| 7 | MACY BENEFIT MANAGEMENT SERVICES. |
|------|--|
| 6 | SEC. 2. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR |
| 5 | Manager Reform Act". |
| 4 | This Act may be cited as the "Pharmacy Benefit |
| 3 | SECTION 1. SHORT TITLE. |
| 2 | tives of the United States of America in Congress assembled, |
| 1 | Be it enacted by the Senate and House of Representa- |
| То | A BILL provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage. |
| Mr. | IN THE SENATE OF THE UNITED STATES SANDERS (for himself, Mr. Cassidy, Mrs. Murray, and Mr. Marshall) introduced the following bill; which was read twice and referred to the Committee on |
| To] | provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage. |
| | TH CONGRESS 1ST SESSION S. |
| | |

(a) PHSA.—Title XXVII of the Public Health Serv-

9 ice Act (42 U.S.C. 300gg et seq.) is amended—

8

| 1 | (1) in part D (42 U.S.C. 300gg-111 et seq.) |
|----|--|
| 2 | by adding at the end the following new section: |
| 3 | "SEC. 2799A-11. OVERSIGHT OF ENTITIES THAT PROVIDE |
| 4 | PHARMACY BENEFIT MANAGEMENT SERV |
| 5 | ICES. |
| 6 | "(a) In General.—For plan years beginning on or |
| 7 | after January 1, 2025, a group health plan or health in- |
| 8 | surance issuer offering group health insurance coverage |
| 9 | or an entity providing pharmacy benefit management serv- |
| 10 | ices on behalf of such a plan or issuer shall not enter into |
| 11 | a contract with an applicable entity that limits the disclo- |
| 12 | sure of information to plan sponsors in such a manner |
| 13 | that prevents the plan or issuer, or an entity providing |
| 14 | pharmacy benefit management services on behalf of a plan |
| 15 | or issuer, from making the reports described in subsection |
| 16 | (b). |
| 17 | "(b) Reports.— |
| 18 | "(1) In general.—For plan years beginning |
| 19 | on or after January 1, 2025, not less frequently |
| 20 | than annually, an entity providing pharmacy benefit |
| 21 | management services on behalf of a covered group |
| 22 | health plan shall submit to the plan sponsor of such |
| 23 | covered group health plan a report in accordance |
| 24 | with this subsection and make such report available |
| 25 | to the plan sponsor in a machine-readable format |

| 1 | and, as the Secretary, the Secretary of Labor, and |
|----|---|
| 2 | the Secretary of the Treasury may determine, other |
| 3 | formats. Each such report shall include, with respect |
| 4 | to the covered group health plan— |
| 5 | "(A) as applicable, information collected |
| 6 | from drug manufacturers by such issuer or en- |
| 7 | tity on the total amount of copayment assist- |
| 8 | ance dollars paid, or copayment cards applied, |
| 9 | that were funded by the drug manufacturer |
| 10 | with respect to the participants and bene- |
| 11 | ficiaries in such plan; |
| 12 | "(B) a list of each drug covered by such |
| 13 | plan or entity providing pharmacy benefit man- |
| 14 | agement services that was billed during the re- |
| 15 | porting period, including, with respect to each |
| 16 | such drug during the reporting period— |
| 17 | "(i) the brand name, generic or non- |
| 18 | proprietary name, and National Drug |
| 19 | Code; |
| 20 | "(ii) the number of participants and |
| 21 | beneficiaries for whom the drug was billed |
| 22 | during the reporting period, the total num- |
| 23 | ber of prescription claims for the drug (in- |
| 24 | cluding original prescriptions and refills), |
| 25 | and the total number of dosage units of |

| 1 | the drug dispensed across the reporting pe- |
|----|---|
| 2 | riod; |
| 3 | "(iii) for each claim or dosage unit de- |
| 4 | scribed in clause (ii), the type of dis- |
| 5 | pensing channel used, such as retail, mail |
| 6 | order, or specialty pharmacy; |
| 7 | "(iv) the wholesale acquisition cost, |
| 8 | listed as cost per days supply, cost per dos- |
| 9 | age unit, and cost per typical course of |
| 10 | treatment (as applicable); |
| 11 | "(v) the total out-of-pocket spending |
| 12 | by participants and beneficiaries on such |
| 13 | drug after application of any benefits |
| 14 | under the plan or coverage, including par- |
| 15 | ticipant and beneficiary spending through |
| 16 | copayments, coinsurance, and deductibles, |
| 17 | but not including any amounts spent by |
| 18 | participants and beneficiaries on drugs not |
| 19 | covered under the plan or coverage or for |
| 20 | which no claim is submitted to the plan or |
| 21 | coverage; and |
| 22 | "(vi) for any drug for which gross |
| 23 | spending by the plan exceeded \$10,000 |
| 24 | and that is one of the 50 prescription |
| 25 | drugs for which the group health plan |
| | |

| 1 | spent the most on prescription drug bene- |
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| 2 | fits during the reporting period— |
| 3 | "(I) a list of all other drugs in |
| 4 | the same therapeutic class, including |
| 5 | brand name drugs and biological |
| 6 | products and generic drugs or bio- |
| 7 | similar biological products that are in |
| 8 | the same therapeutic class as such |
| 9 | drug; and |
| 10 | "(II) if applicable, the rationale |
| 11 | for preferred formulary placement of |
| 12 | such drug in that therapeutic class, |
| 13 | selected from a list of standard ra- |
| 14 | tionales established by the Secretary; |
| 15 | "(C) a list of each therapeutic class of |
| 16 | drugs that were dispensed under the health |
| 17 | plan during the reporting period, and, with re- |
| 18 | spect to each such therapeutic class of drugs, |
| 19 | during the reporting period— |
| 20 | "(i) total gross spending by the plan, |
| 21 | before rebates, fees, alternative discounts, |
| 22 | or other remuneration; |
| 23 | "(ii) the number of participants and |
| 24 | beneficiaries who filled a prescription for a |
| 25 | drug in that class; |

| 1 | "(iii) if applicable to that class, a de- |
|----|---|
| 2 | scription of the formulary tiers and utiliza- |
| 3 | tion management mechanisms (such as |
| 4 | prior authorization or step therapy) em- |
| 5 | ployed for drugs in that class; |
| 6 | "(iv) the total out-of-pocket spending |
| 7 | by participants and beneficiaries, including |
| 8 | participant and beneficiary spending |
| 9 | through copayments, coinsurance, and |
| 10 | deductibles; and |
| 11 | "(v) for each therapeutic class under |
| 12 | which 3 or more drugs are included on the |
| 13 | formulary of such plan— |
| 14 | "(I) the amount received, or ex- |
| 15 | pected to be received, by such entity, |
| 16 | from an applicable entity, in rebates, |
| 17 | fees, alternative discounts, or other |
| 18 | remuneration that— |
| 19 | "(aa) has been paid, or will |
| 20 | be paid, by such an applicable |
| 21 | entity for claims incurred during |
| 22 | the reporting period; or |
| 23 | "(bb) is related to utilization |
| 24 | of drugs or drug spending; |
| | |

| 1 | "(II) the total net spending by |
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| 2 | the health plan on that class of drugs; |
| 3 | and |
| 4 | "(III) the net price per typical |
| 5 | course of treatment or 30-day supply |
| 6 | incurred by the health plan and its |
| 7 | participants and beneficiaries, after |
| 8 | rebates, fees, alternative discounts, or |
| 9 | other remuneration provided by an |
| 10 | applicable entity, for drugs dispensed |
| 11 | within such therapeutic class during |
| 12 | the reporting period; |
| 13 | "(D) total gross spending on prescription |
| 14 | drugs by the plan during the reporting period, |
| 15 | before rebates, fees, alternative discounts, or |
| 16 | other remuneration provided by an applicable |
| 17 | entity; |
| 18 | "(E) the total amount received, or ex- |
| 19 | pected to be received, by the health plan, from |
| 20 | an applicable entity, in rebates, fees, alternative |
| 21 | discounts, and other remuneration received |
| 22 | from any such entities, related to utilization of |
| 23 | drug or drug spending under that health plan |
| 24 | during the reporting period; |

| 1 | "(F) the total net spending on prescription |
|----|---|
| 2 | drugs by the health plan during the reporting |
| 3 | period; |
| 4 | "(G) amounts paid directly or indirectly in |
| 5 | rebates, fees, or any other type of compensation |
| 6 | (as defined in section $408(b)(2)(B)(ii)(dd)(AA)$ |
| 7 | of the Employee Retirement Income Security |
| 8 | Act of 1974) to brokers, consultants, advisors, |
| 9 | or any other individual or firm who referred the |
| 10 | group health plan's business to the pharmacy |
| 11 | benefit manager; and |
| 12 | "(H) a summary document that includes |
| 13 | such information described in subparagraphs |
| 14 | (A) through (G) as the Secretary determines |
| 15 | useful for plan sponsors for purposes of select- |
| 16 | ing pharmacy benefit management services, |
| 17 | such as an estimated net price to plan sponsor |
| 18 | and participant or beneficiary, a cost per claim, |
| 19 | the fee structure or reimbursement model, and |
| 20 | estimated cost per participant or beneficiary. |
| 21 | "(2) Supplementary reporting for intra- |
| 22 | COMPANY PRESCRIPTION DRUG TRANSACTIONS.— |
| 23 | "(A) IN GENERAL.—A health insurance |
| 24 | issuer offering covered group health insurance |
| 25 | coverage or an entity providing pharmacy ben- |

| 1 | efit management services under a covered group |
|----|---|
| 2 | health plan or covered group health insurance |
| 3 | coverage shall submit, together with the report |
| 4 | under paragraph (1), a supplementary repor |
| 5 | every 6 months to the plan sponsor that in- |
| 6 | cludes— |
| 7 | "(i) an explanation of any benefit de- |
| 8 | sign parameters that encourage or require |
| 9 | participants and beneficiaries in the plan |
| 10 | or coverage to fill prescriptions at mai |
| 11 | order, specialty, or retail pharmacies that |
| 12 | are wholly or partially-owned by that issued |
| 13 | or entity providing pharmacy benefit man- |
| 14 | agement services under such plan or cov- |
| 15 | erage, including mandatory mail and spe- |
| 16 | cialty home delivery programs, retail and |
| 17 | mail auto-refill programs, and copayment |
| 18 | incentives funded by an entity providing |
| 19 | pharmacy benefit management services; |
| 20 | "(ii) the percentage of total prescrip- |
| 21 | tions charged to the plan, coverage, or par- |
| 22 | ticipants and beneficiaries in the plan or |
| 23 | coverage, that were dispensed by mai |
| 24 | order, specialty, or retail pharmacies that |
| 25 | are wholly or partially-owned by the issuer |

| 1 | or entity providing pharmacy benefit man- |
|----|---|
| 2 | agement services; and |
| 3 | "(iii) a list of all drugs dispensed by |
| 4 | such wholly or partially-owned pharmacy |
| 5 | and charged to the plan or coverage, or |
| 6 | participants and beneficiaries of the plan |
| 7 | or coverage, during the applicable quarter, |
| 8 | and, with respect to each drug— |
| 9 | "(I) the amounts charged, per |
| 10 | dosage unit, per course of treatment, |
| 11 | per 30-day supply, and per 90-day |
| 12 | supply, with respect to participants |
| 13 | and beneficiaries in the plan or cov- |
| 14 | erage, including amounts charged to |
| 15 | the plan or coverage and amounts |
| 16 | charged to the participants and bene- |
| 17 | ficiaries; |
| 18 | "(II) the median amount charged |
| 19 | to the plan or coverage, per dosage |
| 20 | unit, per course of treatment, per 30- |
| 21 | day supply, and per 90-day supply, in- |
| 22 | cluding amounts paid by the partici- |
| 23 | pants and beneficiaries, when the |
| 24 | same drug is dispensed by other phar- |
| 25 | macies that are not wholly or par- |

