding their plan or benefits, except that such summary document for participants or beneficiaries shall contain only aggregate information.

"(2) REGULATIONS.—Not later than 2 years after the date of enactment of the Pharmacy Benefit Manager Reform Act, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall, through notice and comment rulemaking, promulgate final regulations to implement the requirements of this subsection. In promulgating such regulations, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall, to the extent practicable, align the reporting requirements under this subsection with the reporting requirements under section 2799A–10.

"(3) ADDITIONAL REPORTING.—

"(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format, and such other formats as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may specify. Each such report shall include, with respect to the applicable group health plan—

"(i) the information described in subparagraphs (D), (E), (F), and (G) of paragraph (1);

"(ii) as applicable, information collected from drug manufacturers by such plan on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by applicable

drug manufacturers with respect to the participants and beneficiaries in such plan, except that such information shall not identify any drug manufacturer; and

"(iii) a summary document that includes the information described in clauses (i) and (ii) that the Secretary, the Secretary of Labor, and the Secretary of the Treasury determine useful for plan sponsors for purposes of selecting pharmacy benefit management services, provided that such summary documents include only aggregate information.

"(B) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE.—

"(i) IN GENERAL.—A plan sponsor of group health insurance coverage offered in connection with a group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, elect to require an entity providing pharmacy benefit management services on behalf of a health insurance issuer offering group health in-

surance coverage to submit to such plan sponsor a report in accordance with this subsection.

"(ii) CONTENTS OF REPORTS.—

"(I) COVERED GROUP HEALTH INSURANCE COVERAGE.—In the case of an entity providing pharmacy benefit management services on behalf of an issuer that offers covered group health insurance coverage, a report provided pursuant to clause (i) shall include, with respect to the applicable covered group health insurance coverage, the information required under paragraph (1) for covered group health plans.

"(II) OTHER GROUP HEALTH INSURANCE COVERAGE.—In the case of an entity providing pharmacy benefit management services on behalf of an issuer that offers group health insurance coverage that is not covered group health insurance, a report provided pursuant to clause (i) shall include, with respect to the applicable group health insurance coverage—

"(aa) the information described in subparagraphs (D), (E), (F), and (G) of paragraph (1); and

"(bb) 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 applicable drug manufacturers with respect to the participants and beneficiaries in such plan, except that such information shall not identify any drug manufacturer.

"(iii) REQUIRED REPORTING FOR COVERED GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer that offers covered group health insurance coverage shall annually submit to the plan sponsor the information described in paragraph (1)(I), regardless of whether the plan sponsor made the election described in clause (i) for the applicable year.

"(iv) REQUIRED REPORTING FOR OTHER GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer that offers group health insurance coverage that is not covered group health insurance shall annually submit a summary document that includes such information described in items (aa) and (bb) of clause (ii)(II) as the Secretary and the Secretary of Labor determine useful for plan sponsors for purposes of selecting pharmacy benefit management services, provided that such summary documents include only aggregate information.

"(4) PRIVACY REQUIREMENTS.—

"(A) RELATIONSHIP TO HIPAA REGULATIONS.—Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations, as defined in section 1180(b)(3) of the Social Security Act.

"(B) REQUIREMENT.—A report submitted under paragraph (1) or (3) shall contain only summary health information, as defined in sec-

tion 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

"(C) CLARIFICATION REGARDING CERTAIN DISCLOSURES OF INFORMATION.—

"(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage from placing reasonable restrictions (as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may determine) on the public disclosure of the information contained in a report under paragraph (1) or (3).

"(ii) LIMITATIONS.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human

Services, the Department of Labor, the Department of the Treasury, or any other Federal agency responsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the United States in accordance with paragraph (6).

"(5) USE AND DISCLOSURE BY PLAN SPONSORS.—

"(A) PROHIBITION.—A plan sponsor may not—

"(i) fail or refuse to hire, or discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph (1) or (3) attributed to the employee or a dependent of the employee; or

"(ii) limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the em-

ployee as an employee, because of information submitted under paragraph (1) or (3) attributed to the employee or a dependent of the employee.

"(B) DISCLOSURE AND REDISCLOSURE.—A plan sponsor shall not disclose the information received under paragraph (1) or (3) except—

"(i) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations (or successor regulations);

"(ii) in response to an order of a court, except that the plan sponsor may disclose only the information expressly authorized by such order;

"(iii) to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

"(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, and

as a term of the contract, to abide by the same use and disclosure restrictions as the plan sponsor.

"(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to the HIPAA privacy regulations, as defined in section 1180(b)(3) of the Social Security Act, subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

"(D) WRITTEN NOTICE.—Plan sponsors of group health plans and group health insurance coverage shall provide to each employee written notice informing the employee of the requirement for health insurance issuers or entities providing pharmacy benefit management services on behalf of the plan or coverage to submit reports to plan sponsors under paragraphs (1) and (3), as applicable, which may include incorporating such notification in plan documents provided to the em-

ployee, an employee handbook provided to the employee, or individual notification.

"(E) ENFORCEMENT.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Nondiscrimination Act to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

"(6) SUBMISSIONS TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan shall submit, upon request, to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (3) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (4), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

"(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall specify, through rulemaking, standard formats for entities providing pharmacy benefit management services to submit reports required under this subsection. Such secretaries may provide for separate standard formats for reports to plan sponsors of group health plans and reports to plan sponsors of group health insurance coverage offered in connection with a group health plan.

"(B) FORM OF REPORT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury shall define through rulemaking a form of the reports under paragraphs (1) and (3) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in the case that such secretaries determine that changes to the standard format are necessary to prevent anticompetitive behavior.

"(c) LIMITATIONS ON SPREAD PRICING.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a group health plan or health insurance issuer offering group or individual health insurance coverage shall ensure that the amount required to be paid by a participant, beneficiary, or enrollee for a prescription drug covered under the plan or coverage, and a third-party administrator or an entity providing pharmacy benefit management services on behalf of such a plan or coverage shall ensure that the total amount required to be paid by the plan or issuer

and participant, beneficiary, or enrollee for a prescription drug covered under the plan or coverage, does not exceed the price paid to the pharmacy, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan, issuer, or entity.

"(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

"(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan, issuer, or entity.

"(B) A penalty paid if the original claim payment made by the plan, issuer, or entity to the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan, issuer, or entity.

"(C) A penalty paid if the pharmacist services for which a claim was filed with the plan, issuer, or entity were not rendered by the pharmacy.

"(d) FULL REBATE PASS-THROUGH TO PLAN OR HEALTH INSURANCE ISSUER.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of

enactment of the Pharmacy Benefit Manager Reform Act, a third-party administrator of a group health plan or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage shall—

"(A) remit 100 percent of rebates, fees, alternative discounts, and other remuneration received from any applicable entity that are related to utilization of drugs under such group health plan or health insurance coverage, to the group health plan or health insurance issuer offering group health insurance coverage; and

*"(B) ensure that any contract entered into, by such third-party administrator or entity providing pharmacy benefit management services on behalf of such a plan or coverage, with rebate aggregators (or other purchasing entity designed to aggregate rebates), applicable group purchasing organizations, or any subsidiary, parent, affiliate, or subcontractor of the plan, entity, rebate aggregator (or other purchasing entity designed to aggregate rebates), or applicable group purchasing organization remit 100 percent of rebates, fees, alternative discounts, and other remu-

neration received that are related to utilization of drugs under such group health plan or health insurance coverage, to the third-party administrator or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.—With respect to such rebates, fees, alternative discounts, and other remuneration—

"(A) the rebates, fees, alternative discounts, and other remuneration under paragraph (1)(A) shall be—

"(i) remitted—

"(I) on a quarterly basis, to the group health plan or the group health insurance issuer, not later than 90 days after the end of each quarter; or

"(II) in the case of an underpayment in a remittance for a prior quarter, as soon as practicable, but not later than 90 days after notice of the underpayment is first given;

"(ii) fully disclosed and enumerated to the group health plan or health insurance issuer, as described in paragraphs (1) and (3) of subsection (b); and

"(iii) returned to the issuer or entity providing pharmacy benefit management services on behalf of the group health plan if an audit by a plan sponsor, or a third party designated by a plan sponsor, indicates that the amounts received are incorrect after such amounts have been paid to the group health plan or health insurance issuer;

"(B) the rebates, fees, alternative discounts, and other remuneration under paragraph (1)(B) shall be remitted in accordance with such procedures as the Secretary, Secretary of Labor, and Secretary of the Treasury establish; and

"(C) the records of such rebates, fees, alternative discounts, and other remuneration shall be available for audit by the plan sponsor, issuer, or a third party designated by a plan sponsor, not less than once per plan year.

"(3) AUDIT OF REBATE CONTRACTS.—A third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such group health plan or health insurance coverage shall make rebate con-

tracts with rebate aggregators or drug manufacturers available for audit by the plan sponsor or designated third party, subject to reasonable restrictions (as determined by the Secretary, the Secretary of Labor, and the Secretary of the Treasury) on confidentiality to prevent re-disclosure of such contracts.

''(4) AUDITORS.—Audits carried out under paragraphs (2)(C) and (3) shall be performed by an auditor selected by the applicable plan sponsor.

''(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to—

''(A) prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subsection, provided that such fees are transparent to group health plans and health insurance issuers;

''(B) require a third-party administrator of a group health plan or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering health insurance coverage to remit bona fide service fees to group health plans or health insurance issuers; or

"(C) limit the ability of a group health plan or health insurance issuer to pass through rebates, fees, alternative discounts, and other remuneration to the participant or beneficiary.

"(e) ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary shall enforce this section.

