AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

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.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

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 benefits management services on behalf of a plan or coverage, 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 (whether such coverage is covered group health insurance coverage or not) 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 the drug manufacturer with respect

to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, 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, 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; 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 ge-

neric 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 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 or 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, 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 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 health plan on that class of drugs; and

"(III) the average net spending per 30-day supply and per 90-day supply by the health 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 or coverage during the reporting period;

"(E) the total amount received, or expected to be received, by the health plan or health insurance issuer, from applicable entities, 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 or health insurance coverage during the reporting period;

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

"(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 referral of the group health plan's or health insurance issuer's business to the pharmacy benefit manager, consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer, or 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 under 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, 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, 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 such information described in subparagraphs (A) through (H) as the Secretary, the Secretary of Labor, and the Secretary of the Treasury determines useful for 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 such information described in subparagraphs (D) through

(G) as the Secretary determines useful for 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 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—

''(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 such information described in clauses (i) and (ii) as the Secretary determines 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 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 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 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 COV-

ERAGE.—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 subclauses (aa) and (bb) of clause (ii)(II) as the Secretary determines 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 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 (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 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 group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human Services, the Depart-

ment 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 oth-

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

ble, 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 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 avail-

able 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. The Secretary may provide for separate standard formats for reports to plan spon-

sors 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 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.—

"(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 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 appli-

cable group purchasing organization remit 100 percent of rebates, fees, alternative discounts, and other remuneration received that are related to utilization of drugs under such 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 cov-

erage, 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 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 under such health plan or health insurance cov-

erage to remit bona fide service fees to plan sponsors to the group health plan; 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, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Health and Human Services 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 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) 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 and reevaluated by such Secretaries every 5 years;

''(10) 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

''(11) 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. 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 re-

quired 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 benefits management services on behalf of a plan or coverage, 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 (whether such coverage is covered group health insurance coverage or not) 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 the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

"(B) a list of each drug covered by such plan, 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, 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; 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 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 or 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, 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 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 health plan on that class of drugs; and

"(III) the average net spending per 30-day supply and per 90-day supply by the health 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 or coverage during the reporting period;

"(E) the total amount received, or expected to be received, by the health plan or health insurance issuer, from applicable entities, 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 or health insurance coverage during the reporting period;

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

"(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 referral of the group health plan's or health insurance issuer's business to the pharmacy benefit manager, consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer, or 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 under 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, 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 phar-

macy 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, 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 such information described in subparagraphs (A) through (H) as the Secretary, the Secretary of Labor, and the Secretary of the Treasury determines useful for 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 such information described in subparagraphs (D) through (G) as the Secretary determines useful for 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 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 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 determine. 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 such information described in clauses (i) and (ii) as the Secretary determines 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 Phar-

macy 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 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 subclauses (aa) and (bb) of clause (ii)(II) as the Secretary determines 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 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 (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 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 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) 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 (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, 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) WRITTEN NOTICE.—Plan sponsors of group health plans shall provide to each employee written notice informing the employee of the requirement for health insurance issuers or 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.—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. The Secretary 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 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, 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 reim-

bursement 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.—

"(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 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 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 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 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 under such health plan or health insurance coverage to remit bona fide service fees to plan sponsors to the group health plan; 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, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary of Labor 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 busi-

ness 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 and reevaluated by such Secretaries every 5 years;

''(10) 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

"(11) 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 benefits 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 Re-

form 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 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 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—

''(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 Sec-

retary 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 of drugs for which a claim was filed 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;

"(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 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 health plan on that class of drugs; and

"(III) the average net spending per 30-day supply and per 90-day supply by the health 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 health plan, from applicable entities, 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 for referral of the group health plan's business to the pharmacy benefit manager, consideration of the entity providing pharmacy benefit management services by the group health plan, or the retention of the entity by the group health plan;

"(H)(i) an explanation of any benefit design parameters that encourage or require par-

ticipants 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 under 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, 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 such information described in subparagraphs (A) through (H) as the Secretary, the Secretary of Labor, and the Sec-

retary of the Treasury 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; 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 such information described in subparagraphs (D) through (G) as the Secretary determines useful for 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 Health and Human Services shall, through notice and comment rulemaking, promulgate final regulations final regulations to implement the requirements of this sub-

section. 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 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 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—

''(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 such information described in subparagraphs (A) and (B) as the Secretary determines 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 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 (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 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 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 ap-

plicable 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, 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) 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 be-

half 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.

''(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 man-

agement 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 anti-competitive 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 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 or issuer and participant or beneficiary 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, 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 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 management 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 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 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, issuer, 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 the utilization of drugs under such health 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, Sec-

retary 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, 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 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 under such health plan to remit bona fide service fees to plan sponsors to 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 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 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 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;

"(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 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 and reevaluated by such Secretaries every 5 years;

''(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.".

(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 are appropriated to the Centers for Medicare & Medicaid Services, out of amounts in the Treasury not otherwise appro-

priated, $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 are 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, 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 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 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 product 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 under 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 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 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, 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).