| 1 | tially-owned by the issuer or entity |
|----|--|
| 2 | and that are included in the pharmacy |
| 3 | network of that plan or coverage; |
| 4 | "(III) the interquartile range of |
| 5 | the costs, per dosage unit, per course |
| 6 | of treatment, per 30-day supply, and |
| 7 | per 90-day supply, including amounts |
| 8 | paid by the participants and bene- |
| 9 | ficiaries, when the same drug is dis- |
| 10 | pensed by other pharmacies that are |
| 11 | not wholly or partially-owned by the |
| 12 | issuer or entity and that are included |
| 13 | in the pharmacy network of that plan |
| 14 | or coverage; |
| 15 | "(IV) the lowest cost, per dosage |
| 16 | unit, per course of treatment, per 30- |
| 17 | day supply, and per 90-day supply, |
| 18 | for such drug, including amounts |
| 19 | charged to the plan or issuer and par- |
| 20 | ticipants and beneficiaries, that is |
| 21 | available from any pharmacy included |
| 22 | in the network of the plan or cov- |
| 23 | erage; |
| 24 | "(V) the net acquisition cost per |
| 25 | dosage unit and for a 30 day-supply, |
| | |

| 1 | and the acquisition cost per typical |
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| 2 | course of treatment, if the drug is |
| 3 | subject to a maximum price discount; |
| 4 | and |
| 5 | "(VI) other information with re- |
| 6 | spect to the cost of the drug, as deter- |
| 7 | mined by the Secretary, such as aver- |
| 8 | age sales price, wholesale acquisition |
| 9 | cost, and national average drug acqui- |
| 10 | sition cost per dosage unit, per typical |
| 11 | course of treatment, or per 30-day |
| 12 | supply, for such drug, including |
| 13 | amounts charged to the plan or issuer |
| 14 | and participants and beneficiaries |
| 15 | among all pharmacies included in the |
| 16 | network of the plan or coverage. |
| 17 | "(B) Plans and coverage offered by |
| 18 | SMALL EMPLOYERS.—A health insurance issuer |
| 19 | offering covered group health insurance cov- |
| 20 | erage that is not covered group health insur- |
| 21 | ance coverage or an entity providing pharmacy |
| 22 | benefit management services under a group |
| 23 | health plan that is not a covered group health |
| 24 | plan or under group health insurance coverage |
| 25 | that is not covered group health insurance cov- |
| | |

| 1 | erage that conducts transactions with a wholly |
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| 2 | or partially-owned pharmacy shall submit, to- |
| 3 | gether with the report under paragraph (1), a |
| 4 | supplementary report every 6 months to the |
| 5 | plan sponsor that includes the information de- |
| 6 | scribed in clauses (i) and (ii) of subparagraph |
| 7 | (A). |
| 8 | "(3) Privacy requirements.— |
| 9 | "(A) RELATIONSHIP TO HIPAA REGULA- |
| 10 | TIONS.—Nothing in this section shall be con- |
| 11 | strued to modify the requirements for the cre- |
| 12 | ation, receipt, maintenance, or transmission of |
| 13 | protected health information under the privacy, |
| 14 | security, breach notification, and enforcement |
| 15 | regulations in parts 160 and 164 of title 45, |
| 16 | Code of Federal Regulations (or successor regu- |
| 17 | lations). |
| 18 | "(B) REQUIREMENT.—A report submitted |
| 19 | under paragraph (1) or (2) shall contain only |
| 20 | summary health information, as defined in sec- |
| 21 | tion 164.504(a) of title 45, Code of Federal |
| 22 | Regulations (or successor regulations). |
| 23 | "(C) Clarification regarding certain |
| 24 | DISCLOSURES OF INFORMATION.— |

| 1 | "(i) Reasonable restrictions.— |
|----|---|
| 2 | Nothing in this section prevents a health |
| 3 | insurance issuer offering group health in- |
| 4 | surance coverage or an entity providing |
| 5 | pharmacy benefit management services on |
| 6 | behalf of a group health plan or group |
| 7 | health insurance coverage from placing |
| 8 | reasonable restrictions on the public disclo- |
| 9 | sure of the information contained in a re- |
| 10 | port under paragraph (1) or (2). |
| 11 | "(ii) Limitations.—A health insur- |
| 12 | ance issuer offering group health insurance |
| 13 | coverage or an entity providing pharmacy |
| 14 | benefit management services on behalf of a |
| 15 | group health plan or group health insur- |
| 16 | ance coverage may not restrict disclosure |
| 17 | of such reports to the Department of |
| 18 | Health and Human Services, the Depart- |
| 19 | ment of Labor, the Department of the |
| 20 | Treasury, or any other Federal agency re- |
| 21 | sponsible for enforcement activities under |
| 22 | this section for purposes of enforcement |
| 23 | under this section or other applicable law, |
| 24 | or to the Comptroller General of the |

| 1 | United States in accordance with para- |
|----|---|
| 2 | graph (6). |
| 3 | "(4) Use and disclosure by plan spon- |
| 4 | SORS.— |
| 5 | "(A) Prohibition.—A plan sponsor may |
| 6 | not— |
| 7 | "(i) fail or refuse to hire, or dis- |
| 8 | charge, any employee, or otherwise dis- |
| 9 | criminate against any employee with re- |
| 10 | spect to the compensation, terms, condi- |
| 11 | tions, or privileges of employment of the |
| 12 | employee, because of information sub- |
| 13 | mitted under paragraph (1) or (2) attrib- |
| 14 | uted to the employee or a dependent of the |
| 15 | employee; or |
| 16 | "(ii) limit, segregate, or classify the |
| 17 | employees of the employer in any way that |
| 18 | would deprive or tend to deprive any em- |
| 19 | ployee of employment opportunities or oth- |
| 20 | erwise adversely affect the status of the |
| 21 | employee as an employee, because of infor- |
| 22 | mation submitted under paragraph (1) or |
| 23 | (2) attributed to the employee or a depend- |
| 24 | ent of the employee. |

| 1 | "(B) DISCLOSURE AND REDISCLOSURE.— |
|----|--|
| 2 | A plan sponsor shall not disclose the informa- |
| 3 | tion received under paragraph (1) or (2) ex- |
| 4 | cept— |
| 5 | "(i) to an occupational or other health |
| 6 | researcher if the research is conducted in |
| 7 | compliance with the regulations and pro- |
| 8 | tections provided for under part 46 of title |
| 9 | 45, Code of Federal Regulations (or suc- |
| 10 | cessor regulations); |
| 11 | "(ii) in response to an order of a |
| 12 | court, except that the plan sponsor may |
| 13 | disclose only the information expressly au- |
| 14 | thorized by such order; |
| 15 | "(iii) to the Department of Health |
| 16 | and Human Services, the Department of |
| 17 | Labor, the Department of the Treasury, or |
| 18 | other Federal agency responsible for en- |
| 19 | forcement activities under this section; or |
| 20 | "(iv) to a contractor or agent for pur- |
| 21 | poses of health plan administration, if such |
| 22 | contractor or agent agrees, in writing, to |
| 23 | abide by the same use and disclosure re- |
| 24 | strictions as the plan sponsor. |

| "(C) Relationship to hipaa regula- |
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| TIONS.—With respect to the regulations pro- |
| mulgated 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 pro- |
| hibit 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 pre- |
| vious sentence does not affect the authority of |
| such Secretary to modify such regulations. |
| "(D) Enforcement.— |
| "(i) In general.—The powers, pro- |
| cedures, and remedies provided in section |
| 207 of the Genetic Information Non- |
| discrimination Act to a person alleging a |
| violation of title II of such Act shall be the |
| powers, procedures, and remedies this sub- |
| paragraph provides for any person alleging |
| a violation of this paragraph. |
| "(ii) Prohibition against retalia- |
| TION.—No person shall discriminate |
| against any individual because such indi- |

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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 re- |
|--|
| spect 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 INSUR- |
| ANCE COVERAGE.— |
| "(i) In general.—A plan sponsor |
| may, on an annual basis, beginning with |
| plan years beginning on or after January |
| 1, 2025, elect to require a health insurance |
| issuer offering group health insurance cov- |
| erage to submit to such plan sponsor a re- |
| port 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 cov- |
| erage, the information required under |
| paragraph (1) for covered group |
| health plans. |
| |

| 1 | "(II) OTHER GROUP HEALTH IN- |
|----------------|--|
| 2 | SURANCE COVERAGE.—In the case of |
| 3 | a an issuer that offers group health |
| 4 | insurance coverage that is not covered |
| 5 | group health insurance, a report pro- |
| 6 | vided pursuant to clause (i) shall in- |
| 7 | clude, with respect to the applicable |
| 8 | group health insurance coverage, the |
| 9 | information described in subpara- |
| 10 | graphs (A), (D), (E), (F), and (G) of |
| 11 | paragraph (1). |
| 12 | "(iii) Application.—For purposes of |
| 13 | reports submitted in accordance with this |
| 4 | subparagraph, paragraph (1) shall be ap- |
| 15 | plied by substituting 'group health insur- |
| 16 | ance coverage' or 'health insurance issuer', |
| 17 | as applicable, for 'group health plan', |
| 8 | 'group plan', and 'plan' where such terms |
| 19 | appear in such paragraph. |
| 20 | "(iv) Required reporting for all |
| 21 | GROUP HEALTH INSURANCE COVERAGE.— |
| 22 | Each health insurance issuer of health in- |
| 23 | surance coverage shall annually submit the |
| 24 | information described in paragraph (1)(H), |
| | |
| 21 22 23 | GROUP HEALTH INSURANCE COVERAGE.— Each health insurance issuer of health in surance coverage shall annually submit the |

1 made the election described in clause (i) 2 for the applicable year. 3 "(6) Submissions to gao.—A health insur-4 ance issuer offering group health insurance coverage 5 or an entity providing pharmacy benefit manage-6 ment services on behalf of a group health plan shall 7 submit to the Comptroller General of the United 8 States each of the first 2 reports submitted to a 9 plan sponsor under paragraph (1) or (5) with re-10 spect to such coverage or plan, and other such re-11 ports as requested, in accordance with the privacy 12 requirements under paragraph (3), and such other 13 information that the Comptroller General determines 14 necessary to carry out the study under section 2(f) 15 of the Pharmacy Benefit Manager Reform Act. 16 "(7) STANDARD FORMATS.— 17 "(A) IN GENERAL.—Not later than June 18 1, 2024, the Secretary, the Secretary of Labor, 19 and the Secretary of the Treasury shall specify, 20 through rulemaking, standard formats 21 health insurance issuers and entities providing 22 pharmacy benefit management services to sub-23 mit reports required under this subsection. 24 "(B) LIMITED FORM OF REPORT.—The 25 Secretary, the Secretary of Labor, and the SecTAM23528 RM0 S.L.C.