"(2) VIOLATIONS.—A group health plan, a health insurance issuer, or an entity providing pharmacy benefit management services that violates subsection (a); an entity providing pharmacy benefit management services that fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan, a health insurance issuer, or an entity providing pharmacy benefit management services that violates subsection (d) 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 group health plan, a health insurance issuer, an entity providing pharmacy benefit management services, or a third-

party administrator 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.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary

of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), (c), or (d) by such issuer, plan, or entity.

"(g) DEFINITIONS.—In this section—

"(1) the term 'applicable entity' means—

"(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

"(C) such other entity as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may specify through rulemaking;

"(2) the term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services;

"(3) the term 'covered group health insurance coverage' means health insurance coverage offered in connection with a group health plan maintained by a large employer;

"(4) the term 'covered group health plan' means a group health plan maintained by a large employer;

"(5) the term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration;

"(6) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;

"(7) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the appli-

cation of rebates, fees, alternative discounts, or other remuneration;

"(8) the term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974;

"(9) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Labor, and the Secretary of the Treasury, through rulemaking, which shall be reevaluated by such secretaries every 5 years; and

"(10) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.";

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

(A) in subsection (a)—

(i) in paragraph (1), by inserting "(other than section 2799A–11)" after "part D"; and

(ii) in paragraph (2), by inserting "(other than section 2799A–11)" after "part D";

(B) in subsection (b)—

(i) in paragraph (1), by inserting "(other than section 2799A–11)" after "part D";

(ii) in paragraph (2)(A), by inserting "(other than section 2799A–11)" after "part D"; and

(iii) in paragraph (2)(C)(ii), by inserting "(other than section 2799A–11)" after "part D"; and

(3) in section 2799A–10 (42 U.S.C. 300gg–120), by adding at the end the following:

"(d) ENTITIES PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES.—Beginning 2 years after the date of enactment of the Pharmacy Benefit Manager Reform Act, entities providing pharmacy benefit management services shall report to plan sponsors of group health plans or group health insurance coverage information required under paragraphs (4), (5), (6), (7)(A)(iii), and (7)(B) of subsection (a).".

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(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 ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

"(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an applicable entity unless such applicable entity agrees to—

"(1) not limit the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity providing pharmacy benefit management services on behalf of a plan or issuer, from making the reports described in subsection (b); and

"(2) provide the group health plan or health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of a plan or issuer, relevant information necessary to make the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of

enactment of the Pharmacy Benefit Manager Reform Act, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a covered group health plan or group health insurance coverage (regardless of whether such coverage is covered group health insurance coverage as defined in subsection (g)(3)) shall submit to the plan sponsor of such covered group health plan or issuer of such health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor or issuer in plain language, in a machine-readable format, and, as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may determine, other formats. Each such report shall include, with respect to the covered group health plan or health insurance coverage—

"(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 such drug manufacturers with respect to the participants and beneficiaries in such plan or coverage;

"(B) a list of each drug covered by the plan, coverage, or entity providing pharmacy benefit management services for which a claim was filed during the reporting period, including, with respect to each such drug during the reporting period—

"(i) the brand name, generic or non-proprietary name, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom a claim for the drug was filed during the reporting period, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug for which a claim was filed across the reporting period;

"(iii) for each claim or dosage unit described in clause (ii), the type of dispensing channel used, such as retail, mail order, or specialty pharmacy;

"(iv) the wholesale acquisition cost, listed as cost per days' supply and cost per dosage unit;

"(v) the total out-of-pocket spending by participants and beneficiaries on such drug

after application of any benefits under the plan or coverage—

"(I) including copayments, coinsurance, and deductibles; and

"(II) not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted to the plan or coverage; and

"(vi) for each of the 50 prescription drugs with the highest gross spending under the group health plan or health insurance coverage during the reporting period—

"(I) a list of all other drugs in the same therapeutic class (as defined by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury), including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic class as such drug;

"(II) if applicable, the rationale for preferred formulary placement of such drug in that therapeutic class, se-

lected from a list of standard rationales established by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year;

"(C) a list of each therapeutic class (as defined as described in subparagraph (B)(vi)(I)) of drugs for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class of drugs, during the reporting period—

"(i) total gross spending by the plan or by the issuer offering such coverage;

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

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

"(iv) the total out-of-pocket spending by participants and beneficiaries on drugs in such therapeutic class, after application of any benefits under the plan or coverage—

"(I) including copayments, coinsurance, and deductibles; and

"(II) not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted to the plan or issuer; and

"(v) for each therapeutic 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, by such entity, from applicable entities, in rebates, fees, alternative discounts, or other remuneration—

"(aa) for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs or drug spending;

"(II) the total net spending by the plan or by the issuer with respect to

such coverage on that class of drugs; and

"(III) the average net spending per 30-day supply and per 90-day supply by the plan or by the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

"(D) total gross spending on prescription drugs by the plan or coverage during the reporting period;

"(E) the total amount received, or expected to be received, by the group health plan or health insurance issuer, from applicable entities, in rebates, fees, alternative discounts, and other remuneration received from such entities, related to utilization of drugs or drug spending under that group health plan or health insurance coverage during the reporting period;

"(F) the total net spending on prescription drugs by the group health plan or health insurance issuer with respect to the coverage during the reporting period;

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA)) to brokers, consultants, advisors, or any other individual or firm for—

"(i) referral of the group health plan's or health insurance issuer's business to the pharmacy benefit manager;

"(ii) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

"(iii) the retention of the entity by the group health plan or health insurance issuer;

"(H)(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services on behalf of such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs,

and cost-sharing assistance incentives funded by an entity providing pharmacy benefit management services;

"(ii) the percentage of total prescriptions charged to the plan, issuer, or participants and beneficiaries in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services; and

"(iii) a list of all drugs dispensed by such affiliated pharmacy or pharmacy under common ownership and charged to the plan, issuer, or participants and beneficiaries of the plan or coverage, during the applicable period, and, with respect to each drug—

"(I)(aa) the amount charged, per dosage unit, per 30-day supply, and per 90-day supply, with respect to participants and beneficiaries in the plan or coverage, to the plan or issuer; and

"(bb) the amount charged, per dosage unit, per 30-day supply, and per 90-day supply to participants and beneficiaries;

"(II) the median amount charged to the plan or issuer, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of that plan or coverage;

"(III) the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of that plan or coverage;

"(IV) the lowest cost, per dosage unit, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan and participants and beneficiaries, that is available from any pharmacy included in the network of the plan or coverage;

"(V) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if the drug is subject to a maximum price discount; and

"(VI) other information with respect to the cost of the drug, as determined by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit or per 30-day supply, for such drug, including amounts charged to the plan or issuer and participants and beneficiaries among all pharmacies included in the network of the plan or coverage;

"(I) a summary document for plan sponsors or issuers that includes the information described in subparagraphs (A) through (H) that the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury determine useful to plan sponsors and health insurance issuers for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and partici-

pant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary; and

"(J) a summary document for participants or beneficiaries, which shall be made available to participants or beneficiaries upon request to the plan sponsor, that contains the information described in subparagraphs (D) through (G) that the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury determine useful to participants or beneficiaries in better understanding their plan or benefits, except that such summary document for participants or beneficiaries shall contain only aggregate information.

"(2) REGULATIONS.—Not later than 2 years after the date of enactment of the Pharmacy Benefit Manager Reform Act, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall, through notice and comment rulemaking, promulgate final regulations to implement the requirements of this subsection. In promulgating such regulations, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall, to the extent practicable, align the re-

porting requirements under this subsection with the reporting requirements under section 725.

"(3) ADDITIONAL REPORTING.—

"(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format, and such other formats as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may specify. Each such report shall include, with respect to the applicable group health plan—

"(i) the information described in subparagraphs (D), (E), (F), and (G) of paragraph (1);

"(ii) as applicable, information collected from drug manufacturers by such plan on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by applicable drug manufacturers with respect to the participants and beneficiaries in such plan, except that such information shall not identify any drug manufacturer; and

"(iii) a summary document that includes the information described in clauses (i) and (ii) that the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury determine useful to plan sponsors for purposes of selecting pharmacy benefit management services, provided that such summary documents include only aggregate information.

"(B) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE.—

"(i) IN GENERAL.—A plan sponsor of group health insurance coverage offered in connection with a group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months

after the date of enactment of the Pharmacy Benefit Manager Reform Act, elect to require an entity providing pharmacy benefit management services on behalf of a health insurance issuer offering group health insurance coverage to submit to such plan sponsor a report in accordance with this subsection.

"(ii) CONTENTS OF REPORTS.—

"(I) COVERED GROUP HEALTH INSURANCE COVERAGE.—In the case of an entity providing pharmacy benefit management services on behalf of an issuer that offers covered group health insurance coverage, a report provided pursuant to clause (i) shall include, with respect to the applicable covered group health insurance coverage, the information required under paragraph (1) for covered group health plans.

"(II) OTHER GROUP HEALTH INSURANCE COVERAGE.—In the case of an entity providing pharmacy benefit management services on behalf of an issuer that offers group health insur-

ance coverage that is not covered group health insurance, a report provided pursuant to clause (i) shall include, with respect to the applicable group health insurance coverage—

"(aa) the information described in subparagraphs (D), (E), (F), and (G) of paragraph (1); and

"(bb) 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 applicable drug manufacturers with respect to the participants and beneficiaries in such plan, except that such information shall not identify any drug manufacturer.

"(iii) REQUIRED REPORTING FOR COVERED GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer that offers covered group health insurance cov-

erage shall annually submit to the plan sponsor the information described in paragraph (1)(I), regardless of whether the plan sponsor made the election described in clause (i) for the applicable year.

"(iv) REQUIRED REPORTING FOR OTHER GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer that offers group health insurance coverage that is not covered group health insurance shall annually submit a summary document that includes such information described in items (aa) and (bb) of clause (ii)(II) as the Secretary and the Secretary of Health and Human Services determine useful for plan sponsors for purposes of selecting pharmacy benefit management services, provided that such summary documents include only aggregate information.

