118TH CONGRESS
1ST SESSION

# S. 1339

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

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IN THE SENATE OF THE UNITED STATES

APRIL 27, 2023

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

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# A BILL

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

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

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

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

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

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

**"SEC. 2799A–11. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.**

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an applicable entity that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity providing pharmacy benefit management services on behalf of a plan or issuer, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format

and, as the Secretary, the Secretary of Labor, and the Secretary of the Treasury may determine, other formats. Each such report shall include, with respect to the covered group health plan—

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

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

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

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

the drug dispensed across the reporting period;

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

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

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

''(vi) for any drug for which gross spending by the plan exceeded $10,000 and that is one of the 50 prescription drugs for which the group health plan

spent the most on prescription drug benefits during the reporting period—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(A) IN GENERAL.—A health insurance issuer offering covered group health insurance coverage or an entity providing pharmacy ben-

efit management services under a covered group health plan or covered group health insurance coverage shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes—

"(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and copayment incentives funded by an entity providing pharmacy benefit management services;

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

or entity providing pharmacy benefit management services; and

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

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

''(II) the median amount charged to the plan or coverage, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or par-

tially-owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

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

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

''(V) the net acquisition cost per dosage unit and for a 30 day-supply,

and the acquisition cost per typical course of treatment, if the drug is subject to a maximum price discount; and

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

''(B) PLANS AND COVERAGE OFFERED BY SMALL EMPLOYERS.—A health insurance issuer offering covered group health insurance coverage that is not covered group health insurance coverage or an entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan or under group health insurance coverage that is not covered group health insurance cov-

erage that conducts transactions with a wholly or partially-owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

''(3) PRIVACY REQUIREMENTS.—

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

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

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

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

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

United States in accordance with paragraph (6).

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

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

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

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

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

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

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

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

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

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

"(D) ENFORCEMENT.—

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

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

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

''(5) ADDITIONAL REPORTING.—

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

mine. Each such report shall include, with respect to the applicable group health plan, the information described in subparagraphs (A), (D), (E), (F), (G), and (H) of paragraph (1).

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

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

''(ii) CONTENTS OF REPORTS.—

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

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

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

''(iv) REQUIRED REPORTING FOR ALL GROUP HEALTH INSURANCE COVERAGE.—Each health insurance issuer of health insurance coverage shall annually submit the information described in paragraph (1)(H), regardless of whether the plan sponsor

made the election described in clause (i) for the applicable year.

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

''(7) STANDARD FORMATS.—

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

''(B) LIMITED FORM OF REPORT.—The Secretary, the Secretary of Labor, and the Sec-

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

''(c) LIMITATIONS ON SPREAD PRICING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not contemplated by this subsection, pro-

vided that such fees are transparent to group health plans and health insurance issuers.

''(e) ENFORCEMENT.—

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

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

''(3) FALSE INFORMATION.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be

subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

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

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

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

''(g) DEFINITIONS.—In this section—

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

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

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

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

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

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

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

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

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

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

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

''(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of

Labor, and the Secretary of the Treasury, through notice and comment rulemaking;

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

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

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

(A) in subsection (a)—

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

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

(B) in subsection (b)—

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

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

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

(b) ERISA.—

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

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

**''SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.**

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an applicable entity that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity providing pharmacy benefit manage-

ment services on behalf of a plan or issuer, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format and, as the Secretary may determine, other formats. Each such report shall include, with respect to the covered group health plan—

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

''(B) a list of each drug covered by such plan or entity providing pharmacy benefit management services that was billed during the re-

porting period, including, with respect to each such drug during the reporting period—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

before rebates, fees, alternative discounts, or other remuneration provided by an applicable entity;

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

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

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

''(H) a summary document that includes such information described in subparagraphs (A) through (G) as the Secretary determines useful for plan sponsors for purposes of selecting pharmacy benefit management services,

such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.

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

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

''(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, retail and

mail auto-refill programs, and copayment incentives funded by an entity providing pharmacy benefit management services;

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

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

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

charged to the participants and beneficiaries;

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

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

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

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

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

among all pharmacies included in the network of the plan or coverage.

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

''(3) PRIVACY REQUIREMENTS.—

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

regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

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

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

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

"(ii) LIMITATIONS.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insur-

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

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

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

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

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

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

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

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

"(iii) to the Department of Health and Human Services, the Department of

Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

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

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

"(D) ENFORCEMENT.—

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

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

''(5) ADDITIONAL REPORTING.—

''(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL

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

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

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

"(ii) CONTENTS OF REPORTS.—

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

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

"(iii) APPLICATION.—For purposes of reports submitted in accordance with this subparagraph, paragraph (1) shall be ap-

plied by substituting 'group health insurance coverage' or 'health insurance issuer', as applicable, for 'group health plan', 'group plan', and 'plan' where such terms appear in such paragraph.