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:

| 1 | "(A) A penalty paid if an original claim for |
|----|---|
| 2 | a prescription drug was submitted fraudulently |
| 3 | by the pharmacy to the plan, issuer, or entity. |
| 4 | "(B) A penalty paid if the original claim |
| 5 | payment made by the plan, issuer, or entity to |
| 6 | the pharmacy was inconsistent with the reim- |
| 7 | bursement terms in any contract between the |
| 8 | pharmacy and the plan, issuer, or entity. |
| 9 | "(C) A penalty paid if the pharmacist serv- |
| 10 | ices billed to the plan, issuer, or entity were not |
| 11 | rendered by the pharmacy. |
| 12 | "(d) Full Rebate Pass-through to Plan.— |
| 13 | "(1) In general.—For plan years beginning |
| 14 | on or after January 1, 2025, a third-party adminis- |
| 15 | trator of a group health plan, a health insurance |
| 16 | issuer offering group health insurance coverage, or |
| 17 | an entity providing pharmacy benefit management |
| 18 | services under such health plan or health insurance |
| 19 | coverage shall— |
| 20 | "(A) remit 100 percent of rebates, fees, al- |
| 21 | ternative discounts, and other remuneration re- |
| 22 | ceived from any applicable entity that are re- |
| 23 | lated to utilization of drugs under such health |
| 24 | plan or health insurance coverage, to the group |
| 25 | health plan; and |

| 1 | "(B) ensure that any contract entered into |
|----|--|
| 2 | by such third-party administrator, health insur- |
| 3 | ance issuer, or entity providing pharmacy ben- |
| 4 | efit management services with an applicable en- |
| 5 | tity remit 100 percent of rebates, fees, alter- |
| 6 | native discounts, and other remuneration re- |
| 7 | ceived to the third-party administrator, health |
| 8 | insurance issuer, or entity providing pharmacy |
| 9 | benefit management services. |
| 10 | "(2) Form and manner of remittance.— |
| 11 | Such rebates, fees, alternative discounts, and other |
| 12 | remuneration shall be— |
| 13 | "(A) remitted to the group health plan or |
| 14 | group health insurance coverage in a timely |
| 15 | fashion after the period for which such rebates |
| 16 | fees, alternative discounts, or other remunera- |
| 17 | tion is calculated, and in no case later than 90 |
| 18 | days after the end of such period; |
| 19 | "(B) fully disclosed and enumerated to the |
| 20 | group health plan sponsor, as described in para- |
| 21 | graphs (1) and (4) of subsection (b); |
| 22 | "(C) available for audit by the plan spon- |
| 23 | sor, or a third-party designated by a plan spon- |
| 24 | sor not less than once per plan year; and |
| | |

1 "(D) returned to the issuer or entity pro-2 pharmaceutical benefit viding management 3 services by the group health plan if audits by such issuer or entity indicate that the amounts 4 5 received are incorrect after such amounts have 6 been paid to the group health plan. 7 "(3) Audit of Rebate Contracts.—A third-8 party administrator of a group health plan, a health 9 insurance issuer offering group health insurance cov-10 erage, or an entity providing pharmacy benefit man-11 agement services under such health plan or health 12 insurance coverage shall make rebate contracts with 13 rebate aggregators or drug manufacturers available 14 for audit by such plan sponsor or designated third-15 party, subject to confidentiality agreements to pre-16 vent re-disclosure of such contracts. 17 "(4) AUDITORS.—The applicable plan sponsor 18 may select an auditor for purposes of carrying out 19 audits under paragraphs (2)(C) and (3). "(5) Rule of Construction.—Nothing in 20 21 this subsection shall be construed to prohibit pay-22 ments to entities offering pharmacy benefit manage-23 ment services for bona fide services using a fee 24 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 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.

19 "(f) RULE OF CONSTRUCTION.—Nothing in this sec20 tion shall be construed to permit a health insurance issuer,
21 group health plan, or other entity to restrict disclosure to,
22 or otherwise limit the access of, the Department of Health
23 and Human Services to a report described in subsection
24 (b)(1) or information related to compliance with sub-

section (a) by such issuer, plan, or entity.

| 1 | "(g) Definitions.—In this section— |
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| 2 | "(1) the term 'applicable entity' means— |
| 3 | "(A) a drug manufacturer, distributor, |
| 4 | wholesaler, rebate aggregator (or other pur- |
| 5 | chasing entity designed to aggregate rebates), |
| 6 | group purchasing organization, or associated |
| 7 | third party; |
| 8 | "(B) any subsidiary, parent, affiliate, or |
| 9 | subcontractor of a group health plan, health in- |
| 10 | surance issuer, entity that provides pharmacy |
| 11 | benefit management services on behalf of such |
| 12 | a plan or issuer, or any entity described in sub- |
| 13 | paragraph (A); or |
| 14 | "(C) such other entity as the Secretary, |
| 15 | the Secretary of Labor, and the Secretary of |
| 16 | the Treasury may specify through rulemaking; |
| 17 | "(2) the term 'covered group health insurance |
| 18 | coverage' means health insurance coverage offered in |
| 19 | connection with a group health plan maintained by |
| 20 | a large employer; |
| 21 | "(3) the term 'covered group health plan' |
| 22 | means a group health plan maintained by a large |
| 23 | employer; |
| 24 | "(4) the term 'gross spending', with respect to |
| 25 | prescription drug benefits under a group health plan |

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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

| 1 | Labor, and the Secretary of the Treasury, through |
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| 2 | notice and comment rulemaking; |
| 3 | "(9) the term 'small employer' means, in con- |
| 4 | nection with a group health plan with respect to a |
| 5 | calendar year and a plan year, an employer who em- |
| 6 | ployed an average of at least 1 but not more than |
| 7 | 49 employees on business days during the preceding |
| 8 | calendar year and who employs at least 1 employee |
| 9 | on the first day of the plan year; and |
| 10 | "(10) the term 'wholesale acquisition cost' has |
| 11 | the meaning given such term in section |
| 12 | 1847A(c)(6)(B) of the Social Security Act."; and |
| 13 | (2) in section 2723 (42 U.S.C. 300gg–22)— |
| 14 | (A) in subsection (a)— |
| 15 | (i) in paragraph (1), by inserting |
| 16 | "(other than section 2799A–11)" after |
| 17 | "part D"; and |
| 18 | (ii) in paragraph (2), by inserting |
| 19 | "(other than section 2799A–11)" after |
| 20 | "part D"; |
| 21 | (B) in subsection (b)— |
| 22 | (i) in paragraph (1), by inserting |
| 23 | "(other than section 2799A–11)" after |
| 24 | "part D"; |

| (ii) in paragraph (2)(A), by inserting |
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| "(other than section 2799A-11)" after |
| "part D"; and |
| (iii) in paragraph (2)(C)(ii), by insert- |
| ing "(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 fol- |
| lowing: |
| iowing. |
| "SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR- |
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| "SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR- |
| "SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES. |
| "SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES. "(a) IN GENERAL.—For plan years beginning on or |
| "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 in- |
| "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 |
| "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 |
| "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 |
| "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 |
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32 ment services on behalf of a plan or issuer, from making 2 the reports described in subsection (b). 3 "(b) Reports.— 4 "(1) In General.—For plan years beginning 5 on or after January 1, 2025, not less frequently 6 than annually, an entity providing pharmacy benefit 7 management services on behalf of a covered group 8 health plan shall submit to the plan sponsor of such 9 covered group health plan a report in accordance 10 with this subsection and make such report available 11 to the plan sponsor in a machine-readable format 12 and, as the Secretary may determine, other formats. 13 Each such report shall include, with respect to the

covered group health plan—

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"(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-

| 1 | porting period, including, with respect to each |
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| 2 | such drug during the reporting period— |
| 3 | "(i) the brand name, generic or non- |
| 4 | proprietary name, and National Drug |
| 5 | Code; |
| 6 | "(ii) the number of participants and |
| 7 | beneficiaries for whom the drug was billed |
| 8 | during the reporting period, the total num- |
| 9 | ber of prescription claims for the drug (in- |
| 10 | cluding original prescriptions and refills), |
| 11 | and the total number of dosage units of |
| 12 | the drug dispensed across the reporting pe- |
| 13 | $\operatorname{riod};$ |
| 14 | "(iii) for each claim or dosage unit de- |
| 15 | scribed in clause (ii), the type of dis- |
| 16 | pensing channel used, such as retail, mail |
| 17 | order, or specialty pharmacy; |
| 18 | "(iv) the wholesale acquisition cost, |
| 19 | listed as cost per days supply, cost per dos- |
| 20 | age unit, and cost per typical course of |
| 21 | treatment (as applicable); |
| 22 | "(v) the total out-of-pocket spending |
| 23 | by participants and beneficiaries on such |
| 24 | drug after application of any benefits |
| 25 | under the plan or coverage, including par- |

| 1 | ticipant and beneficiary spending through |
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| 2 | copayments, coinsurance, and deductibles, |
| 3 | but not including any amounts spent by |
| 4 | participants and beneficiaries on drugs not |
| 5 | covered under the plan or coverage or for |
| 6 | which no claim is submitted to the plan or |
| 7 | coverage; and |
| 8 | "(vi) for any drug for which gross |
| 9 | spending by the plan exceeded \$10,000 |
| 10 | and that is one of the 50 prescription |
| 11 | drugs for which the group health plan |
| 12 | spent the most on prescription drug bene- |
| 13 | fits during the reporting period— |
| 14 | "(I) a list of all other drugs in |
| 15 | the same therapeutic class, including |
| 16 | brand name drugs and biological |
| 17 | products and generic drugs or bio- |
| 18 | similar biological products that are in |
| 19 | the same therapeutic class as such |
| 20 | drug; and |
| 21 | "(II) if applicable, the rationale |
| 22 | for preferred formulary placement of |
| 23 | such drug in that therapeutic class, |
| 24 | selected from a list of standard ra- |
| 25 | tionales established by the Secretary; |

| 1 | "(C) a list of each therapeutic class of |
|----|---|
| 2 | drugs that were dispensed under the health |
| 3 | plan during the reporting period, and, with re- |
| 4 | spect to each such therapeutic class of drugs, |
| 5 | during the reporting period— |
| 6 | "(i) total gross spending by the plan, |
| 7 | before rebates, fees, alternative discounts, |
| 8 | or other remuneration; |
| 9 | "(ii) the number of participants and |
| 10 | beneficiaries who filled a prescription for a |
| 11 | drug in that class; |
| 12 | "(iii) if applicable to that class, a de- |
| 13 | scription of the formulary tiers and utiliza- |
| 14 | tion management mechanisms (such as |
| 15 | prior authorization or step therapy) em- |
| 16 | ployed for drugs in that class; |
| 17 | "(iv) the total out-of-pocket spending |
| 18 | by participants and beneficiaries, including |
| 19 | participant and beneficiary spending |
| 20 | through copayments, coinsurance, and |
| 21 | deductibles; and |
| 22 | "(v) for each therapeutic class under |
| 23 | which 3 or more drugs are included on the |
| 24 | formulary of such plan— |

| 1 | "(I) the amount received, or ex- |
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| 2 | pected to be received, by such entity, |
| 3 | from an applicable entity, in rebates, |
| 4 | fees, alternative discounts, or other |
| 5 | remuneration that— |
| 6 | "(aa) has been paid, or will |
| 7 | be paid, by such an applicable |
| 8 | entity for claims incurred during |
| 9 | the reporting period; or |
| 10 | "(bb) is related to utilization |
| 11 | of drugs or drug spending; |
| 12 | "(II) the total net spending by |
| 13 | the health plan on that class of drugs; |
| 14 | and |
| 15 | "(III) the net price per typical |
| 16 | course of treatment or 30-day supply |
| 17 | incurred by the health plan and its |
| 18 | participants and beneficiaries, after |
| 19 | rebates, fees, alternative discounts, or |
| 20 | other remuneration provided by an |
| 21 | applicable entity, for drugs dispensed |
| 22 | within such therapeutic class during |
| 23 | the reporting period; |
| 24 | "(D) total gross spending on prescription |
| 25 | drugs by the plan during the reporting period, |

| 1 | before rebates, fees, alternative discounts, or |
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| 2 | other remuneration provided by an applicable |
| 3 | entity; |
| 4 | "(E) the total amount received, or ex- |
| 5 | pected to be received, by the health plan, from |
| 6 | an applicable entity, in rebates, fees, alternative |
| 7 | discounts, and other remuneration received |
| 8 | from any such entities, related to utilization of |
| 9 | drug or drug spending under that health plan |
| 10 | during the reporting period; |
| 11 | "(F) the total net spending on prescription |
| 12 | drugs by the health plan during the reporting |
| 13 | period; |
| 14 | "(G) amounts paid directly or indirectly in |
| 15 | rebates, fees, or any other type of compensation |
| 16 | (as defined in section $408(b)(2)(B)(ii)(dd)(AA)$) |
| 17 | to brokers, consultants, advisors, or any other |
| 18 | individual or firm who referred the group health |
| 19 | plan's business to the pharmacy benefit man- |
| 20 | ager; and |
| 21 | "(H) a summary document that includes |
| 22 | such information described in subparagraphs |
| 23 | (A) through (G) as the Secretary determines |
| 24 | useful for plan sponsors for purposes of select- |
| 25 | ing pharmacy benefit management services, |