"(4) PRIVACY REQUIREMENTS.—

"(A) RELATIONSHIP TO HIPAA REGULATIONS.—Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA

privacy regulations, as defined in section 1180(b)(3) of the Social Security Act (42 U.S.C. 1320d–9(b)(3)).

"(B) REQUIREMENT.—A report submitted under paragraph (1) or (3) shall contain only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

"(C) CLARIFICATION REGARDING CERTAIN DISCLOSURES OF INFORMATION.—

"(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage from placing reasonable restrictions (as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may determine) on the public disclosure of the information contained in a report under paragraph (1) or (3).

"(ii) LIMITATIONS.—A health insurance issuer offering group health insurance

coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or any other Federal agency responsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the United States in accordance with paragraph (6).

"(5) USE AND DISCLOSURE BY PLAN SPONSORS.—

"(A) PROHIBITION.—A plan sponsor may not—

"(i) fail or refuse to hire, or discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph

(1) or (3) attributed to the employee or a dependent of the employee; or

"(ii) limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any employee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of information submitted under paragraph (1) or (3) attributed to the employee or a dependent of the employee.

"(B) DISCLOSURE AND REDISCLOSURE.—A plan sponsor shall not disclose the information received under paragraph (1) or (3) except—

"(i) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations (or successor regulations);

"(ii) in response to an order of a court, except that the plan sponsor may disclose only the information expressly authorized by such order;

"(iii) to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

"(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, and as a term of the contract, to abide by the same use and disclosure restrictions as the plan sponsor.

"(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to HIPAA privacy regulations, as defined in section 1180(b)(3) of the Social Security Act (42 U.S.C. 1320d–9(b)(3)), subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2)) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

"(D) WRITTEN NOTICE.—Plan sponsors of group health plans and group health insurance coverage shall provide to each employee written notice informing the employee of the requirement for health insurance issuers or entities providing pharmacy benefit management services on behalf of the plan or coverage to submit reports to plan sponsors under paragraphs (1) and (3), as applicable, which may include incorporating such notification in plan documents provided to the employee, an employee handbook provided to the employee, or individual notification.

"(E) ENFORCEMENT.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Nondiscrimination Act (42 U.S.C. 2000ff–6) to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such indi-

vidual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

"(6) SUBMISSIONS TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan shall submit, upon request, to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (3) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (4), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

"(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall specify, through rulemaking, standard formats for entities providing pharmacy benefit management services to submit reports required under this subsection. Such secretaries may provide for separate standard formats for reports to plan sponsors of group health plans and reports to plan sponsors of group health insurance coverage offered in connection with a group health plan.

"(B) FORM OF REPORT.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall define through rulemaking a form of the reports under paragraphs (1) and (3) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in the case that such secretaries determine that changes to the standard format are necessary to prevent anticompetitive behavior.

"(c) LIMITATIONS ON SPREAD PRICING.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a group health plan or health insurance issuer offering group health insurance coverage shall ensure that the amount required to be paid by a participant or beneficiary for a prescription drug covered under the plan or coverage, and a third-party administrator or an entity providing pharmacy benefit management services on behalf of such a plan or coverage shall ensure that the total amount required to be paid by the plan or issuer and participant or beneficiary for a prescription drug covered under the plan or coverage, does not exceed the price paid to the pharmacy, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan, issuer, or entity.

"(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

"(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan, issuer, or entity.

"(B) A penalty paid if the original claim payment made by the plan, issuer, or entity to

the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan, issuer, or entity.

"(C) A penalty paid if the pharmacist services for which a claim was filed with the plan, issuer, or entity were not rendered by the pharmacy.

"(d) FULL REBATE PASS-THROUGH TO PLAN OR HEALTH INSURANCE ISSUER.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a third-party administrator of a group health plan or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage shall—

"(A) remit 100 percent of rebates, fees, alternative discounts, and other remuneration received from any applicable entity that are related to utilization of drugs under such group health plan or health insurance coverage, to the group health plan or health insurance issuer offering group health insurance coverage; and

"(B) ensure that any contract entered into, by such third-party administrator or entity providing pharmacy benefit management services on behalf of such a plan or coverage, with rebate aggregators (or other purchasing entity designed to aggregate rebates), applicable group purchasing organizations, or any subsidiary, parent, affiliate, or subcontractor of the plan, entity, rebate aggregator (or other purchasing entity designed to aggregate rebates), or applicable group purchasing organization remit 100 percent of rebates, fees, alternative discounts, and other remuneration received that are related to utilization of drugs under such group health plan or health insurance coverage, to the third-party administrator or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.—With respect to such rebates, fees, alternative discounts, and other remuneration—

"(A) the rebates, fees, alternative discounts, and other remuneration under paragraph (1)(A) shall be—

"(i) remitted—

"(I) on a quarterly basis, to the group health plan or the group health insurance issuer, not later than 90 days after the end of each quarter; or

"(II) in the case of an underpayment in a remittance for a prior quarter, as soon as practicable, but not later than 90 days after notice of the underpayment is first given;

"(ii) fully disclosed and enumerated to the group health plan or health insurance issuer, as described in paragraphs (1) and (3) of subsection (b); and

"(iii) returned to the issuer or entity providing pharmacy benefit management services on behalf of the group health plan if an audit by a plan sponsor, or a third party designated by a plan sponsor, indicates that the amounts received are incorrect after such amounts have been paid to the group health plan or health insurance issuer;

"(B) the rebates, fees, alternative discounts, and other remuneration under paragraph (1)(B) shall be remitted in accordance with such proce-

dures as the Secretary, Secretary of Health and Human Services, and Secretary of the Treasury establish; and

"(C) the records of such rebates, fees, alternative discounts, and other remuneration shall be available for audit by the plan sponsor, issuer, or a third party designated by a plan sponsor, not less than once per plan year.

"(3) AUDIT OF REBATE CONTRACTS.—A third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such group health plan or health insurance coverage shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by the plan sponsor or designated third party, subject to reasonable restrictions (as determined by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury) on confidentiality to prevent re-disclosure of such contracts.

"(4) AUDITORS.—Audits carried out under paragraphs (2)(C) and (3) shall be performed by an auditor selected by the applicable plan sponsor.

"(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to—

"(A) prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subsection, provided that such fees are transparent to group health plans and health insurance issuers;

"(B) require a third-party administrator of a group health plan or an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage to remit bona fide service fees to the group health plans or health insurance issuers; or

"(C) limit the ability of a group health plan or health insurance issuer to pass through rebates, fees, alternative discounts, and other remuneration to the participant or beneficiary.

"(e) ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary shall enforce this section.

"(2) VIOLATIONS.—A group health plan, a health insurance issuer, or an entity providing pharmacy benefit management services that violates subsection

(a); an entity providing pharmacy benefit management services that fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan, a health insurance issuer, or an entity providing pharmacy benefit management services that violates subsection (d) 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 group health plan, a health insurance issuer, an entity providing pharmacy benefit management services, or a third-party administrator 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 Secretary shall impose civil monetary penalties under this subsection in the same manner and according to the same procedures

as the Secretary imposes civil monetary penalties as described in section 502(c)(10).

"(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.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Labor, the Secretary of Health and Human Services, or the Secretary of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), (c), or (d) by such issuer, plan, or entity.

"(g) DEFINITIONS.—In this section—

"(1) the term 'applicable entity' means—

"(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

"(C) such other entity as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may specify through rulemaking;

"(2) the term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services;

"(3) the term 'covered group health insurance coverage' means health insurance coverage offered in connection with a group health plan maintained by a large employer;

"(4) the term 'covered group health plan' means a group health plan maintained by a large employer;

"(5) the term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on

prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration;

"(6) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;

"(7) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration;

"(8) the term 'plan sponsor' has the meaning given such term in section 3(16)(B);

"(9) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, through rulemaking, which shall be reevaluated by such secretaries every 5 years; and

"(10) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B))."; and

(B) in section 502(b)(3) (29 U.S.C. 1132(b)(3)), by inserting "(other than section 726)" after "part 7".

(2) CLERICAL AMENDMENT.—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 relating to section 725 the following new item:

"Sec. 726. Oversight of entities that provide pharmacy benefit management services.".

(3) ADDITIONAL REPORTING REQUIREMENT.—Section 725 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185n) is amended by adding at the end the following:

"(d) ENTITIES PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES.—Beginning 2 years after the date of enactment of the Pharmacy Benefit Manager Reform Act, entities providing pharmacy benefit management services shall report to plan sponsors of group health plans information required under paragraphs (4), (5), (6), (7)(A)(iii), and (7)(B) of subsection (a).".

