

# Calendar No. 113

118TH CONGRESS  
1ST SESSION

# S. 1339

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

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## IN THE SENATE OF THE UNITED STATES

APRIL 27, 2023

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

JUNE 22, 2023

Reported by Mr. SANDERS, with an amendment

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

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## A BILL

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

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmacy Benefit  
5 ~~Manager Reform Act~~”.

1 **SEC. 2. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
 2 **MACY BENEFIT MANAGEMENT SERVICES.**

3 (a) PHSA.—Title XXVII of the Public Health Serv-  
 4 ice Act (42 U.S.C. 300gg et seq.) is amended—

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

7 **“SEC. 2799A-11. OVERSIGHT OF ENTITIES THAT PROVIDE**  
 8 **PHARMACY BENEFIT MANAGEMENT SERV-**  
 9 **ICES.**

10 “(a) IN GENERAL.—For plan years beginning on or  
 11 after January 1, 2025, a group health plan or health in-  
 12 surance issuer offering group health insurance coverage  
 13 or an entity providing pharmacy benefit management serv-  
 14 ices on behalf of such a plan or issuer shall not enter into  
 15 a contract with an applicable entity that limits the disclo-  
 16 sure of information to plan sponsors in such a manner  
 17 that prevents the plan or issuer, or an entity providing  
 18 pharmacy benefit management services on behalf of a plan  
 19 or issuer, from making the reports described in subsection  
 20 (b).

21 “(b) REPORTS.—

22 “(1) IN GENERAL.—For plan years beginning  
 23 on or after January 1, 2025, not less frequently  
 24 than annually, an entity providing pharmacy benefit  
 25 management services on behalf of a covered group  
 26 health plan shall submit to the plan sponsor of such

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

8 “(A) as applicable, information collected  
9 from drug manufacturers by such issuer or en-  
10 tity on the total amount of copayment assist-  
11 ance dollars paid, or copayment cards applied,  
12 that were funded by the drug manufacturer  
13 with respect to the participants and bene-  
14 ficiaries in such plan;

15 “(B) a list of each drug covered by such  
16 plan or entity providing pharmacy benefit man-  
17 agement services that was billed during the re-  
18 porting period, including, with respect to each  
19 such drug during the reporting period—

20 “(i) the brand name, generic or non-  
21 proprietary name, and National Drug  
22 Code;

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

1           ber of prescription claims for the drug (in-  
2           cluding original prescriptions and refills);  
3           and the total number of dosage units of  
4           the drug dispensed across the reporting pe-  
5           riod;

6           “(iii) for each claim or dosage unit de-  
7           scribed in clause (ii); the type of dis-  
8           pensing channel used, such as retail, mail  
9           order, or specialty pharmacy;

10          “(iv) the wholesale acquisition cost,  
11          listed as cost per days supply, cost per dos-  
12          age unit, and cost per typical course of  
13          treatment (as applicable);

14          “(v) the total out-of-pocket spending  
15          by participants and beneficiaries on such  
16          drug after application of any benefits  
17          under the plan or coverage, including par-  
18          ticipant and beneficiary spending through  
19          copayments, coinsurance, and deductibles,  
20          but not including any amounts spent by  
21          participants and beneficiaries on drugs not  
22          covered under the plan or coverage or for  
23          which no claim is submitted to the plan or  
24          coverage; and

1           “(vi) for any drug for which gross  
2           spending by the plan exceeded \$10,000  
3           and that is one of the 50 prescription  
4           drugs for which the group health plan  
5           spent the most on prescription drug bene-  
6           fits during the reporting period—

7           “(I) a list of all other drugs in  
8           the same therapeutic class, including  
9           brand name drugs and biological  
10          products and generic drugs or bio-  
11          similar biological products that are in  
12          the same therapeutic class as such  
13          drug; and

14          “(II) if applicable, the rationale  
15          for preferred formulary placement of  
16          such drug in that therapeutic class,  
17          selected from a list of standard ra-  
18          tionales established by the Secretary;

19          “(C) a list of each therapeutic class of  
20          drugs that were dispensed under the health  
21          plan during the reporting period, and, with re-  
22          spect to each such therapeutic class of drugs,  
23          during the reporting period—

1           “(i) total gross spending by the plan;  
2 before rebates, fees, alternative discounts,  
3 or other remuneration;

4           “(ii) the number of participants and  
5 beneficiaries who filled a prescription for a  
6 drug in that class;

7           “(iii) if applicable to that class, a de-  
8 scription of the formulary tiers and utiliza-  
9 tion management mechanisms (such as  
10 prior authorization or step therapy) em-  
11 ployed for drugs in that class;

12           “(iv) the total out-of-pocket spending  
13 by participants and beneficiaries, including  
14 participant and beneficiary spending  
15 through copayments, coinsurance, and  
16 deductibles; and

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

20           “(I) the amount received, or ex-  
21 pected to be received, by such entity,  
22 from an applicable entity, in rebates,  
23 fees, alternative discounts, or other  
24 remuneration that—

1                   “(aa) has been paid, or will  
2                   be paid, by such an applicable  
3                   entity for claims incurred during  
4                   the reporting period; or

5                   “(bb) is related to utilization  
6                   of drugs or drug spending;

7                   “(H) the total net spending by  
8                   the health plan on that class of drugs;  
9                   and

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

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

24                  “(E) the total amount received, or ex-  
25                  pected to be received, by the health plan, from

1 an applicable entity, in rebates, fees, alternative  
2 discounts, and other remuneration received  
3 from any such entities, related to utilization of  
4 drug or drug spending under that health plan  
5 during the reporting period;

6 “(F) the total net spending on prescription  
7 drugs by the health plan during the reporting  
8 period;

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

17 “(H) a summary document that includes  
18 such information described in subparagraphs  
19 (A) through (G) as the Secretary determines  
20 useful for plan sponsors for purposes of select-  
21 ing pharmacy benefit management services,  
22 such as an estimated net price to plan sponsor  
23 and participant or beneficiary, a cost per claim,  
24 the fee structure or reimbursement model, and  
25 estimated cost per participant or beneficiary.