| 1 | such as an estimated net price to plan sponsor |
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| 2 | and participant or beneficiary, a cost per claim, |
| 3 | the fee structure or reimbursement model, and |
| 4 | estimated cost per participant or beneficiary. |
| 5 | "(2) Supplementary reporting for intra- |
| 6 | COMPANY PRESCRIPTION DRUG TRANSACTIONS.— |
| 7 | "(A) In General.—A health insurance |
| 8 | issuer offering covered group health insurance |
| 9 | coverage or an entity providing pharmacy ben- |
| 10 | efit management services under a covered group |
| 11 | health plan or covered group health insurance |
| 12 | coverage shall submit, together with the report |
| 13 | under paragraph (1), a supplementary report |
| 14 | every 6 months to the plan sponsor that in- |
| 15 | cludes— |
| 16 | "(i) an explanation of any benefit de- |
| 17 | sign parameters that encourage or require |
| 18 | participants and beneficiaries in the plan |
| 19 | or coverage to fill prescriptions at mail |
| 20 | order, specialty, or retail pharmacies that |
| 21 | are wholly or partially-owned by that issuer |
| 22 | or entity providing pharmacy benefit man- |
| 23 | agement services under such plan or cov- |
| 24 | erage, including mandatory mail and spe- |
| 25 | cialty home delivery programs, retail and |

| 1 | mail auto-refill programs, and copayment |
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| 2 | incentives funded by an entity providing |
| 3 | pharmacy benefit management services; |
| 4 | "(ii) the percentage of total prescrip- |
| 5 | tions charged to the plan, coverage, or par- |
| 6 | ticipants and beneficiaries in the plan or |
| 7 | coverage, that were dispensed by mail |
| 8 | order, specialty, or retail pharmacies that |
| 9 | are wholly or partially-owned by the issuer |
| 10 | or entity providing pharmacy benefit man- |
| 11 | agement services; and |
| 12 | "(iii) a list of all drugs dispensed by |
| 13 | such wholly or partially-owned pharmacy |
| 14 | and charged to the plan or coverage, or |
| 15 | participants and beneficiaries of the plan |
| 16 | or coverage, during the applicable quarter, |
| 17 | and, with respect to each drug— |
| 18 | "(I) the amounts charged, per |
| 19 | dosage unit, per course of treatment, |
| 20 | per 30-day supply, and per 90-day |
| 21 | supply, with respect to participants |
| 22 | and beneficiaries in the plan or cov- |
| 23 | erage, including amounts charged to |
| 24 | the plan or coverage and amounts |

| 1 | charged to the participants and bene- |
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| 2 | ficiaries; |
| 3 | "(II) the median amount charged |
| 4 | to the plan or coverage, per dosage |
| 5 | unit, per course of treatment, per 30- |
| 6 | day supply, and per 90-day supply, in- |
| 7 | cluding amounts paid by the partici- |
| 8 | pants and beneficiaries, when the |
| 9 | same drug is dispensed by other phar- |
| 10 | macies that are not wholly or par- |
| 11 | tially-owned by the issuer or entity |
| 12 | and that are included in the pharmacy |
| 13 | network of that plan or coverage; |
| 14 | "(III) the interquartile range of |
| 15 | the costs, per dosage unit, per course |
| 16 | of treatment, per 30-day supply, and |
| 17 | per 90-day supply, including amounts |
| 18 | paid by the participants and bene- |
| 19 | ficiaries, when the same drug is dis- |
| 20 | pensed by other pharmacies that are |
| 21 | not wholly or partially-owned by the |
| 22 | issuer or entity and that are included |
| 23 | in the pharmacy network of that plan |
| 24 | or coverage; |
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| 1 | "(IV) the lowest cost, per dosage |
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| 2 | unit, per course of treatment, per 30- |
| 3 | day supply, and per 90-day supply, |
| 4 | for such drug, including amounts |
| 5 | charged to the plan or issuer and par- |
| 6 | ticipants and beneficiaries, that is |
| 7 | available from any pharmacy included |
| 8 | in the network of the plan or cov- |
| 9 | erage; |
| 10 | "(V) the net acquisition cost per |
| 11 | dosage unit and for a 30 day-supply, |
| 12 | and the acquisition cost per typical |
| 13 | course of treatment, if the drug is |
| 14 | subject to a maximum price discount; |
| 15 | and |
| 16 | "(VI) other information with re- |
| 17 | spect to the cost of the drug, as deter- |
| 18 | mined by the Secretary, such as aver- |
| 19 | age sales price, wholesale acquisition |
| 20 | cost, and national average drug acqui- |
| 21 | sition cost per dosage unit, per typical |
| 22 | course of treatment, or per 30-day |
| 23 | supply, for such drug, including |
| 24 | amounts charged to the plan or issuer |
| 25 | and participants and beneficiaries |

1 among all pharmacies included in the 2 network of the plan or coverage. 3 "(B) Plans and Coverage offered by SMALL EMPLOYERS.—A health insurance issuer 4 5 offering covered group health insurance cov-6 erage that is not covered group health insur-7 ance coverage or an entity providing pharmacy 8 benefit management services under a group 9 health plan that is not a covered group health 10 plan or under group health insurance coverage 11 that is not covered group health insurance cov-12 erage that conducts transactions with a wholly 13 or partially-owned pharmacy shall submit, to-14 gether with the report under paragraph (1), a 15 supplementary report every 6 months to the 16 plan sponsor that includes the information de-17 scribed in clauses (i) and (ii) of subparagraph 18 (A). 19 "(3) Privacy requirements.— 20 "(A) Relationship to hipaa regula-21 TIONS.—Nothing in this section shall be con-22 strued to modify the requirements for the cre-23 ation, receipt, maintenance, or transmission of 24 protected health information under the privacy, 25 security, breach notification, and enforcement

| 1 | regulations in parts 160 and 164 of title 45, |
|----|---|
| 2 | Code of Federal Regulations (or successor regu- |
| 3 | lations). |
| 4 | "(B) REQUIREMENT.—A report submitted |
| 5 | under paragraph (1) or (2) shall contain only |
| 6 | summary health information, as defined in sec- |
| 7 | tion 164.504(a) of title 45, Code of Federal |
| 8 | Regulations (or successor regulations). |
| 9 | "(C) CLARIFICATION REGARDING CERTAIN |
| 10 | DISCLOSURES OF INFORMATION.— |
| 11 | "(i) Reasonable restrictions.— |
| 12 | Nothing in this section prevents a health |
| 13 | insurance issuer offering group health in- |
| 14 | surance coverage or an entity providing |
| 15 | pharmacy benefit management services on |
| 16 | behalf of a group health plan or group |
| 17 | health insurance coverage from placing |
| 18 | reasonable restrictions on the public disclo- |
| 19 | sure of the information contained in a re- |
| 20 | port under paragraph (1) or (2). |
| 21 | "(ii) Limitations.—A health insur- |
| 22 | ance issuer offering group health insurance |
| 23 | coverage or an entity providing pharmacy |
| 24 | benefit management services on behalf of a |
| 25 | group health plan or group health insur- |

| 1 | ance coverage may not restrict disclosure |
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| 2 | of such reports to the Department of |
| 3 | Health and Human Services, the Depart- |
| 4 | ment of Labor, the Department of the |
| 5 | Treasury, or any other Federal agency re- |
| 6 | sponsible for enforcement activities under |
| 7 | this section for purposes of enforcement |
| 8 | under this section or other applicable law, |
| 9 | or to the Comptroller General of the |
| 10 | United States in accordance with para- |
| 11 | graph (6). |
| 12 | "(4) USE AND DISCLOSURE BY PLAN SPON- |
| 13 | SORS.— |
| 14 | "(A) Prohibition.—A plan sponsor may |
| 15 | not— |
| 16 | "(i) fail or refuse to hire, or dis- |
| 17 | charge, any employee, or otherwise dis- |
| 18 | criminate against any employee with re- |
| 19 | spect to the compensation, terms, condi- |
| | |
| 20 | tions, or privileges of employment of the |
| | tions, or privileges of employment of the employee, because of information sub- |
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| 21 | employee, because of information sub- |

| 1 | "(ii) limit, segregate, or classify the |
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| 2 | employees of the employer in any way that |
| 3 | would deprive or tend to deprive any em- |
| 4 | ployee of employment opportunities or oth- |
| 5 | erwise adversely affect the status of the |
| 6 | employee as an employee, because of infor- |
| 7 | mation submitted under paragraph (1) or |
| 8 | (2) attributed to the employee or a depend- |
| 9 | ent of the employee. |
| 10 | "(B) DISCLOSURE AND REDISCLOSURE.— |
| 11 | A plan sponsor shall not disclose the informa- |
| 12 | tion received under paragraph (1) or (2) ex- |
| 13 | cept— |
| 14 | "(i) to an occupational or other health |
| 15 | researcher if the research is conducted in |
| 16 | compliance with the regulations and pro- |
| 17 | tections provided for under part 46 of title |
| 18 | 45, Code of Federal Regulations (or suc- |
| 19 | cessor regulations); |
| 20 | "(ii) in response to an order of a |
| 21 | court, except that the plan sponsor may |
| 22 | disclose only the information expressly au- |
| 23 | thorized by such order; |
| 24 | "(iii) to the Department of Health |
| 25 | and Human Services, the Department of |

| 1 | Labor, the Department of the Treasury, or |
|----|--|
| 2 | other Federal agency responsible for en- |
| 3 | forcement activities under this section; or |
| 4 | "(iv) to a contractor or agent for pur- |
| 5 | poses of health plan administration, if such |
| 6 | contractor or agent agrees, in writing, to |
| 7 | abide by the same use and disclosure re- |
| 8 | strictions as the plan sponsor. |
| 9 | "(C) RELATIONSHIP TO HIPAA REGULA- |
| 10 | TIONS.—With respect to the regulations pro- |
| 11 | mulgated by the Secretary of Health and |
| 12 | Human Services under part C of title XI of the |
| 13 | Social Security Act (42 U.S.C. 1320d et seq.) |
| 14 | and section 264 of the Health Insurance Port- |
| 15 | ability and Accountability Act of 1996 (42 |
| 16 | U.S.C. 1320d–2), subparagraph (B) does not |
| 17 | prohibit a covered entity (as defined for pur- |
| 18 | poses of such regulations) from any use or dis- |
| 19 | closure of health information that is authorized |
| 20 | for the covered entity under such regulations. |
| 21 | The previous sentence does not affect the au- |
| 22 | thority of such Secretary to modify such regula- |
| 23 | tions. |
| 24 | "(D) Enforcement.— |

| 1 | "(1) IN GENERAL.—The powers, pro- |
|----|--|
| 2 | cedures, and remedies provided in section |
| 3 | 207 of the Genetic Information Non- |
| 4 | discrimination Act (42 U.S.C. 2000ff-6) to |
| 5 | a person alleging a violation of title II of |
| 6 | such Act shall be the powers, procedures, |
| 7 | and remedies this subparagraph provides |
| 8 | for any person alleging a violation of this |
| 9 | paragraph. |
| 10 | "(ii) Prohibition against retalia- |
| 11 | TION.—No person shall discriminate |
| 12 | against any individual because such indi- |
| 13 | vidual has opposed any act or practice |
| 14 | made unlawful by this paragraph or be- |
| 15 | cause such individual made a charge, testi- |
| 16 | fied, assisted, or participated in any man- |
| 17 | ner in an investigation, proceeding, or |
| 18 | hearing under this paragraph. The rem- |
| 19 | edies and procedures otherwise provided |
| 20 | for under this subparagraph shall be avail- |
| 21 | able to aggrieved individuals with respect |
| 22 | to violations of this clause. |
| 23 | "(5) Additional reporting.— |
| 24 | "(A) Reporting with respect to |
| 25 | GROUP HEALTH PLANS OFFERED BY SMALL |