(c) INTERNAL REVENUE CODE OF 1986.—

(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 ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

"(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a group health plan or an entity providing pharmacy benefit management services on behalf of such a plan shall not enter into a contract with an applicable entity unless such applicable entity agrees to—

"(1) not limit the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity providing pharmacy benefit management services on behalf of a plan, from making the reports described in subsection (b); and

"(2) provide the group health plan or an entity providing pharmacy benefit management services on behalf of a plan, relevant information necessary to make the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform

Act, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in plain language, in a machine-readable format, and, as the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services may determine, other formats. Each such report shall include, with respect to the covered 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 such drug manufacturers with respect to the participants and beneficiaries in such plan;

"(B) a list of each drug covered by the plan or entity providing pharmacy benefit management services for which a claim was filed during the reporting period, including, with respect to each such drug during the reporting period—

"(i) the brand name, generic or nonproprietary name, and National Drug Code;

"(ii) the number of participants and beneficiaries for whom a claim for the drug was filed during the reporting period, the total number of prescription claims for the drug (including original prescriptions and refills), and the total number of dosage units of the drug for which a claim was filed across the reporting period;

"(iii) for each claim or dosage unit described in clause (ii), the type of dispensing channel used, such as retail, mail order, or specialty pharmacy;

"(iv) the wholesale acquisition cost, listed as cost per days' supply and cost per dosage unit;

"(v) the total out-of-pocket spending by participants and beneficiaries on such drug after application of any benefits under the plan—

"(I) including copayments, coinsurance, and deductibles; and

"(II) not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or

for which no claim is submitted to the plan; and

"(vi) for each of the 50 prescription drugs with the highest gross spending under the group health plan during the reporting period—

"(I) a list of all other drugs in the same therapeutic class (as defined by the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services), including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic class as such drug;

"(II) if applicable, the rationale for preferred formulary placement of such drug in that therapeutic class, selected from a list of standard rationales established by the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year;

"(C) a list of each therapeutic class (as defined as described in subparagraph (B)(vi)(I)) of drugs for which a claim was filed under the group health plan during the reporting period, and, with respect to each such therapeutic class of drugs, during the reporting period—

"(i) total gross spending by the plan;

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

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

"(iv) the total out-of-pocket spending by participants and beneficiaries on drugs in such therapeutic class, after application of any benefits under the plan—

"(I) including copayments, coinsurance, and deductibles; and

"(II) not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or for which no claim is submitted to the plan; and

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

"(I) the amount received, or expected to be received, by such entity, from applicable entities, in rebates, fees, alternative discounts, or other remuneration—

"(aa) for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs or drug spending;

"(II) the total net spending by the plan on that class of drugs; and

"(III) the average net spending per 30-day supply and per 90-day supply by the plan and its participants and beneficiaries, among all drugs within the therapeutic class for

which a claim was filed during the reporting period;

"(D) total gross spending on prescription drugs by the plan during the reporting period;

"(E) the total amount received, or expected to be received, by the group health plan, from applicable entities, in rebates, fees, alternative discounts, and other remuneration received from such entities, related to utilization of drugs or drug spending under that group health plan during the reporting period;

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

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(dd)(A))) to brokers, consultants, advisors, or any other individual or firm for—

"(i) referral of the group health plan's business to the pharmacy benefit manager;

"(ii) consideration of the entity providing pharmacy benefit management services by the group health plan; or

"(iii) the retention of the entity by the group health plan;

"(H)(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services on behalf of such plan, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost-sharing assistance incentives funded by an entity providing pharmacy benefit management services;

"(ii) the percentage of total prescriptions charged to the plan or participants and beneficiaries in the plan, that were dispensed by mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services; and

"(iii) a list of all drugs dispensed by such affiliated pharmacy or pharmacy under common ownership and charged to the plan, or participants and beneficiaries of the plan, during the applicable period, and, with respect to each drug—

"(I)(aa) the amount charged, per dosage unit, per 30-day supply, and per 90-day supply, with respect to participants and beneficiaries in the plan, to the plan; and

"(bb) the amount charged, per dosage unit, per 30-day supply, and per 90-day supply to participants and beneficiaries;

"(II) the median amount charged to the plan, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of that plan;

"(III) the interquartile range of the costs, per dosage unit, per 30-day supply,

and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of that plan;

"(IV) the lowest cost, per dosage unit, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan and participants and beneficiaries, that is available from any pharmacy included in the network of the plan;

"(V) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if the drug is subject to a maximum price discount; and

"(VI) other information with respect to the cost of the drug, as determined by the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit or per 30-day supply, for such drug, including amounts

charged to the plan and participants and beneficiaries among all pharmacies included in the network of the plan;

"(I) a summary document for plan sponsors that includes the information described in subparagraphs (A) through (H) that the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services determine useful to plan sponsors for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary; and

"(J) a summary document for participants or beneficiaries, which shall be made available to participants or beneficiaries upon request to the plan sponsor, that contains the information described in subparagraphs (D) through (G) that the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services determine useful to participants or beneficiaries in better understanding their plan or benefits, except that such summary document for partici-

pants or beneficiaries shall contain only aggregate information.

"(2) REGULATIONS.—Not later than 2 years after the date of enactment of the Pharmacy Benefit Manager Reform Act, the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services shall, through notice and comment rulemaking, promulgate final regulations to implement the requirements of this subsection. In promulgating such regulations, the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services shall, to the extent practicable, align the reporting requirements under this subsection with the reporting requirements under section 9825.

"(3) ADDITIONAL REPORTING.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format, and such other formats as the Secretary, the

Secretary of Labor, and the Secretary of Health and Human Services may specify. Each such report shall include, with respect to the applicable group health plan—

"(A) the information described in subparagraphs (D), (E), (F), and (G) of paragraph (1);

"(B) as applicable, information collected from drug manufacturers by such plan on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by applicable drug manufacturers with respect to the participants and beneficiaries in such plan, except that such information shall not identify any drug manufacturer; and

"(C) a summary document that includes that information described in subparagraphs (A) and (B) that the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services determine useful for plan sponsors for purposes of selecting pharmacy benefit management services, provided that such summary documents include only aggregate information.

"(4) PRIVACY REQUIREMENTS.—

"(A) RELATIONSHIP TO HIPAA REGULATIONS.—Nothing in this section shall be con-

strued to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations, as defined in section 1180(b)(3) of the Social Security Act (42 U.S.C. 1320d–9(b)(3)).

"(B) REQUIREMENT.—A report submitted under paragraph (1) or (3) shall contain only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

"(C) CLARIFICATION REGARDING CERTAIN DISCLOSURES OF INFORMATION.—

"(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents an entity providing pharmacy benefit management services on behalf of a group health plan from placing reasonable restrictions (as the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services may determine) on the public disclosure of the information contained in a report under paragraph (1) or (3).

"(ii) LIMITATIONS.—An entity providing pharmacy benefit management serv-

ices on behalf of a group health plan may not restrict disclosure of such reports to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or any other Federal agency responsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the United States in accordance with paragraph (6).

"(5) USE AND DISCLOSURE BY PLAN SPONSORS.—

"(A) PROHIBITION.—A plan sponsor may not—

"(i) fail or refuse to hire, or discharge, any employee, or otherwise discriminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph (1) or (3) attributed to the employee or a dependent of the employee; or

"(ii) limit, segregate, or classify the employees of the employer in any way that would deprive or tend to deprive any em-

ployee of employment opportunities or otherwise adversely affect the status of the employee as an employee, because of information submitted under paragraph (1) or (3) attributed to the employee or a dependent of the employee.

"(B) DISCLOSURE AND REDISCLOSURE.—A plan sponsor shall not disclose the information received under paragraph (1) or (3) except—

"(i) to an occupational or other health researcher if the research is conducted in compliance with the regulations and protections provided for under part 46 of title 45, Code of Federal Regulations (or successor regulations);

"(ii) in response to an order of a court, except that the plan sponsor may disclose only the information expressly authorized by such order;

"(iii) to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

"(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, and as a term of the contract, to abide by the same use and disclosure restrictions as the plan sponsor.

"(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to the HIPAA privacy regulations, as defined in section 1180(b)(3) of the Social Security Act (42 U.S.C. 1320d–9(b)(3)), subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations promulgated under section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2)) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

"(D) WRITTEN NOTICE.—Plan sponsors of group health plans shall provide to each employee written notice informing the employee of the requirement for entities providing pharmacy benefit management services to submit reports to plan sponsors under paragraphs (1) and (3), as

applicable, which may include incorporating such notification in plan documents provided to the employee, an employee handbook provided to the employee, or individual notification.

"(E) ENFORCEMENT.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Nondiscrimination Act (42 U.S.C. 2000ff–6) to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved

individuals with respect to violations of this clause.

"(6) SUBMISSIONS TO GAO.—An entity providing pharmacy benefit management services on behalf of a group health plan shall submit, upon request, to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (3) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (4), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

"(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall specify, through rulemaking, standard formats for entities providing pharmacy benefit management services to submit reports required under this subsection. Such secretaries may provide for separate standard formats for reports to plan sponsors of group health plans and reports to plan sponsors of group health insurance cov-

erage offered in connection with a group health plan.

"(B) FORM.—The Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall define through rulemaking a form of the reports under paragraphs (1) and (3) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in the case that such secretaries determine that changes to the standard format are necessary to prevent anticompetitive behavior.

"(c) LIMITATIONS ON SPREAD PRICING.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a group health plan shall ensure that the amount required to be paid by a participant or beneficiary for a prescription drug covered under the plan, and a third-party administrator or an entity providing pharmacy benefit management services on behalf of such a plan shall ensure that the total amount required to be paid by the plan and participant or ben-

eficiary for a prescription drug covered under the plan, does not exceed the price paid to the pharmacy, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan or entity.

"(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

"(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan or entity.

"(B) A penalty paid if the original claim payment made by the plan or entity to the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan or entity.

"(C) A penalty paid if the pharmacist services for which a claim was filed with the plan or entity were not rendered by the pharmacy.