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

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

necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

''(7) STANDARD FORMATS.—

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

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

''(c) LIMITATIONS ON SPREAD PRICING.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(e) ENFORCEMENT.—

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

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates sub-

section (c); or a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services that violates subsection (d) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

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

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

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

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

''(g) DEFINITIONS.—In this section—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(10) the term 'wholesale acquisition cost' has the meaning given such term in section

1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).''; and

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

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new item:

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

(c) INTERNAL REVENUE CODE.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

**''SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.**

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity providing pharmacy benefit management services on behalf of such a plan shall not enter into a contract with an applicable entity that limits the disclosure of information to plan sponsors in such a manner that prevents the plan, or an entity providing pharmacy benefit management

services on behalf of a plan, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a covered group health plan shall submit to the plan sponsor of such covered group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format and, as the Secretary may determine, other formats. Each such report shall include, with respect to the covered group health plan—

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

''(B) a list of each drug covered by such plan or entity providing pharmacy benefit management services that was billed during the re-

porting period, including, with respect to each such drug during the reporting period—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

before rebates, fees, alternative discounts, or other remuneration provided by an applicable entity;

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

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

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(dd)(A))) to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's business to the pharmacy benefit manager; and

''(H) a summary document that includes such information described in subparagraphs (A) through (G) as the Secretary determines

useful for plan sponsors for purposes of selecting pharmacy benefit management services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.

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

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

''(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that entity providing pharmacy benefit management services under such plan, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and co-payment incentives funded by an entity

providing pharmacy benefit management services;

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

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

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

''(II) the median amount charged to the plan, per dosage unit, per

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

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

''(IV) the lowest cost, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan and participants and beneficiaries, that is available

from any pharmacy included in the network of the plan;

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

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

''(B) PLANS OFFERED BY SMALL EMPLOYERS.—An entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan that conducts transactions with a wholly or partially-

owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

''(3) PRIVACY REQUIREMENTS.—

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

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

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

''(i) REASONABLE RESTRICTIONS.—Nothing in this section prevents an entity providing pharmacy benefit management

services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report under paragraph (1) or (2).

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

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

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

''(i) fail or refuse to hire, or discharge, any employee, or otherwise dis-

criminate against any employee with respect to the compensation, terms, conditions, or privileges of employment of the employee, because of information submitted under paragraph (1) or (2) attributed to the employee or a dependent of the employee; or

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

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

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

45, Code of Federal Regulations (or successor regulations);

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

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

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

''(C) RELATIONSHIP TO HIPAA REGULATIONS.—With respect to the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2), subparagraph (B) does not prohibit a covered entity (as defined for pur-

poses of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

''(D) ENFORCEMENT.—

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

''(ii) PROHIBITION AGAINST RETALIATION.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The rem-

edies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

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

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

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

''(7) STANDARD FORMATS.—

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

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

''(c) LIMITATIONS ON SPREAD PRICING.—

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

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

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

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

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

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

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

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

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

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

"(A) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, alternative discounts, or other re-

muneration is calculated, and in no case later than 90 days after the end of such period;

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

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

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

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

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

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

''(e) ENFORCEMENT.—

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

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

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

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

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this 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 the Treasury to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such plan or entity.

''(g) DEFINITIONS.—In this section—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''Sec. 9826. Oversight of entities that provide pharmacy benefit management services.''.

(d) FUNDING.—

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

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

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

(1) The impact on the impact of making no such regulatory changes, as well as potential behavioral changes by plan sponsors, members, and phar-

maceutical manufacturers, such as tighter formularies, changes to price concessions, changes in utilization, if such regulatory changes are made.

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

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

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

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

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

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

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

(f) GAO STUDY.—

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

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

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

(i) whether such networks are designed to encourage participants and beneficiaries of a plan or coverage to use such

pharmacies over other network pharmacies for specific services or drugs, and if so, the reasons the networks give for encouraging use of such pharmacies; and

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

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

(D) pharmacy network design parameters that encourage participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity; and

(E) the degree to which mail order, specialty, or retail pharmacies that dispense pre-

scription drugs to participants and beneficiaries in a group health plan or health insurance coverage that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefit management services or pharmacy benefit administrative services under group health plan or group or individual health insurance coverage receive reimbursement that is greater than the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to participants and beneficiaries in the plan or coverage by other pharmacies included in the pharmacy network of that plan, issuer, or entity that are not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefit management services.

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

(A) information that would allow for identification of a specific individual, plan sponsor, health insurance issuer, plan, or entity pro-

viding 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).

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