| EMPLOYERS.—For plan years beginning on or |
|---|
| after January 1, 2025, not less frequently than |
| annually, an entity providing pharmacy benefit |
| management services on behalf of a group |
| health plan that is not a covered group health |
| plan shall submit to the plan sponsor of such |
| group health plan a report in accordance with |
| this paragraph, and make such report available |
| to the plan sponsor in a machine-readable for- |
| mat, and such other formats as the Secretary, |
| the Secretary of Health and Human Services, |
| and the Secretary of Labor may determine. |
| Each such report shall include, with respect to |
| the applicable group health plan, the informa- |
| tion described in subparagraphs (A), (D), (E), |
| (F), (G), and (H) of paragraph (1). |
| "(B) Opt-in for group health insur- |
| ANCE COVERAGE.— |
| "(i) In general.—A plan sponsor |
| may, on an annual basis, beginning with |
| plan years beginning on or after January |
| 1, 2025, elect to require a health insurance |
| issuer offering group health insurance cov- |
| erage to submit to such plan sponsor a re- |
| port in accordance with this subsection. |

| 1 | "(ii) Contents of Reports.— |
|----|---|
| 2 | "(I) Covered group health |
| 3 | INSURANCE COVERAGE.—In the case |
| 4 | of an issuer that offers covered group |
| 5 | health insurance coverage, a report |
| 6 | provided pursuant to clause (i) shall |
| 7 | include, with respect to the applicable |
| 8 | covered group health insurance cov- |
| 9 | erage, the information required under |
| 10 | paragraph (1) for covered group |
| 11 | health plans. |
| 12 | "(II) OTHER GROUP HEALTH IN- |
| 13 | SURANCE COVERAGE.—In the case of |
| 14 | a an issuer that offers group health |
| 15 | insurance coverage that is not covered |
| 16 | group health insurance, a report pro- |
| 17 | vided pursuant to clause (i) shall in- |
| 18 | clude, with respect to the applicable |
| 19 | group health insurance coverage, the |
| 20 | information described in subpara- |
| 21 | graphs (A), (D), (E), (F), and (G) of |
| 22 | paragraph (1). |
| 23 | "(iii) Application.—For purposes of |
| 24 | reports submitted in accordance with this |
| 25 | subparagraph, paragraph (1) shall be ap- |

| 1 | plied by substituting 'group health insur- |
|----|--|
| 2 | ance coverage' or 'health insurance issuer', |
| 3 | as applicable, for 'group health plan', |
| 4 | 'group plan', and 'plan' where such terms |
| 5 | appear in such paragraph. |
| 6 | "(iv) Required reporting for all |
| 7 | GROUP HEALTH INSURANCE COVERAGE.— |
| 8 | Each health insurance issuer of health in- |
| 9 | surance coverage shall annually submit the |
| 10 | information described in paragraph (1)(H), |
| 11 | regardless of whether the plan sponsor |
| 12 | made the election described in clause (i) |
| 13 | for the applicable year. |
| 14 | "(6) Submissions to gao.—A health insur- |
| 15 | ance issuer offering group health insurance coverage |
| 16 | or an entity providing pharmacy benefit manage- |
| 17 | ment services on behalf of a group health plan shall |
| 18 | submit to the Comptroller General of the United |
| 19 | States each of the first 2 reports submitted to a |
| 20 | plan sponsor under paragraph (1) or (5) with re- |
| 21 | spect to such coverage or plan, and other such re- |
| 22 | ports as requested, in accordance with the privacy |
| 23 | requirements under paragraph (3), and such other |
| 24 | information that the Comptroller General determines |
| | |

| 1 | necessary to carry out the study under section 2(f) |
|----|---|
| 2 | of the Pharmacy Benefit Manager Reform Act. |
| 3 | "(7) STANDARD FORMATS.— |
| 4 | "(A) In General.—Not later than June |
| 5 | 1, 2024, the Secretary, the Secretary of Health |
| 6 | and Human Services, and the Secretary of the |
| 7 | Treasury shall specify, through rulemaking |
| 8 | standard formats for health insurance issuers |
| 9 | and entities providing pharmacy benefit man- |
| 10 | agement services to submit reports required |
| 11 | under this subsection. |
| 12 | "(B) Limited form of report.—The |
| 13 | Secretary, the Secretary of Health and Human |
| 14 | Services, and the Secretary of the Treasury |
| 15 | shall define through rulemaking a limited form |
| 16 | of the reports under paragraphs (1) and (2) re- |
| 17 | quired to be submitted to plan sponsors who |
| 18 | also are drug manufacturers, drug wholesalers |
| 19 | entities providing pharmacy benefit manage |
| 20 | ment services, or other direct participants in |
| 21 | the drug supply chain, in order to prevent anti- |
| 22 | competitive behavior. |
| 23 | "(c) Limitations on Spread Pricing.— |
| 24 | "(1) In general.—For plan years beginning |
| 25 | on or after January 1, 2025, a group health plan or |

1 health insurance issuer offering group health insur-2 ance coverage shall not charge participants and 3 beneficiaries, and an entity providing pharmacy ben-4 efit management services under such a plan or cov-5 erage shall not charge the plan, issuer, or partici-6 pants and beneficiaries, a price for a prescription 7 drug that exceeds the price paid to the pharmacy for 8 such drug, excluding penalties paid by the pharmacy 9 (as described in paragraph (2)) to such plan, issuer, 10 or entity. 11 "(2) Rule of construction.—For purposes 12 of paragraph (1), penalties paid by pharmacies in-13 clude only the following: 14 "(A) A penalty paid if an original claim for 15 a prescription drug was submitted fraudulently 16 by the pharmacy to the plan, issuer, or entity. 17 "(B) A penalty paid if the original claim 18 payment made by the plan, issuer, or entity to 19 the pharmacy was inconsistent with the reim-20 bursement terms in any contract between the 21 pharmacy and the plan, issuer, or entity. 22 "(C) A penalty paid if the pharmacist serv-23 ices billed to the plan, issuer, or entity were not 24 rendered by the pharmacy. "(d) Full Rebate Pass-through to Plan.— 25

1 "(1) In General.—For plan years beginning 2 on or after January 1, 2025, a third-party adminis-3 trator of a group health plan, a health insurance issuer offering group health insurance coverage, or 4 5 an entity providing pharmacy benefit management 6 services under such health plan or health insurance 7 coverage shall— "(A) remit 100 percent of rebates, fees, al-8 9 ternative discounts, and other applicable remu-10 neration received from any applicable entity 11 that are related to utilization of drugs under 12 such health plan or health insurance coverage, 13 to the group health plan; and 14 "(B) ensure that any contract entered into 15 by such third-party administrator, health insur-16 ance issuer, or entity providing pharmacy ben-17 efit management services with an applicable en-18 tity remit 100 percent of rebates, fees, alter-19 native discounts, and other remuneration re-20 ceived to the third-party administrator, health 21 insurance issuer, or entity providing pharmacy 22 benefit management services. 23 "(2) Form and manner of remittance.— 24 Such rebates, fees, alternative discounts, and other 25 remuneration shall be—

| 1 | "(A) remitted to the group health plan or |
|----|---|
| 2 | group health insurance coverage in a timely |
| 3 | fashion after the period for which such rebates |
| 4 | fees, alternative discounts, or other remunera- |
| 5 | tion is calculated, and in no case later than 90 |
| 6 | days after the end of such period; |
| 7 | "(B) fully disclosed and enumerated to the |
| 8 | group health plan sponsor, as described in para- |
| 9 | graphs (1) and (4) of subsection (b); |
| 10 | "(C) available for audit by the plan spon- |
| 11 | sor, or a third-party designated by a plan spon- |
| 12 | sor not less than once per plan year; and |
| 13 | "(D) returned to the issuer or entity pro- |
| 14 | viding pharmaceutical benefit management |
| 15 | services by the group health plan if audits by |
| 16 | such issuer or entity indicate that the amounts |
| 17 | received are incorrect after such amounts have |
| 18 | been paid to the group health plan. |
| 19 | "(3) Audit of rebate contracts.—A third- |
| 20 | party administrator of a group health plan, a health |
| 21 | insurance issuer offering group health insurance cov- |
| 22 | erage, or an entity providing pharmacy benefit man- |
| 23 | agement services under such health plan or health |
| 24 | insurance coverage shall make rebate contracts with |
| 25 | rebate aggregators or drug manufacturers available |

1 for audit by such plan sponsor or designated third-2 party, subject to confidentiality agreements to pre-3 vent re-disclosure of such contracts. "(4) AUDITORS.—The applicable plan sponsor 4 5 may select an auditor for purposes of carrying out 6 audits under paragraphs (2)(C) and (3). 7 "(5) Rule of construction.—Nothing in 8 this subsection shall be construed to prohibit pay-9 ments to entities offering pharmacy benefit manage-10 ment services for bona fide services using a fee 11 structure not contemplated by this subsection, pro-12 vided that such fees are transparent to group health 13 plans and health insurance issuers. 14 "(e) Enforcement.— 15 "(1) IN GENERAL.—The Secretary, in consulta-16 tion with the Secretary of Health and Human Serv-17 ices and the Secretary of the Treasury, shall enforce 18 this section. 19 "(2) Failure to provide timely informa-20 TION.—A health insurance issuer or an entity pro-21 viding pharmacy benefit management services that 22 violates subsection (a) or fails to provide information 23 required under subsection (b); a group health plan, 24 health insurance issuer, or entity providing phar-

macy benefit management services that violates sub-

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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 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.

| 1 | "(5) Waivers.—The Secretary may waive pen- |
|----|--|
| 2 | alties under paragraph (2), or extend the period of |
| 3 | time for compliance with a requirement of this sec- |
| 4 | tion, for an entity in violation of this section that |
| 5 | has made a good-faith effort to comply with this sec- |
| 6 | tion. |
| 7 | "(f) Rule of Construction.—Nothing in this sec- |
| 8 | tion shall be construed to permit a health insurance issuer |
| 9 | group health plan, or other entity to restrict disclosure to |
| 10 | or otherwise limit the access of, the Department of Labor |
| 11 | to a report described in subsection (b)(1) or information |
| 12 | related to compliance with subsection (a) by such issuer |
| 13 | plan, or entity. |
| 14 | "(g) Definitions.—In this section— |
| 15 | "(1) the term 'applicable entity' means— |
| 16 | "(A) a drug manufacturer, distributor |
| 17 | wholesaler, rebate aggregator (or other pur- |
| 18 | chasing entity designed to aggregate rebates) |
| 19 | group purchasing organization, or associated |
| 20 | third party; |
| 21 | "(B) any subsidiary, parent, affiliate, or |
| 22 | subcontractor of a group health plan, health in- |
| 23 | surance issuer, entity that provides pharmacy |
| 24 | benefit management services on behalf of such |

| 1 | a plan or issuer, or any entity described in sub- |
|----|--|
| 2 | paragraph (A); or |
| 3 | "(C) such other entity as the Secretary |
| 4 | the Secretary of Health and Human Services |
| 5 | and the Secretary of the Treasury may specify |
| 6 | through rulemaking; |
| 7 | "(2) the term 'covered group health insurance |
| 8 | coverage' means health insurance coverage offered in |
| 9 | connection with a group health plan maintained by |
| 10 | a large employer; |
| 11 | "(3) the term 'covered group health plan |
| 12 | means a group health plan maintained by a large |
| 13 | employer; |
| 14 | "(4) the term 'gross spending', with respect to |
| 15 | prescription drug benefits under a group health plan |
| 16 | or health insurance coverage, means the amount |
| 17 | spent by a group health plan or health insurance |
| 18 | issuer on prescription drug benefits, calculated be- |
| 19 | fore the application of manufacturer rebates, fees |
| 20 | alternative discounts, or other remuneration; |
| 21 | "(5) the term 'large employer' means, in con- |
| 22 | nection with a group health plan with respect to a |
| 23 | calendar year and a plan year, an employer who em- |
| 24 | ployed an average of at least 50 employees on busi- |
| 25 | ness days during the preceding calendar year and |