"(d) FULL REBATE PASS-THROUGH TO PLAN.—

"(1) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of the Pharmacy Benefit Manager Reform Act, a third-party administrator of a group health plan or an entity providing pharmacy benefit man-

agement services on behalf of a group health plan shall—

"(A) remit 100 percent of rebates, fees, alternative discounts, and other remuneration received from any applicable entity that are related to utilization of drugs under such plan, to the group health plan; and

"(B) ensure that any contract entered into, by such third-party administrator or entity providing pharmacy benefit management services on behalf of such a plan, with rebate aggregators (or other purchasing entity designed to aggregate rebates), applicable group purchasing organizations, or any subsidiary, parent, affiliate, or subcontractor of the plan, entity, rebate aggregator (or other purchasing entity designed to aggregate rebates), or applicable group purchasing organization remit 100 percent of rebates, fees, alternative discounts, and other remuneration received that are related to utilization of drugs under such plan, to the third-party administrator or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.—With respect to such rebates, fees, alternative discounts, and other remuneration—

"(A) the rebates, fees, alternative discounts, and other remuneration under paragraph (1)(A) shall be—

"(i) remitted—

"(I) on a quarterly basis, to the group health plan, not later than 90 days after the end of each quarter; or

"(II) in the case of an underpayment in a remittance for a prior quarter, as soon as practicable, but not later than 90 days after notice of the underpayment is first given;

"(ii) fully disclosed and enumerated to the group health plan, as described in paragraphs (1) and (3) of subsection (b); and

"(iii) returned to the entity providing pharmacy benefit management services on behalf of the group health plan if an audit by a plan sponsor, or a third party designated by a plan sponsor, indicates that the amounts received are incorrect after

such amounts have been paid to the group health plan;

"(B) the rebates, fees, alternative discounts, and other remuneration under paragraph (1)(B) shall be remitted in accordance with such procedures as the Secretary, Secretary of Health and Human Services, and Secretary of Labor establish; and

"(C) the records of such rebates, fees, alternative discounts, and other remuneration shall be available for audit by the plan sponsor, or a third party designated by a plan sponsor, not less than once per plan year.

"(3) AUDIT OF REBATE CONTRACTS.—A third-party administrator of a group health plan or an entity providing pharmacy benefit management services on behalf of such group health plan shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by the plan sponsor or designated third party, subject to reasonable restrictions (as determined by the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services) on confidentiality to prevent re-disclosure of such contracts.

"(4) AUDITORS.—Audits carried out under paragraphs (2)(C) and (3) shall be performed by an auditor selected by the applicable plan sponsor.

"(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to—

"(A) prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not described in this subsection, provided that such fees are transparent to group health plans;

"(B) require a third-party administrator of a group health plan or an entity providing pharmacy benefit management services on behalf of a group health plan to remit bona fide service fees to plan sponsors of the group health plan; or

"(C) limit the ability of a group health plan to pass through rebates, fees, alternative discounts, and other remuneration to the participant or beneficiary.

"(e) ENFORCEMENT.—

"(1) IN GENERAL.—The Secretary shall enforce this section.

"(2) VIOLATIONS.—A group health plan or an entity providing pharmacy benefit management services that violates subsection (a); an entity providing

pharmacy benefit management services that fails to provide information required under subsection (b); a group health plan or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan or an entity providing pharmacy benefit management services that violates subsection (d) 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 group health plan, an entity providing pharmacy benefit management services, or a third-party administrator 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.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a group health plan, entity providing pharmacy benefit management services on behalf of a group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), (c), or (d) by such plan or entity.

"(g) DEFINITIONS.—In this section—

"(1) the term 'applicable entity' means—

"(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a

plan or issuer, or any entity described in subparagraph (A); or

"(C) such other entity as the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor may specify through rulemaking;

"(2) the term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services;

"(3) the term 'covered group health plan' means a group health plan maintained by a large employer;

"(4) the term 'gross spending', with respect to prescription drug benefits under a group health plan, means the amount spent by a group health plan on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration;

"(5) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and

who employs at least 1 employee on the first day of the plan year;

"(6) the term 'net spending', with respect to prescription drug benefits under a group health plan, means the amount spent by a group health plan on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration;

"(7) the term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(B));

"(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, through rulemaking, which shall be reevaluated by such secretaries every 5 years; and

"(9) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).".

(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 entities that provide pharmacy benefit management services.".

(3) ADDITIONAL REPORTING REQUIREMENT.—Section 9825 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(d) ENTITIES PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES.—Beginning 2 years after the date of enactment of the Pharmacy Benefit Manager Reform Act, entities providing pharmacy benefit management services shall report to plan sponsors of group health plans information required under paragraphs (4), (5), (6), (7)(A)(iii), and (7)(B) of subsection (a).".

(d) FUNDING.—

(1) For purposes of carrying out the amendments made by subsection (a) there is appropriated to the Centers for Medicare & Medicaid Services, out of amounts in the Treasury not otherwise appropriated, $40,000,000 for fiscal year 2023, to remain available until expended.

(2) For purposes of carrying out the amendments made by subsection (b), there is appropriated to the Department of Labor, out of amounts in the Treasury not otherwise appropriated, $4,500,000 for fiscal year 2023, to remain available until expended.

(e) ASPE STUDY.—The Assistant Secretary for Planning and Evaluation of the Department of Health and

Human Services shall conduct or commission a study on how the United States health care market would be impacted by potential regulatory changes disallowing manufacturer rebates in the manner and to the extent allowed on the date of enactment of this Act, with a focus on the impact to stakeholders in the commercial insurance market, and, not later than 1 year after the date of enactment of this Act, submit a report to Congress on the results of such study. Such study and report shall consider the following:

(1) The impact of making no such regulatory changes, as well as potential behavioral changes by plan sponsors, members, and pharmaceutical manufacturers, such as tighter formularies, changes to price concessions, or changes in utilization, if such regulatory changes are made.

(2) The mechanics needed in the pharmaceutical supply chain (whether existing or not) to move a manufacturer rebate to the point of sale.

(3) The feasibility of a partial point-of-sale manufacturer rebate versus a full point-of-sale manufacturer rebate.

(4) The impact on patient out-of-pocket costs, premiums, and other cost-sharing.

(5) Possible behavioral changes by other third parties in the pharmaceutical supply chain including

drug manufacturers, distributors, wholesalers, rebate aggregators, pharmacy services administrative organizations, or group purchasing organizations.

(6) Behavioral changes between entities that contract with pharmaceutical manufacturers and entities that participate in the pharmaceutical supply chain.

(7) Alternative price negotiation mechanisms, including the impact of the Act of June 19, 1936 (commonly known as the "Robinson–Patman Act"; 49 Stat. 1526, chapter 592; 15 U.S.C. 13a et seq.), and the amendments made by that Act, on drug pricing negotiations.

(8) The impact on pharmacies, including pharmacy rebates, pharmacy fees, and dispensing channels.

(9) The impact of manufacturer rebates on getting insulin products to market, and the market dynamics and extent to which biosimilar biological product development and competition could increase, or is increasing, the number of biological products approved and available to patients, including by examining barriers to—

(A) placement of biosimilar biological products on health insurance formularies;

(B) market entry of insulin products in the United States, as compared to other highly developed nations; and

(C) patient and provider education around biosimilar biological products.

(f) GAO STUDY.—

(1) IN GENERAL.—Not later than January 1, 2029, the Comptroller General of the United States shall report to Congress on—

(A) pharmacy networks of a selection of group health plans, health insurance issuers, and entities providing pharmacy benefit management services on behalf of such group health plan or group or individual health insurance coverage, including networks that have pharmacies that are affiliated with or in common ownership with group health plans, health insurance issuers, or entities providing pharmacy benefit management services or pharmacy benefit administrative services under group health plan or group or individual health insurance coverage;

(B) as it relates to pharmacy networks that include pharmacies affiliated with or in common ownership with plans, issuers, or entities, as described in subparagraph (A)—

(i) whether such networks are designed to encourage participants and beneficiaries 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 participants and beneficiaries disproportionately more in the aggregate or for specific drugs compared to other network pharmacies;

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

(D) pharmacy network design parameters that encourage participants and beneficiaries 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) for a selection of plans and issuers, the degree to which mail order, specialty, or retail pharmacies that dispense prescription drugs to participants and beneficiaries in a group health plan or group health insurance coverage that are affiliated with or in common ownership with group health plans, health insurance issuers, or entities providing pharmacy benefit management services or pharmacy benefit administrative services under a group health plan or group 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 participants and beneficiaries in the plan or coverage by other pharmacies included in the pharmacy network of that plan or issuer that are not affiliated with or in common ownership with the health insurance issuer or entity providing pharmacy benefit management services.

(2) REQUIREMENT.—In carrying out paragraph (1), the Comptroller General of the United States shall not disclose—

(A) information that would allow for identification of a specific individual, plan sponsor, health insurance issuer, group health plan, or entity providing pharmacy benefit management services; or

(B) 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).

SEC. 3. REPORTING ON JUSTIFICATION FOR DRUG PRICE INCREASES.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART W—DRUG PRICE REPORTING; DRUG VALUE FUND

"SEC. 399OO. REPORTING ON JUSTIFICATION FOR DRUG PRICE INCREASES.

"(a) DEFINITIONS.—In this section:

"(1) MANUFACTURER.—The term 'manufacturer' means the person—

"(A) that holds the application for a drug approved under section 505 of the Federal Food,

Drug, and Cosmetic Act or the license issued under section 351 of this Act; or

"(B) who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

"(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of this Act—

"(A) that has a wholesale acquisition cost of $100 or more per month supply, or per a course of treatment that lasts less than a month, and is—

"(i) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;

"(ii) not a vaccine; and

"(iii) not an antibiotic; and

"(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales was for individuals enrolled under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) or under a State Medicaid plan under title XIX of

such Act (42 U.S.C. 1396 et seq.) or under a waiver of such plan.

"(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).

"(b) REPORT.—

"(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary for each planned increase in price of a qualifying drug that will result in an increase in the wholesale acquisition cost of that drug that is equal to—

"(A) 10 percent or more over a 12-month period; or

"(B) 25 percent or more over a 36-month period.

"(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary not later than 30 days prior to the effective date of such planned increase in price.