1 who employs at least 1 employee on the first day of 2 the plan year; and 3 "(6) the term 'net spending', with respect to 4 prescription drug benefits under a group health plan 5 or health insurance coverage, means the amount 6 spent by a group health plan or health insurance 7 issuer on prescription drug benefits, calculated after 8 the application of manufacturer rebates, fees, alter-9 native discounts, or other remuneration; 10 "(7) the term 'plan sponsor' has the meaning 11 given such term in section 3(16)(B); 12 "(8) the term 'remuneration' has the meaning 13 given such term by the Secretary, the Secretary of 14 Health and Human Services, and the Secretary of 15 the Treasury, through notice and comment rule-16 making; 17 "(9) the term 'small employer' means, in con-18 nection with a group health plan with respect to a 19 calendar year and a plan year, an employer who em-20 ployed an average of at least 1 but not more than 21 49 employees on business days during the preceding 22 calendar year and who employs at least 1 employee 23 on the first day of the plan year. 24 "(10) the term 'wholesale acquisition cost' has 25 the meaning given such term in section

| 1 | 1847A(c)(6)(B) of the Social Security Act (42 |
|--|---|
| 2 | U.S.C. $1395w-3a(e)(6)(B)$)."; and |
| 3 | (B) in section 502(b)(3) (29 U.S.C. |
| 4 | 1132(b)(3)), by inserting "(other than section |
| 5 | 726)" after "part 7". |
| 6 | (2) CLERICAL AMENDMENT.—The table of con- |
| 7 | tents in section 1 of the Employee Retirement In- |
| 8 | come Security Act of 1974 (29 U.S.C. 1001 et seq.) |
| 9 | is amended by inserting after the item relating to |
| 10 | section 725 the following new item: |
| | "Sec. 726. Oversight of entities that provide pharmacy benefit management services.". |
| 11 | (c) Internal Revenue Code.— |
| | |
| 12 | (1) IN GENERAL.—Subchapter B of chapter |
| 12 13 | (1) In General.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amend- |
| | |
| 13 | 100 of the Internal Revenue Code of 1986 is amend- |
| 13 14 | 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following: |
| 13 14 15 | 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following: "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR- |
| 13 14 15 16 | 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. |
| 13 14 15 16 17 | 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 |
| 13 14 15 16 17 18 | 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 |
| 13 14 15 16 17 18 | 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following: "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES. "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity providing pharmacy benefit management services on be- |
| 13 14 15 16 17 18 19 20 | 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 |

61 1 services on behalf of a plan, from making the reports de-2 scribed in subsection (b). 3 "(b) Reports.— 4 "(1) In General.—For plan years beginning 5 on or after January 1, 2025, not less frequently 6 than annually, an entity providing pharmacy benefit 7 management services on behalf of a covered group 8 health plan shall submit to the plan sponsor of such 9 covered group health plan a report in accordance 10 with this subsection and make such report available

with this subsection and make such report available

11 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

14 covered group health plan—

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"(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-

| 1 | porting period, including, with respect to each |
|----|---|
| 2 | such drug during the reporting period— |
| 3 | "(i) the brand name, generic or non- |
| 4 | proprietary name, and National Drug |
| 5 | Code; |
| 6 | "(ii) the number of participants and |
| 7 | beneficiaries for whom the drug was billed |
| 8 | during the reporting period, the total num- |
| 9 | ber of prescription claims for the drug (in- |
| 10 | cluding original prescriptions and refills), |
| 11 | and the total number of dosage units of |
| 12 | the drug dispensed across the reporting pe- |
| 13 | riod; |
| 14 | "(iii) for each claim or dosage unit de- |
| 15 | scribed in clause (ii), the type of dis- |
| 16 | pensing channel used, such as retail, mail |
| 17 | order, or specialty pharmacy; |
| 18 | "(iv) the wholesale acquisition cost, |
| 19 | listed as cost per days supply, cost per dos- |
| 20 | age unit, and cost per typical course of |
| 21 | treatment (as applicable); |
| 22 | "(v) the total out-of-pocket spending |
| 23 | by participants and beneficiaries on such |
| 24 | drug after application of any benefits |
| 25 | under the plan, including participant and |

| 1 | beneficiary spending through copayments, |
|----|---|
| 2 | coinsurance, and deductibles, but not in- |
| 3 | cluding any amounts spent by participants |
| 4 | and beneficiaries on drugs not covered |
| 5 | under the plan or for which no claim is |
| 6 | submitted to the plan; and |
| 7 | "(vi) for any drug for which gross |
| 8 | spending by the plan exceeded \$10,000 |
| 9 | and that is one of the 50 prescription |
| 10 | drugs for which the group health plan |
| 11 | spent the most on prescription drug bene- |
| 12 | fits during the reporting period— |
| 13 | "(I) a list of all other drugs in |
| 14 | the same therapeutic class, including |
| 15 | brand name drugs and biological |
| 16 | products and generic drugs or bio- |
| 17 | similar biological products that are in |
| 18 | the same therapeutic class as such |
| 19 | drug; and |
| 20 | "(II) if applicable, the rationale |
| 21 | for preferred formulary placement of |
| 22 | such drug in that therapeutic class, |
| 23 | selected from a list of standard ra- |
| 24 | tionales established by the Secretary; |

| 1 | (C) a list of each therapeutic class of |
|----|---|
| 2 | drugs that were dispensed under the health |
| 3 | plan during the reporting period, and, with re- |
| 4 | spect to each such therapeutic class of drugs, |
| 5 | during the reporting period— |
| 6 | "(i) total gross spending by the plan, |
| 7 | before rebates, fees, alternative discounts, |
| 8 | or other remuneration; |
| 9 | "(ii) the number of participants and |
| 10 | beneficiaries who filled a prescription for a |
| 11 | drug in that class; |
| 12 | "(iii) if applicable to that class, a de- |
| 13 | scription of the formulary tiers and utiliza- |
| 14 | tion management mechanisms (such as |
| 15 | prior authorization or step therapy) em- |
| 16 | ployed for drugs in that class; |
| 17 | "(iv) the total out-of-pocket spending |
| 18 | by participants and beneficiaries, including |
| 19 | participant and beneficiary spending |
| 20 | through copayments, coinsurance, and |
| 21 | deductibles; and |
| 22 | "(v) for each therapeutic class under |
| 23 | which 3 or more drugs are included on the |
| 24 | formulary of such plan— |
| | |

| 1 | "(I) the amount received, or ex- |
|----|--|
| 2 | pected to be received, by such entity, |
| 3 | from an applicable entity, in rebates, |
| 4 | fees, alternative discounts, or other |
| 5 | remuneration that— |
| 6 | "(aa) has been paid, or will |
| 7 | be paid, by such an applicable |
| 8 | entity for claims incurred during |
| 9 | the reporting period; or |
| 10 | "(bb) is related to utilization |
| 11 | of drugs or drug spending; |
| 12 | "(II) the total net spending by |
| 13 | the health plan on that class of drugs; |
| 14 | and |
| 15 | "(III) the net price per typical |
| 16 | course of treatment or 30-day supply |
| 17 | incurred by the health plan and its |
| 18 | participants and beneficiaries, after |
| 19 | rebates, fees, alternative discounts, or |
| 20 | other remuneration provided by an |
| 21 | applicable entity, for drugs dispensed |
| 22 | within such therapeutic class during |
| 23 | the reporting period; |
| 24 | "(D) total gross spending on prescription |
| 25 | drugs by the plan during the reporting period, |

| 1 | before rebates, fees, alternative discounts, or |
|----|---|
| 2 | other remuneration provided by an applicable |
| 3 | entity; |
| 4 | "(E) the total amount received, or ex- |
| 5 | pected to be received, by the health plan, from |
| 6 | an applicable entity, in rebates, fees, alternative |
| 7 | discounts, and other remuneration received |
| 8 | from any such entities, related to utilization of |
| 9 | drug or drug spending under that health plan |
| 10 | during the reporting period; |
| 11 | "(F) the total net spending on prescription |
| 12 | drugs by the health plan during the reporting |
| 13 | period; |
| 14 | "(G) amounts paid directly or indirectly in |
| 15 | rebates, fees, or any other type of compensation |
| 16 | (as defined in section $408(b)(2)(B)(ii)(dd)(AA)$ |
| 17 | of the Employee Retirement Income Security |
| 18 | Act of 1974 (29 U.S.C. |
| 19 | 1108(b)(2)(B)(ii)(dd)(A))) to brokers, consult- |
| 20 | ants, advisors, or any other individual or firm |
| 21 | who referred the group health plan's business to |
| 22 | the pharmacy benefit manager; and |
| 23 | "(H) a summary document that includes |
| 24 | such information described in subparagraphs |
| 25 | (A) through (G) as the Secretary determines |

| 1 | useful for plan sponsors for purposes of select- |
|----|---|
| 2 | ing pharmacy benefit management services, |
| 3 | such as an estimated net price to plan sponsor |
| 4 | and participant or beneficiary, a cost per claim, |
| 5 | the fee structure or reimbursement model, and |
| 6 | estimated cost per participant or beneficiary. |
| 7 | "(2) Supplementary reporting for intra- |
| 8 | COMPANY PRESCRIPTION DRUG TRANSACTIONS.— |
| 9 | "(A) IN GENERAL.—An entity providing |
| 10 | pharmacy benefit management services under a |
| 11 | covered group health plan shall submit, to- |
| 12 | gether with the report under paragraph (1), a |
| 13 | supplementary report every 6 months to the |
| 14 | plan sponsor that includes— |
| 15 | "(i) an explanation of any benefit de- |
| 16 | sign parameters that encourage or require |
| 17 | participants and beneficiaries in the plan |
| 18 | to fill prescriptions at mail order, specialty, |
| 19 | or retail pharmacies that are wholly or |
| 20 | partially-owned by that entity providing |
| 21 | pharmacy benefit management services |
| 22 | under such plan, including mandatory mail |
| 23 | and specialty home delivery programs, re- |
| 24 | tail and mail auto-refill programs, and co- |
| 25 | payment incentives funded by an entity |

| 1 | providing pharmacy benefit management |
|----|---|
| 2 | services; |
| 3 | "(ii) the percentage of total prescrip- |
| 4 | tions charged to the plan or participants |
| 5 | and beneficiaries in the plan, that were |
| 6 | dispensed by mail order, specialty, or retail |
| 7 | pharmacies that are wholly or partially- |
| 8 | owned by the entity providing pharmacy |
| 9 | benefit management services; and |
| 10 | "(iii) a list of all drugs dispensed by |
| 11 | such wholly or partially-owned pharmacy |
| 12 | and charged to the plan, or participants |
| 13 | and beneficiaries of the plan, during the |
| 14 | applicable quarter, and, with respect to |
| 15 | each drug— |
| 16 | "(I) the amounts charged, per |
| 17 | dosage unit, per course of treatment, |
| 18 | per 30-day supply, and per 90-day |
| 19 | supply, with respect to participants |
| 20 | and beneficiaries in the plan, includ- |
| 21 | ing amounts charged to the plan and |
| 22 | amounts charged to the participants |
| 23 | and beneficiaries; |
| 24 | "(II) the median amount charged |
| 25 | to the plan, per dosage unit, per |