"(c) CONTENTS.—A report under subsection (b) shall, at a minimum, include—

"(1) with respect to the qualifying drug—

"(A) the percentage by which the manufacturer will raise the wholesale acquisition cost of the drug on the planned effective date of such planned increase in price;

"(B) a justification for, and description of, each manufacturer's planned increase in price that will occur during the 12-month period described in subsection (b)(1)(A) or the 36-month period described in subsection (b)(1)(B), as applicable, that shall be accompanied by information to substantiate the basis for the justification and a certification that, to the manufacturer's knowledge and belief, the justification is truthful and nonmisleading and does not describe uses of the drug beyond those listed as an indication or use in its approved labeling;

"(C) the identity of the initial developer of the drug, if applicable;

"(D) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the man-

ufacturer acquired such approved application or license, as applicable;

"(E) the current wholesale acquisition cost of the drug;

"(F) the total expenditures of the manufacturer for the 3 years preceding the planned increase in price on—

"(i) materials and manufacturing for such drug; and

"(ii) acquiring patents and licensing for such drug;

"(G) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

"(H) the total expenditures of the manufacturer on research and development, for the 3 years preceding the planned increase in price for such drug, that is necessary to demonstrate that it meets applicable standards for approval under section 505 of the Federal Food, Drug, and Cosmetic Act or licensure under such section 351, as applicable;

"(I) the total expenditures of the manufacturer on research and development for such drug

that is pursuing new or expanded indications for such drug through supplemental applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of this Act;

"(J) the total expenditures of the manufacturer on research and development for such drug that is carrying out postmarket requirements related to such drug, including those under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

"(K) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351, or since the manufacturer acquired such approved application or license; and

"(L) the total costs associated with marketing and advertising for the qualifying drug;

"(2) with respect to the manufacturer—

"(A) the total revenue and the net profit of the manufacturer—

"(i) for the 12-month period preceding the date of the report, in the case of a report

based on an increase described in subsection (b)(1)(A);

"(ii) for the 36-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(B);

"(B) all stock-based performance metrics used by the manufacturer to determine executive compensation—

"(i) for the 12-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(A); or

"(ii) for the 36-month period preceding the date of the report, in the case of a report based on an increase described in subsection (b)(1)(B); and

"(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

"(i) drug research and development; or

"(ii) clinical trials on drugs, conducted with the intent of using the data to support approval of an application under section 505(b) of the Federal Food, Drug, and Cos-

metic Act or section 351(a), but for which such application was not submitted or filed, or failed to receive approval by the Food and Drug Administration; and

"(3) such other related information as the Secretary considers appropriate, as specified through notice and comment rulemaking.

"(d) CIVIL MONEY PENALTY.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, or knowingly provides false information, shall be subject to a civil money penalty of $100,000 for each day on which the violation continues.

"(e) PUBLIC POSTING.—

"(1) IN GENERAL.—Subject to paragraph (3), not later than 30 days after the submission of a report under subsection (b), the Secretary shall post the report on the public website of the Department of Health and Human Services, accompanied by language indicating that such public posting does not represent an endorsement or validation of the report's content by the Secretary.

"(2) FORMAT.—In developing the format of such report for public posting, the Secretary shall consult stakeholders, including beneficiary groups, and shall seek feedback on the content and format from con-

sumer advocates and readability experts to ensure such public reports are user-friendly to the public and are written in plain language that consumers can readily understand.

''(3) TRADE SECRETS AND CONFIDENTIAL INFORMATION.—This section does not authorize the disclosure of confidential commercial information or trade secrets.''.

''SEC. 399OO–1. USE OF CIVIL PENALTY AMOUNTS.

''The Secretary shall, without further appropriation, collect civil penalties under section 399OO and use the funds derived from such civil penalties, in addition to any other amounts available to the Secretary, to carry out activities described in this part and to improve consumer and provider information about drug value and drug price transparency.

''SEC. 399OO–2. ANNUAL REPORT TO CONGRESS.

''(a) IN GENERAL.—Subject to subsection (b), the Secretary shall submit to Congress, and post on the public website of the Department of Health and Human Services in a way that is easy to find, use, and understand, an annual report—

''(1) summarizing the information reported pursuant to section 399OO; and

"(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to section 399OO.

"(b) TRADE SECRETS AND CONFIDENTIAL INFORMATION.— This section does not authorize the disclosure of confidential commercial information or trade secrets.".

SEC. 4. STUDY ON FIDUCIARY DUTIES OF PHARMACY BENEFIT MANAGERS.

(a) IN GENERAL.—The Secretary of Labor shall conduct, and submit to Congress a report describing the results of, a study on the impacts of a change in policy described in subsection (b).

(b) POLICY DESCRIBED.—Under a policy referred to in subsection (a)—

(1) an entity providing pharmacy benefit management services would be considered a fiduciary within the meaning of section 3(21) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(21)) with respect to a group health plan or group health insurance coverage; and

(2) such an entity would—

(A) be subject to the responsibilities, obligations, and duties imposed on fiduciaries under part 4 of subtitle B of title I of such Act (29 U.S.C. 1101 et seq.); and

(B) make the required fiduciary disclosure under section 408(b)(2)(B)(iii) of such Act (29 U.S.C. 1108(b)(2)(B)(iii)) with respect to the pharmacy benefit management services provided to the plan or coverage.

(c) DEFINITION OF PHARMACY BENEFIT MANAGEMENT SERVICES.—In this section, the term "pharmacy benefit management services" means services related to—

(1) negotiating prices with respect to prescription drugs on behalf of a group health plan or health insurance issuer offering group health insurance coverage; and

(2) managing the prescription drug benefits provided by such plan or coverage, including designing and implementing a drug formulary, 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.

SEC. 5. CLARIFICATION OF REQUIREMENT TO DISCLOSE DIRECT AND INDIRECT COMPENSATION FOR BROKERS AND CONSULTANTS TO EMPLOYER-SPONSORED HEALTH PLANS.

(a) IN GENERAL.—Section 408(b)(2)(B)(ii)(I)(bb) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(I)(bb)) is amended by adding at the end the following:

"(CC) Pharmacy benefit management services provided by pharmacy benefit managers or other service providers and related services provided by third-party administrators (or other entities providing such services) for which the covered service provider, an affiliate, or a subcontractor reasonably expects to receive indirect compensation or direct compensation described in item (dd).".

(b) REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary of Labor shall promulgate regulations, through notice and comment rulemaking, clarifying the requirements of section 408(b)(2)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)) with respect to covered service providers providing services described in subitem (CC) of subclause (I)(bb) of such section, as amended by subsection (a). Such regulations shall apply with respect to any plan

year that begins on or after the date that is 6 months after such regulations are promulgated.

(c) SENSE OF CONGRESS.—It is the sense of Congress that the amendment made by subsection (a) clarifies the existing requirement of covered service providers with respect to services described in section 408(b)(2)(B)(ii)(I)(bb)(BB) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(I)(bb)(BB)) that were in effect since the application date described in section 202(e) of the No Surprises Act (Public Law 116–260; 29 U.S.C. 1108 note), and does not impose any additional requirement under section 408(b)(2)(B) of such Act.

SEC. 6. STUDY ON NALOXONE ACCESS.

(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study on actions that may be taken to ensure appropriate access and affordability of naloxone for individuals seeking to purchase naloxone. Such study shall address what is known about—

(1) coverage of naloxone (in any available form), including whether naloxone can be covered as an over-the-counter drug under a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91));

(2) the out-of-pocket cost to consumers purchasing naloxone—

(A) with a prescription, with and without coverage under any such plan or coverage; and

(B) over the counter, with and without coverage under any such plan or coverage; and

(3) other factors impacting coverage, including barriers in covering naloxone as an over-the-counter drug, the relative net costs of naloxone when purchased over the counter without insurance coverage compared to when purchased with a prescription and covered under a group health plan or health insurance coverage, and the availability of naloxone purchased and distributed through public health entities.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that contains the findings of the study conducted under subsection (a).

SEC. 7. PROHIBITION ON BLOCKING CONSUMER DECISION-SUPPORT TOOLS.

(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 2, is further amended by adding at the end the following:

"SEC. 2799A–12. PROHIBITION ON BLOCKING CONSUMER DECISION-SUPPORT TOOLS.

"(a) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not enter into a contract with an entity that provides pharmacy benefit management services with respect to such plan or coverage if such contract includes any terms, conditions, or costs that would prevent or restrict a covered third party from accessing or using information, for purposes of the consumer decision-support tool, relevant to the operability, implementation, and utilization of the consumer-decision support tool regarding prescription drug benefits under the plan or coverage that are administered by the entity providing pharmacy benefit management services in contract with the plan or issuer.

"(b) DEFINITIONS.—In this section:

"(1) CONSUMER DECISION-SUPPORT TOOL.—The term 'consumer decision-support tool' means a tool designed to inform enrollees in a group health plan or health insurance coverage about all costs to the enrollee for prescription drugs covered by the plan or coverage, including out-of-pocket, copayment, and coinsurance responsibility, as well as means for reducing the cost to the enrollee, such as manufacturer copayment assistance, purchasing at the cash price, and purchasing through mail order pharmacy benefits.

"(2) COVERED THIRD PARTY.—The term 'covered third party' means a third party that is in contract, as a business associate (as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations)), with a group health plan or a health insurance issuer offering group or individual health insurance coverage to provide a consumer decision-support tool.

"(c) RULES OF CONSTRUCTION REGARDING PRIVACY.—

"(1) Nothing in this section shall be construed to alter existing obligations of a covered entity or business associate under the privacy, security, and breach notification regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

"(2) Nothing in this section shall be construed to require a group health plan, a health insurance issuer offering group or individual health insurance coverage, or an entity providing pharmacy benefit management services to share protected health information, as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), with a covered third party.".

(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 2, is further amended by adding at the end the following:

"SEC. 727. PROHIBITION ON BLOCKING CONSUMER DECISION-SUPPORT TOOLS.

"(a) IN GENERAL.—A group health plan or a health insurance issuer offering group health insurance coverage shall not enter into a contract with an entity that provides pharmacy benefit management services with respect to such plan or coverage if such contract includes any terms, conditions, or costs that would prevent or restrict a covered third party from accessing or using information, for purposes of the consumer decision-support tool, relevant to the operability, implementation, and utilization of the consumer-decision support tool regarding prescription drug benefits under the plan or coverage that are administered by the entity providing pharmacy benefit management services in contract with the plan or issuer.