| 1 | course of treatment, per 30-day sup- |
|----|---|
| 2 | ply, and per 90-day supply, including |
| 3 | amounts paid by the participants and |
| 4 | beneficiaries, when the same drug is |
| 5 | dispensed by other pharmacies that |
| 6 | are not wholly or partially-owned by |
| 7 | the entity and that are included in the |
| 8 | pharmacy network of that plan; |
| 9 | "(III) the interquartile range of |
| 10 | the costs, per dosage unit, per course |
| 11 | of treatment, per 30-day supply, and |
| 12 | per 90-day supply, including amounts |
| 13 | paid by the participants and bene- |
| 14 | ficiaries, when the same drug is dis- |
| 15 | pensed by other pharmacies that are |
| 16 | not wholly or partially-owned by the |
| 17 | entity and that are included in the |
| 18 | pharmacy network of that plan; |
| 19 | "(IV) the lowest cost, per dosage |
| 20 | unit, per course of treatment, per 30- |
| 21 | day supply, and per 90-day supply, |
| 22 | for such drug, including amounts |
| 23 | charged to the plan and participants |
| 24 | and beneficiaries, that is available |

| 1 | from any pharmacy included in the |
|----|---|
| 2 | network of the plan; |
| 3 | "(V) the net acquisition cost per |
| 4 | dosage unit and for a 30 day-supply |
| 5 | and the acquisition cost per typical |
| 6 | course of treatment, if the drug is |
| 7 | subject to a maximum price discount |
| 8 | and |
| 9 | "(VI) other information with re- |
| 10 | spect to the cost of the drug, as deter- |
| 11 | mined by the Secretary, such as aver- |
| 12 | age sales price, wholesale acquisition |
| 13 | cost, and national average drug acqui- |
| 14 | sition cost per dosage unit, per typical |
| 15 | course of treatment, or per 30-day |
| 16 | supply, for such drug, including |
| 17 | amounts charged to the plan and par- |
| 18 | ticipants and beneficiaries among all |
| 19 | pharmacies included in the network of |
| 20 | the plan. |
| 21 | "(B) Plans offered by small employ- |
| 22 | ERS.—An entity providing pharmacy benefit |
| 23 | management services under a group health plan |
| 24 | that is not a covered group health plan that |
| 25 | conducts transactions with a wholly or partially- |

| 1 | owned pharmacy shall submit, together with the |
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| 2 | report under paragraph (1), a supplementary |
| 3 | report every 6 months to the plan sponsor that |
| 4 | includes the information described in clauses (i) |
| 5 | and (ii) of subparagraph (A). |
| 6 | "(3) Privacy requirements.— |
| 7 | "(A) RELATIONSHIP TO HIPAA REGULA- |
| 8 | TIONS.—Nothing in this section shall be con- |
| 9 | strued to modify the requirements for the cre- |
| 10 | ation, receipt, maintenance, or transmission of |
| 11 | protected health information under the privacy, |
| 12 | security, breach notification, and enforcement |
| 13 | regulations in parts 160 and 164 of title 45, |
| 14 | Code of Federal Regulations (or successor regu- |
| 15 | lations). |
| 16 | "(B) REQUIREMENT.—A report submitted |
| 17 | under paragraph (1) or (2) shall contain only |
| 18 | summary health information, as defined in sec- |
| 19 | tion 164.504(a) of title 45, Code of Federal |
| 20 | Regulations (or successor regulations). |
| 21 | "(C) CLARIFICATION REGARDING CERTAIN |
| 22 | DISCLOSURES OF INFORMATION.— |
| 23 | "(i) Reasonable restrictions.— |
| 24 | Nothing in this section prevents an entity |
| 25 | providing pharmacy benefit management |

| 1 | services on behalf of a group health plan |
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| 2 | from placing reasonable restrictions on the |
| 3 | public disclosure of the information con- |
| 4 | tained in a report under paragraph (1) or |
| 5 | (2). |
| 6 | "(ii) Limitations.—An entity pro- |
| 7 | viding pharmacy benefit management serv- |
| 8 | ices on behalf of a group health plan or |
| 9 | group health insurance coverage may not |
| 10 | restrict disclosure of such reports to the |
| 11 | Department of Health and Human Serv- |
| 12 | ices, the Department of Labor, the Depart- |
| 13 | ment of the Treasury, or any other Federa |
| 14 | agency responsible for enforcement activi- |
| 15 | ties under this section for purposes of en- |
| 16 | forcement under this section or other ap- |
| 17 | plicable law, or to the Comptroller General |
| 18 | of the United States in accordance with |
| 19 | paragraph (6). |
| 20 | "(4) USE AND DISCLOSURE BY PLAN SPON- |
| 21 | SORS.— |
| 22 | "(A) Prohibition.—A plan sponsor may |
| 23 | not— |
| 24 | "(i) fail or refuse to hire, or dis- |
| 25 | charge, any employee, or otherwise dis- |

| I | criminate against any employee with re- |
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| 2 | spect to the compensation, terms, condi- |
| 3 | tions, or privileges of employment of the |
| 4 | employee, because of information sub- |
| 5 | mitted under paragraph (1) or (2) attrib- |
| 6 | uted to the employee or a dependent of the |
| 7 | employee; or |
| 8 | "(ii) limit, segregate, or classify the |
| 9 | employees of the employer in any way that |
| 10 | would deprive or tend to deprive any em- |
| 11 | ployee of employment opportunities or oth- |
| 12 | erwise adversely affect the status of the |
| 13 | employee as an employee, because of infor- |
| 14 | mation submitted under paragraph (1) or |
| 15 | (2) attributed to the employee or a depend- |
| 16 | ent of the employee. |
| 17 | "(B) Disclosure and redisclosure.— |
| 18 | A plan sponsor shall not disclose the informa- |
| 19 | tion received under paragraph (1) or (2) ex- |
| 20 | cept— |
| 21 | "(i) to an occupational or other health |
| 22 | researcher if the research is conducted in |
| 23 | compliance with the regulations and pro- |
| 24 | tections provided for under part 46 of title |

| 1 | 45, Code of Federal Regulations (or suc- |
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| 2 | cessor regulations); |
| 3 | "(ii) in response to an order of a |
| 4 | court, except that the plan sponsor may |
| 5 | disclose only the information expressly au- |
| 6 | thorized by such order; |
| 7 | "(iii) to the Department of Health |
| 8 | and Human Services, the Department of |
| 9 | Labor, the Department of the Treasury, or |
| 10 | other Federal agency responsible for en- |
| 11 | forcement activities under this section; or |
| 12 | "(iv) to a contractor or agent for pur- |
| 13 | poses of health plan administration, if such |
| 14 | contractor or agent agrees, in writing, to |
| 15 | abide by the same use and disclosure re- |
| 16 | strictions as the plan sponsor. |
| 17 | "(C) Relationship to hipaa regula- |
| 18 | TIONS.—With respect to the regulations pro- |
| 19 | mulgated by the Secretary of Health and |
| 20 | Human Services under part C of title XI of the |
| 21 | Social Security Act (42 U.S.C. 1320d et seq.) |
| 22 | and section 264 of the Health Insurance Port- |
| 23 | ability and Accountability Act of 1996 (42 |
| 24 | U.S.C. 1320d–2), subparagraph (B) does not |
| 25 | prohibit a covered entity (as defined for pur- |

1 poses of such regulations) from any use or dis-2 closure of health information that is authorized 3 for the covered entity under such regulations. 4 The previous sentence does not affect the au-5 thority of such Secretary to modify such regula-6 tions. 7 "(D) Enforcement.— 8 "(i) In general.—The powers, pro-9 cedures, and remedies provided in section 207 of the Genetic Information Non-10 11 discrimination Act (42 U.S.C. 2000ff–6) to 12 a person alleging a violation of title II of 13 such Act shall be the powers, procedures, 14 and remedies this subparagraph provides 15 for any person alleging a violation of this 16 paragraph. 17 "(ii) Prohibition against retalia-18 TION.—No person shall discriminate 19 against any individual because such indi-20 vidual has opposed any act or practice 21 made unlawful by this paragraph or be-22 cause such individual made a charge, testi-23 fied, assisted, or participated in any man-24 ner in an investigation, proceeding, or

hearing under this paragraph. The rem-

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1 edies and procedures otherwise provided 2 for under this subparagraph shall be avail-3 able to aggrieved individuals with respect 4 to violations of this clause. 5 "(5) Reporting with respect to group 6 HEALTH PLANS OFFERED BY SMALL EMPLOYERS.— 7 For plan years beginning on or after January 1, 8 2025, not less frequently than annually, an entity 9 providing pharmacy benefit management services on 10 behalf of a group health plan that is not a covered 11 group health plan shall submit to the plan sponsor 12 of such group health plan a report in accordance 13 with this paragraph, and make such report available 14 to the plan sponsor in a machine-readable format. 15 Each such report shall include, with respect to the 16 applicable group health plan, the information de-17 scribed in subparagraphs (A), (D), (E), (F), (G), 18 and (H) of paragraph (1). 19 "(6) Submissions to gao.—An entity pro-20 viding pharmacy benefit management services on be-21 half of a group health plan shall submit to the 22 Comptroller General of the United States each of 23 the first 2 reports submitted to a plan sponsor under 24 paragraph (1) or (5) with respect to such plan, and 25 other such reports as requested, in accordance with TAM23528 RM0 S.L.C.

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.

| 1 | "(c) LIMITATIONS ON SPREAD PRICING.— |
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| 2 | "(1) In general.—A group health plan shall |
| 3 | not charge participants and beneficiaries, and an en- |
| 4 | tity providing pharmacy benefit management serv- |
| 5 | ices under such a plan shall not charge the plan or |
| 6 | participants and beneficiaries, a price for a prescrip- |
| 7 | tion drug that exceeds the price paid to the phar- |
| 8 | macy for such drug, excluding penalties paid by the |
| 9 | pharmacy (as described in paragraph (2)) to such |
| 10 | plan or entity. |
| 11 | "(2) Rule of construction.—For purposes |
| 12 | of paragraph (1), penalties paid by pharmacies in- |
| 13 | clude only the following: |
| 14 | "(A) A penalty paid if an original claim for |
| 15 | a prescription drug was submitted fraudulently |
| 16 | by the pharmacy to the plan or entity. |
| 17 | "(B) A penalty paid if the original claim |
| 18 | payment made by the plan, issuer, or entity to |
| 19 | the pharmacy was inconsistent with the reim- |
| 20 | bursement terms in any contract between the |
| 21 | pharmacy and the plan or entity. |
| 22 | "(C) A penalty paid if the pharmacist serv- |
| 23 | ices billed to the plan or entity were not ren- |
| 24 | dered by the pharmacy. |
| 25 | "(d) Full Rebate Pass-through to Plan.— |

| 1 | "(1) In general.—For plan years beginning |
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| 2 | on or after January 1, 2025, a third-party adminis- |
| 3 | trator of a group health plan or an entity providing |
| 4 | pharmacy benefit management services under such |
| 5 | health plan shall— |
| 6 | "(A) remit 100 percent of rebates, fees, al- |
| 7 | ternative discounts, and other remuneration re- |
| 8 | ceived from any applicable entity that are re- |
| 9 | lated to utilization of drugs under such health |
| 10 | plan, to the group health plan; and |
| 11 | "(B) ensure that any contract entered into |
| 12 | by such third-party administrator or entity pro- |
| 13 | viding pharmacy benefit management services |
| 14 | with an applicable entity remit 100 percent of |
| 15 | rebates, fees, alternative discounts, and other |
| 16 | remuneration received to the third-party admin- |
| 17 | istrator or entity providing pharmacy benefit |
| 18 | management services. |
| 19 | "(2) Form and manner of remittance.— |
| 20 | Such rebates, fees, alternative discounts, and other |
| 21 | remuneration shall be— |
| 22 | "(A) remitted to the group health plan in |
| 23 | a timely fashion after the period for which such |
| 24 | rebates, fees, alternative discounts, or other re- |
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| 1 | muneration is calculated, and in no case later |
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| 2 | than 90 days after the end of such period; |
| 3 | "(B) fully disclosed and enumerated to the |
| 4 | group health plan sponsor, as described in para- |
| 5 | graphs (1) and (4) of subsection (b); |
| 6 | "(C) available for audit by the plan spon- |
| 7 | sor, or a third-party designated by a plan spon- |
| 8 | sor not less than once per plan year; and |
| 9 | "(D) returned to the issuer or entity pro- |
| 10 | viding pharmaceutical benefit management |
| 11 | services by the group health plan if audits by |
| 12 | such entity indicate that the amounts received |
| 13 | are incorrect after such amounts have been paid |
| 14 | to the group health plan. |
| 15 | "(3) Audit of rebate contracts.—A third- |
| 16 | party administrator of a group health plan or an en- |
| 17 | tity providing pharmacy benefit management serv- |
| 18 | ices under such health plan shall make rebate con- |
| 19 | tracts with rebate aggregators or drug manufactur- |
| 20 | ers available for audit by such plan sponsor or des- |
| 21 | ignated third-party, subject to confidentiality agree- |
| 22 | ments to prevent re-disclosure of such contracts. |
| 23 | "(4) Auditors.—The applicable plan sponsor |
| 24 | may select an auditor for purposes of carrying out |
| 25 | 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.