"(b) DEFINITIONS.—In this section:

"(1) CONSUMER DECISION-SUPPORT TOOL.—The term 'consumer decision-support tool' means a tool designed to inform participants and beneficiaries in a group health plan or health insurance coverage

about all costs to the participant or beneficiary for prescription drugs covered by the plan or coverage, including out-of-pocket, copayment, and coinsurance responsibility, as well as means for reducing the cost to the participant or beneficiary, such as manufacturer copayment assistance, purchasing at the cash price, and purchasing through mail order pharmacy benefits.

"(2) COVERED THIRD PARTY.—The term 'covered third party' means a third party that is in contract, as a business associate (as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations)), with a group health plan or a health insurance issuer offering group health insurance coverage to provide a consumer decision-support tool.

"(c) RULES OF CONSTRUCTION.—

"(1) Nothing in this section shall be construed to alter existing obligations of a covered entity or business associate under the privacy, security, and breach notification regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

"(2) Nothing in this section shall be construed to require a group health plan, a health insurance issuer offering group health insurance coverage, or an entity

providing pharmacy benefit management services to share protected health information, as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), with a covered third party.".

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.), as amended by section 2, is further amended by inserting after the item relating to section 726 the following:

"Sec. 727. Prohibition on blocking consumer decision-support tools.".

(c) INTERNAL REVENUE CODE.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 2, is further amended by adding at the end the following new section:

"SEC. 9827. PROHIBITION ON BLOCKING CONSUMER DECISION-SUPPORT TOOLS.

"(a) IN GENERAL.—A group health plan offering group health insurance coverage shall not enter into a contract with an entity that provides pharmacy benefit management services with respect to such plan if such contract includes any terms, conditions, or costs that would prevent or restrict a covered third party from accessing or using information, for purposes of the consumer decision-support

tool, relevant to the operability, implementation, and utilization of the consumer-decision support tool regarding prescription drug benefits under the plan that are administered by the entity providing pharmacy benefit management services in contract with the plan.

"(b) DEFINITIONS.—In this section:

"(1) CONSUMER DECISION-SUPPORT TOOL.—The term 'consumer decision-support tool' means a tool designed to inform participants and beneficiaries in a group health plan about all costs to the participant or beneficiary for prescription drugs covered by the plan, including out-of-pocket, copayment, and coinsurance responsibility, as well as means for reducing the cost to the participant or beneficiary, such as manufacturer copayment assistance, purchasing at the cash price, and purchasing through mail order pharmacy benefits.

"(2) COVERED THIRD PARTY.—The term 'covered third party' means a third party that is in contract, as a business associate (as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations)), with a group health plan or a health insurance issuer offering group health insurance coverage to provide a consumer decision-support tool.

"(c) RULES OF CONSTRUCTION.—

"(1) Nothing in this section shall be construed to alter existing obligations of a covered entity or business associate under the privacy, security, and breach notification regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

"(2) Nothing in this section shall be construed to require a group health plan or an entity providing pharmacy benefit management services to share protected health information, as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), with a covered third party.".

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

"Sec. 9827. Prohibition on blocking consumer decision-support tools.".

(d) APPLICATION.—The amendments made by subsections (a), (b), and (c) shall apply with respect to plan years beginning on or after the date that is 2 years after the date of enactment of this Act.

(e) REGULATIONS.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall jointly promulgate regulations to carry out the amendments made by subsections (a), (b), and

(c), and shall issue draft regulations not later than 1 year after the date of enactment of this Act.

SEC. 8. REQUIREMENT TO PROVIDE HEALTH CLAIMS, NETWORK, AND COST INFORMATION.

(a) IN GENERAL.—Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended by inserting after section 2715A the following:

"SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS, NETWORK, AND COST INFORMATION.

"(a) IN GENERAL.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall make available for access, exchange, and use without special effort, through application programming interfaces (or successor technology or standards), consistent with standards and implementation specifications adopted under section 3004, the information described in subsection (b), in the manner described in subsection (b), as applicable, and otherwise consistent with this section.

"(b) ELECTRONIC INFORMATION.—The following electronic information is required to be made available, as the Secretary may specify:

"(1) Historical claims, provider encounter, and payment data for each enrollee, which—

"(A) may include adjudicated medical and prescription drug claims and equivalent encoun-

ters, including all data elements contained in such transactions—

"(i) that were adjudicated by the group health plan or health insurance issuer during the previous 5 years or the enrollee's entire period of enrollment in the applicable plan or coverage if such period is less than the previous 5 years;

"(ii) that involve benefits managed by any third party, such as a pharmacy benefits manager or radiology benefits manager that manages benefits or adjudicates claims on behalf of the plan or coverage; and

"(iii) from any other group health plan or health insurance coverage offered by the same insurance issuer, in which the same enrollee was enrolled during the previous 5 years; and

"(B) shall be available to an enrollee or former enrollee, the enrollee's providers, and any third-party applications or services authorized by the enrollee—

"(i) through the application programming interfaces (or successor technology or standards) consistent with standards and

specifications adopted under section 3004, in a single, longitudinal format that is easy to understand, secure, and that may update automatically;

"(ii) as soon as practicable, and in no case later than the period of time determined by the Secretary, after the claim is adjudicated or the data is received by the group health plan or health insurance issuer; and

"(iii) for a period of 5 years after the end date of the enrollee's enrollment in the plan or in any coverage offered by the health insurance issuer.

"(2) Identifying directory information for all in-network providers, including facilities and practitioners, that participate in the plan or coverage, which shall—

"(A) include—

"(i) the national provider identifier for in-network facilities and practitioners; and

"(ii) the name, address, phone number, and specialty for each such facility and practitioner, within a timeframe determined by the Secretary, from when the plan

or coverage receives provider directory information or updates from that facility or practitioner;

"(B) be capable of returning the information necessary to establish a list of participating in-network facilities and practitioners, in a given specialty or at a particular facility type, within a specified geographic radius; and

"(C) be capable of returning the network status, when presented with identifiers for a given enrollee and facility or practitioner.

"(3) Estimated enrollee out-of-pocket costs, including costs expected to be incurred through a deductible, co-payment, coinsurance, or other form of cost-sharing, for—

"(A) a designated set of common services or episodes of care, to be established by the Secretary through rulemaking, including, at a minimum—

"(i) in the case of services provided by a hospital, the 100 most common diagnosis-related groups, as used in the Medicare Inpatient Prospective Patient System (or successor episode-based reimbursement methodology) at that hospital, based on claims

data adjudicated by the group health plan or health insurance issuer;

"(ii) in the case of services provided in an out-patient setting, including radiology, lab tests, and out-patient surgical procedures, any service rendered by the facility or practitioner, and reimbursed by the group health plan or health insurance issuer; and

"(iii) in the case of post-acute care, including home health providers, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals, the patient out-of-pocket costs for an episode of care, as the Secretary may determine, which permits users to reasonably compare costs across different facility and service types; and

"(B) all prescription drugs currently included on any tier of the formulary of the plan or coverage.

"(c) AVAILABILITY AND ACCESS.—Subject to all applicable Federal and State privacy, security, and breach notification laws, and within a timeframe determined by the Secretary, the application programming interfaces (or suc-

cessor technology or standards), including all data required to be made available through such interfaces, shall—

"(1) be made available by the applicable group health plan or health insurance issuer, at no charge, to—

"(A) enrollees and prospective enrollees in the group health plan or health insurance coverage;

"(B) third parties authorized by the enrollee;

"(C) facilities and practitioners who are under contract with the plan or coverage; and

"(D) business associates of such facilities and practitioners, as defined in section 160.103 of title 45, Code of Federal Regulations (or any successor regulations);

"(2) be available to enrollees in the group health plan or health insurance coverage, and to third-party applications or services facilitating such access by enrollees, during the enrollment process and for a minimum of 5 years after the end date of the enrollee's enrollment in the plan or in any coverage offered by the health insurance issuer;

"(3) permit persistent access by third-party applications or services authorized by the enrollee, for a reasonable period of time;

"(4) employ the applicable content, vocabulary, and technical standards, as determined by the Secretary pursuant to title XXX; and

"(5) employ security and authentication standards, as the Secretary determines appropriate.

"(d) DENIAL OR DISCONTINUANCE OF ACCESS.—A group health plan or health insurance issuer offering group or individual health insurance coverage may deny access or discontinue access of the application programming interfaces (or successor technology or standards) to third-party applications or services on the basis of reasonable privacy or security concerns, as determined by the Secretary, including at the request of the enrollee.

"(e) NOTIFICATION.—When obtaining enrollee authorization to share information with a third party under this section, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall include a notification for the enrollee that information shared with a third party that is not a covered entity or business associate is not subject to the privacy, security, or breach notification rules under parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

"(f) RULE OF CONSTRUCTION REGARDING PRIVACY.—Nothing in this section shall be construed to alter existing obligations of a covered entity or business associate under the privacy, security, and breach notification rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act or section 13402 of the HITECH Act, or to alter the Secretary's existing authority to modify such rules, under part 2 of title 42, Code of Federal Regulations (or successor regulations), under section 444 of the General Education Provisions Act (20 U.S.C. 1232g) (commonly referred to as the 'Family Educational Rights and Privacy Act of 1974'), under the amendments made by the Genetic Information Nondiscrimination Act, or under State privacy law.".

(b) EFFECTIVE DATE.—Section 2715B of the Public Health Service Act, as added by subsection (a), shall take effect 18 months after the date of enactment of this Act.

SEC. 9. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.

(a) SHORT TITLE.—This section may be cited as the "Safe Step Act".