82 "(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 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

13 14 same manner as such provisions apply to a penalty

or proceeding under section 1128A of the Social Se-

16 curity Act.

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"(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.

23 "(f) Rule of Construction.—Nothing in this sec-

tion shall be construed to permit a group health plan or

25 other entity to restrict disclosure to, or otherwise limit the

| 1 | access of, the Department of the Treasury to a report de- |
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| 2 | scribed in subsection (b)(1) or information related to com- |
| 3 | pliance with subsection (a) by such plan or entity. |
| 4 | "(g) Definitions.—In this section— |
| 5 | "(1) the term 'applicable entity' means— |
| 6 | "(A) a drug manufacturer, distributor, |
| 7 | wholesaler, rebate aggregator (or other pur- |
| 8 | chasing entity designed to aggregate rebates), |
| 9 | group purchasing organization, or associated |
| 10 | third party; |
| 11 | "(B) any subsidiary, parent, affiliate, or |
| 12 | subcontractor of a group health plan, health in- |
| 13 | surance issuer, entity that provides pharmacy |
| 14 | benefit management services on behalf of such |
| 15 | a plan or issuer, or any entity described in sub- |
| 16 | paragraph (A); or |
| 17 | "(C) such other entity as the Secretary, |
| 18 | the Secretary of Health and Human Services, |
| 19 | and the Secretary of Labor may specify through |
| 20 | rulemaking; |
| 21 | "(2) the term 'covered group health insurance |
| 22 | coverage' means health insurance coverage offered in |
| 23 | connection with a group health plan maintained by |
| 24 | a large employer; |

1 "(3) the term 'covered group health plan' 2 means a group health plan maintained by a large 3 employer; 4 "(4) the term 'gross spending', with respect to 5 prescription drug benefits under a group health plan 6 or health insurance coverage, means the amount 7 spent by a group health plan or health insurance 8 issuer on prescription drug benefits, calculated be-9 fore the application of manufacturer rebates, fees, 10 alternative discounts, or other remuneration; 11 "(5) the term 'large employer' means, in con-12 nection with a group health plan with respect to a 13 calendar year and a plan year, an employer who em-14 ployed an average of at least 50 employees on busi-15 ness days during the preceding calendar year and 16 who employs at least 1 employee on the first day of 17 the plan year; 18 "(6) the term 'net spending', with respect to 19 prescription drug benefits under a group health plan 20 or health insurance coverage, means the amount 21 spent by a group health plan or health insurance 22 issuer on prescription drug benefits, calculated after 23 the application of manufacturer rebates, fees, alter-24 native discounts, or other remuneration;

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| 1 | "(7) the term 'plan sponsor' has the meaning |
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| 2 | given such term in section 3(16)(B) of the Employee |
| 3 | Retirement Income Security Act of 1974 (29 U.S.C. |
| 4 | 1002(16)(B)); |
| 5 | "(8) the term 'remuneration' has the meaning |
| 6 | given such term by the Secretary, the Secretary of |
| 7 | Labor, and the Secretary of Health and Human |
| 8 | Services, through notice and comment rulemaking; |
| 9 | "(9) the term 'small employer' means, in con- |
| 10 | nection with a group health plan with respect to a |
| 11 | calendar year and a plan year, an employer who em- |
| 12 | ployed an average of at least 1 but not more than |
| 13 | 49 employees on business days during the preceding |
| 14 | calendar year and who employs at least 1 employee |
| 15 | on the first day of the plan year; and |
| 16 | "(10) the term 'wholesale acquisition cost' has |
| 17 | the meaning given such term in section |
| 18 | 1847A(c)(6)(B) of the Social Security Act (42) |
| 19 | U.S.C. $1395w-3a(e)(6)(B)$).". |
| 20 | (2) CLERICAL AMENDMENT.—The table of sec- |
| 21 | tions for subchapter B of chapter 100 of the Inter- |
| 22 | nal Revenue Code of 1986 is amended by adding at |
| 23 | the end the following new item: |
| | "Sec. 9826. Oversight of entities that provide pharmacy benefit management |

services.".

^{24 (}d) Funding.—

| 1 | (1) For purposes of carrying out the amend- |
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| 2 | ments made by subsection (a), there are appro- |
| 3 | priated to the Centers for Medicare & Medicaid |
| 4 | Services, out of amounts in the Treasury not other- |
| 5 | wise appropriated, \$80,000,000 for fiscal year 2024. |
| 6 | (2) For purposes of carrying out the amend- |
| 7 | ments made by subsection (b), there are appro- |
| 8 | priated to the Department of Labor, out of amounts |
| 9 | in the Treasury not otherwise appropriated, |
| 10 | \$43,750,000 for fiscal year 2024. |
| 11 | (e) ASPE Study.—The Assistant Secretary for |
| 12 | Planning and Evaluation of the Department of Health and |
| 13 | Human Services shall conduct or commission a study on |
| 14 | how the United States health care market would be im- |
| 15 | pacted by potential regulatory changes disallowing manu- |
| 16 | facturer rebates in the manner and to the extent allowed |
| 17 | on the date of enactment of this Act, with a focus on the |
| 18 | impact to stakeholders in the commercial insurance mar- |
| 19 | ket, and, not later than 1 year after the date of enactment |
| 20 | of this Act, submit a report to Congress on the results |
| 21 | of such study. Such study and report shall consider the |
| 22 | following: |
| 23 | (1) The impact on the impact of making no |
| 24 | such regulatory changes, as well as potential behav- |
| 25 | ioral changes by plan sponsors, members, and phar- |
| | |

1 maceutical manufacturers, such as tighter 2 formularies, changes to price concessions, changes in 3 utilization, if such regulatory changes are made. 4 The mechanics needed in the pharma-5 ceutical supply chain (whether existing or not) to 6 move a manufacturer rebate to the point of sale. 7 (3) The feasibility of a partial point-of-sale 8 manufacturer rebate versus a full point-of-sale man-9 ufacturer rebate. 10 (4) The impact on patient out-of-pocket costs, 11 premiums, and other cost-sharing. 12 (5) Possible behavioral changes by other third 13 parties in the pharmaceutical supply chain including 14 drug manufacturer, distributor, wholesaler, rebate 15 aggregators, pharmacy services administrative orga-16 nizations, or group purchasing organizations. 17 (6) Behavioral changes between entities that 18 contract with pharmaceutical manufacturers and 19 pharmaceutical supply chain. 20 (7) Alternative price negotiation mechanisms, 21 including the impact of the Act of June 19, 1936 22 (commonly known as the "Robinson-Patman Act"; 23 49 Stat. 1526, chapter 592; 15 U.S.C. 13a et seq.), 24 and the amendments made by that Act, on drug

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pricing negotiations.

| 1 | (8) The impact on pharmacies, including phar- |
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| 2 | macy rebates, pharmacy fees, and dispensing chan- |
| 3 | nels. |
| 4 | (f) GAO STUDY.— |
| 5 | (1) In general.—Not later than January 1. |
| 6 | 2029, the Comptroller General of the United States |
| 7 | shall report to Congress on— |
| 8 | (A) pharmacy networks of group health |
| 9 | plans, health insurance issuers, and entities |
| 10 | providing pharmacy benefit management serv- |
| 11 | ices under such group health plan or group or |
| 12 | individual health insurance coverage, including |
| 13 | networks that have pharmacies that are under |
| 14 | common ownership (in whole or part) with |
| 15 | group health plans, health insurance issuers, or |
| 16 | entities providing pharmacy benefit manage- |
| 17 | ment services or pharmacy benefit administra- |
| 18 | tive services under group health plan or group |
| 19 | or individual health insurance coverage; |
| 20 | (B) as it relates to pharmacy networks |
| 21 | that include pharmacies under common owner- |
| 22 | ship described in subparagraph (A)— |
| 23 | (i) whether such networks are de- |
| 24 | signed to encourage participants and bene- |
| 25 | ficiaries of a plan or coverage to use such |

| 1 | pharmacies over other network pharmacies |
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| 2 | for specific services or drugs, and if so, the |
| 3 | reasons the networks give for encouraging |
| 4 | use of such pharmacies; and |
| 5 | (ii) whether such pharmacies are used |
| 6 | by participants and beneficiaries dispropor- |
| 7 | tionately more in the aggregate or for spe- |
| 8 | cific services or drugs compared to other |
| 9 | network pharmacies; |
| 10 | (C) whether group health plans and health |
| 11 | insurance issuers offering group or individual |
| 12 | health insurance coverage have options to elect |
| 13 | different network pricing arrangements in the |
| 14 | marketplace with entities that provide phar- |
| 15 | macy benefit management services, the preva- |
| 16 | lence of electing such different network pricing |
| 17 | arrangements; |
| 18 | (D) pharmacy network design parameters |
| 19 | that encourage participants and beneficiaries in |
| 20 | the plan or coverage to fill prescriptions at mai |
| 21 | order, specialty, or retail pharmacies that are |
| 22 | wholly or partially-owned by that issuer or enti- |
| 23 | ty; and |
| 24 | (E) the degree to which mail order, spe- |
| 25 | cialty, or retail pharmacies that dispense pre- |
| | |

| scription drugs to participants and beneficiaries |
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| in a group health plan or health insurance cov- |
| erage that are under common ownership (in |
| whole or part) with group health plans, health |
| insurance issuers, or entities providing phar- |
| macy benefit management services or pharmacy |
| benefit administrative services under group |
| health plan or group or individual health insur- |
| ance 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 net- |
| work of that plan, issuer, or entity that are not |
| wholly or partially owned by the health insur- |
| ance issuer or entity providing pharmacy ben- |
| efit 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 iden- |
| tification of a specific individual, plan sponsor, |
| health insurance issuer, plan, or entity pro- |

| 1 | viding pharmacy benefit management services; |
|---|---|
| 2 | or |
| 3 | (B) commercial or financial information |
| 4 | that is privileged or confidential. |
| 5 | (3) Definitions.—In this subsection, the |
| 6 | terms "group health plan", "health insurance cov- |
| 7 | erage", and "health insurance issuer" have the |
| 8 | meanings given such terms in section 2791 of the |
| 9 | Public Health Service Act (42 U.S.C. 300gg-91). |