(b) REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.—The Employee Retirement Income Security Act of 1974 is amended by inserting

after section 713 of such Act (29 U.S.C. 1185b) the following new section:

"SEC. 713A. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION STEP THERAPY PROTOCOLS.

"(a) IN GENERAL.—In the case of a group health plan or health insurance issuer offering coverage offered in connection with such a plan that provides coverage of a prescription drug pursuant to a medication step therapy protocol, the plan or issuer shall—

"(1) implement a clear, prompt, and transparent process for a participant or beneficiary (or the prescribing health care provider (referred to in this section as the 'prescriber') on behalf of the participant or beneficiary) to request an exception to such medication step therapy protocol, pursuant to subsection (b); and

"(2) where the participant or beneficiary or prescriber's request for an exception to the medication step therapy protocols satisfies the criteria and requirements of subsection (b), cover the requested drug in accordance with the terms established by the plan or coverage for patient cost-sharing rates or amounts at the beginning of the plan year.

"(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—The circumstances requiring an exception to a medication

step therapy protocol, pursuant to a request under subsection (a), are any of the following:

"(1) Any treatments otherwise required under the protocol, or treatments in the same pharmacological class or having the same mechanism of action, including treatments provided prior to the effective date of the participant's or beneficiary's coverage under the plan or coverage, have been ineffective in the treatment of the disease or condition of the participant or beneficiary, when prescribed consistent with clinical indications, clinical guidelines, or other peer-reviewed evidence, based on the prescribing health care professional's judgement or relevant information provided by the participant or beneficiary (including the medical records of the participant or beneficiary).

"(2) Delay of effective treatment would lead to severe or irreversible consequences, or worsen disease progression or a comorbidity and the treatment otherwise required under the protocol is reasonably expected by the prescriber to be ineffective based upon the documented physical or mental characteristics of the participant or beneficiary and the known characteristics of such treatment.

"(3) Any treatments otherwise required under the protocol are contraindicated for the participant or

beneficiary or have caused, or are likely to cause, based on clinical, peer-reviewed evidence, an adverse reaction or other physical or mental harm to the participant or beneficiary.

"(4) Any treatment otherwise required under the protocol has prevented, will prevent, or is likely to prevent a participant or beneficiary from achieving or maintaining reasonable and safe functional ability in performing occupational responsibilities or activities of daily living (as defined in section 441.505 of title 42, Code of Federal Regulations (or successor regulations)).

"(5) The participant or beneficiary is stable for his or her disease or condition on the prescription drug or drugs selected by the prescriber and has previously received approval for coverage of the relevant drug or drugs for the disease or condition by any public or private health plan.

"(6) Other circumstances, as determined by the Secretary.

"(c) REQUIREMENT OF A CLEAR PROCESS.—

"(1) IN GENERAL.—The process required by subsection (a) shall—

"(A) provide the prescriber or participant or beneficiary an opportunity to present such

prescriber's clinical rationale and relevant medical information for the group health plan or health insurance issuer to evaluate such request for exception;

"(B) develop and use a standard form and instructions for the request of an exception under subsection (b), available in paper and electronic forms, and allow for submission of such form by paper and electronic means;

"(C) provide both paper and electronic means for the submission of requests for additional information;

"(D) clearly set forth all required information and the specific criteria that will be used to determine whether an exception is warranted, which may require disclosure of—

"(i) the medical history or other health records of the participant or beneficiary demonstrating that the participant or beneficiary seeking an exception—

"(I) has tried other drugs included in the drug therapy class without success; or

"(II) has taken the requested drug for a clinically appropriate amount of

time to establish stability, in relation to the condition being treated and prescription guidelines given by the prescribing physician; or

"(ii) other clinical information that may be relevant to conducting the exception review;

"(E) not require the submission of any information or supporting documentation beyond what is strictly necessary (as determined by the Secretary) to determine whether a circumstance listed in subsection (b) exists;

"(F) clearly outline conditions under which an exception request warrants expedited resolution from the group health plan or health insurance issuer, pursuant to subsection (d)(2); and

"(G) allow a representative of a participant or beneficiary, which may include a designated third-party advocate, to act on behalf of the participant or beneficiary.

"(2) AVAILABILITY OF PROCESS INFORMATION.—The group health plan or health insurance issuer shall make information regarding the process required under subsection (a) readily available in the relevant plan materials, including the summary of benefits

and, if available, on the website of the group health plan or health insurance issuer. Such information shall include—

"(A) the requirements for requesting an exception to a medication step therapy protocol pursuant to this section; and

"(B) any forms, supporting information, and contact information, as appropriate.

"(d) TIMING FOR DETERMINATION OF EXCEPTION.—The process required under subsection (a)(1) shall provide for the disposition of requests received under such paragraph in accordance with the following:

"(1) Subject to paragraph (2), not later than 72 hours after receiving an initial exception request, the plan or issuer shall respond to the participant or beneficiary and, if applicable, the requesting prescriber with either a determination of exception eligibility or a request for additional required information strictly necessary to make a determination of whether the conditions specified in subsection (b) are met. The plan or issuer shall respond to the participant or beneficiary and, if applicable, the requesting prescriber, with a determination of exception eligibility no later than 72 hours after receipt of the additional required information.

"(2) In the case of a request under circumstances in which the applicable medication step therapy protocol may seriously jeopardize the life or health of the participant or beneficiary, may jeopardize the ability of the participant or beneficiary to regain maximum function, or may subject the participant or beneficiary to severe pain that cannot be adequately managed without the treatment that is the subject of the request, the plan or issuer shall conduct a review of the request and respond to the participant or beneficiary and, if applicable, the requesting prescriber, with either a determination of exception eligibility or a request for additional required information strictly necessary to make a determination of whether the conditions specified in subsection (b) are met, in accordance with the following:

"(A) If the plan or issuer can make a determination of exception eligibility without additional information, such determination shall be made on an expedited basis, and no later than 24 hours after receipt of such request.

"(B) If the plan or issuer requires additional information before making a determination of exception eligibility, the plan or issuer shall respond to the participant or beneficiary

and, if applicable, the requesting prescriber, with a request for such information within 24 hours of the request for a determination, and shall respond with a determination of exception eligibility as quickly as the condition or disease requires, and no later than 24 hours after receipt of the additional required information.

"(e) DURATION OF A GRANT.—If an exception to a medication step therapy protocol is granted under this section to a participant or beneficiary, coverage for the requested drug shall remain in effect with respect to such participant or beneficiary for not less than one year.

"(f) MEDICATION STEP THERAPY PROTOCOL.—In this section, the term 'medication step therapy protocol' means a drug therapy utilization management protocol or program under which a group health plan or health insurance issuer offering group health insurance coverage of prescription drugs requires a participant or beneficiary to try an alternative preferred prescription drug or drugs before the plan or health insurance issuer approves coverage for the non-preferred drug therapy prescribed.

"(g) CLARIFICATION.—This section shall apply with respect to any group health plan or health insurance coverage offered in connection with such a plan that provides coverage of a prescription drug pursuant to a policy that

meets the definition of the term 'medication step therapy protocol' in subsection (f), regardless of whether such policy is described by such group health plan or health insurance coverage as a step therapy protocol.

"(h) REPORTING.—

"(1) REPORTING TO THE SECRETARY.—Not later than 3 years after the date of enactment of the Safe Step Act and not later than October 1 of each year thereafter, each group health plan and health insurance issuer offering group health insurance coverage shall report to the Secretary, in such manner as the Secretary shall require, the following:

"(A) The number of step therapy exception requests received for each exception circumstance described in paragraphs (1) through (6) of subsection (b), and the numbers of such requests for each such circumstance that were—

"(i) approved;

"(ii) deemed approved under subsection (d)(3) due to the failure of the plan or issuer to timely respond;

"(iii) denied, and the reasons for the denials;

"(iv) initially denied and appealed; and

"(v) initially denied and then subsequently reversed by internal appeals or external reviews.

"(B) The number of times a plan or issuer requested additional information in response to a step therapy exception request, by exception circumstance described in paragraphs (1) through (6) of subsection (b).

"(C) The number of exception requests submitted by participants or beneficiaries, and the number of exception requests submitted by prescribers, by medical specialty.

"(D) The medical conditions for which participants and beneficiaries were granted exceptions due to the likelihood that switching from a prescription drug will likely cause an adverse reaction by, or physical or mental harm to, the participant or beneficiary, as described in subsection (b)(3).

"(E) The entities responsible for providing pharmacy benefit management services for the group health plan or health insurance coverage.

"(2) INFORMATION.—A group health plan or health insurance issuer offering group health insurance coverage shall not enter into a contract with a

third-party administrator or an entity providing pharmacy benefit management services on behalf of the plan or coverage that prevents the plan or issuer from obtaining from the third-party administrator or the entity providing pharmacy benefit management services any information needed for the plan or issuer to comply with the reporting requirements under paragraph (1).

"(3) REPORTS TO CONGRESS.—Not later than 3 years after the date of enactment of the Safe Step Act, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains a summary and analysis of the information reported under paragraph (1), including an analysis of, with respect to requests for exceptions under this section, approvals, and denials, including the reasons for denials; appeals and external reviews; and trends, if any, in exception requests by medical specialty or medical condition.".

(c) CLERICAL AMENDMENT.—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 relating to section 713 the following new items:

"Sec. 713A. Required exceptions process for medication step therapy protocols.".

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by subsection (b) applies with respect to plan years beginning with the first plan year that begins at least 6 months after the date of the enactment of this Act.

(2) REGULATIONS.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Labor shall issue final regulations, through notice and comment rulemaking, to implement the provisions of section 713A of the Employee Retirement Income Security Act of 1974, as added by subsection (b).

Calendar No. 113

118TH CONGRESS
1ST SESSION

S. 1339

A BILL

To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.

JUNE 22, 2023

Reported with an amendment