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

3           “(A) IN GENERAL.—A health insurance  
4           issuer offering covered group health insurance  
5           coverage or an entity providing pharmacy ben-  
6           efit management services under a covered group  
7           health plan or covered group health insurance  
8           coverage shall submit, together with the report  
9           under paragraph (1), a supplementary report  
10          every 6 months to the plan sponsor that in-  
11          cludes—

12           “(i) an explanation of any benefit de-  
13          sign parameters that encourage or require  
14          participants and beneficiaries in the plan  
15          or coverage to fill prescriptions at mail  
16          order, specialty, or retail pharmacies that  
17          are wholly or partially-owned by that issuer  
18          or entity providing pharmacy benefit man-  
19          agement services under such plan or cov-  
20          erage, including mandatory mail and spe-  
21          cialty home delivery programs, retail and  
22          mail auto-refill programs, and copayment  
23          incentives funded by an entity providing  
24          pharmacy benefit management services;

1           “(ii) the percentage of total prescrip-  
2           tions charged to the plan, coverage, or par-  
3           ticipants and beneficiaries in the plan or  
4           coverage, that were dispensed by mail  
5           order, specialty, or retail pharmacies that  
6           are wholly or partially-owned by the issuer  
7           or entity providing pharmacy benefit man-  
8           agement services; and

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

15               “(I) the amounts charged, per  
16               dosage unit, per course of treatment,  
17               per 30-day supply, and per 90-day  
18               supply, with respect to participants  
19               and beneficiaries in the plan or cov-  
20               erage, including amounts charged to  
21               the plan or coverage and amounts  
22               charged to the participants and bene-  
23               ficiaries;

24               “(II) the median amount charged  
25               to the plan or coverage, per dosage

1 unit, per course of treatment, per 30-  
2 day supply, and per 90-day supply, in-  
3 cluding amounts paid by the partici-  
4 pants and beneficiaries, when the  
5 same drug is dispensed by other phar-  
6 macies that are not wholly or par-  
7 tially-owned by the issuer or entity  
8 and that are included in the pharmacy  
9 network of that plan or coverage;

10 “(III) the interquartile range of  
11 the costs, per dosage unit, per course  
12 of treatment, per 30-day supply, and  
13 per 90-day supply, including amounts  
14 paid by the participants and bene-  
15 ficiaries, when the same drug is dis-  
16 pensed by other pharmacies that are  
17 not wholly or partially-owned by the  
18 issuer or entity and that are included  
19 in the pharmacy network of that plan  
20 or coverage;

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

1            participants and beneficiaries, that is  
2            available from any pharmacy included  
3            in the network of the plan or cov-  
4            erage;

5            “(V) the net acquisition cost per  
6            dosage unit and for a 30 day-supply,  
7            and the acquisition cost per typical  
8            course of treatment, if the drug is  
9            subject to a maximum price discount;  
10           and

11           “(VI) other information with re-  
12           spect to the cost of the drug, as deter-  
13           mined by the Secretary, such as aver-  
14           age sales price, wholesale acquisition  
15           cost, and national average drug acqui-  
16           sition cost per dosage unit, per typical  
17           course of treatment, or per 30-day  
18           supply, for such drug, including  
19           amounts charged to the plan or issuer  
20           and participants and beneficiaries  
21           among all pharmacies included in the  
22           network of the plan or coverage.

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

1           erage that is not covered group health insur-  
2           ance coverage or an entity providing pharmacy  
3           benefit management services under a group  
4           health plan that is not a covered group health  
5           plan or under group health insurance coverage  
6           that is not covered group health insurance cov-  
7           erage that conducts transactions with a wholly  
8           or partially-owned pharmacy shall submit, to-  
9           gether with the report under paragraph (1), a  
10          supplementary report every 6 months to the  
11          plan sponsor that includes the information de-  
12          scribed in clauses (i) and (ii) of subparagraph  
13          (A).

14          “(3) PRIVACY REQUIREMENTS.—

15                 “(A) RELATIONSHIP TO HIPAA REGULA-  
16                 TIONS.—Nothing in this section shall be con-  
17                 strued to modify the requirements for the ere-  
18                 ation, receipt, maintenance, or transmission of  
19                 protected health information under the privacy,  
20                 security, breach notification, and enforcement  
21                 regulations in parts 160 and 164 of title 45,  
22                 Code of Federal Regulations (or successor regu-  
23                 lations).

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

1 summary health information, as defined in sec-  
2 tion 164.504(a) of title 45, Code of Federal  
3 Regulations (or successor regulations).

4 “(C) CLARIFICATION REGARDING CERTAIN  
5 DISCLOSURES OF INFORMATION.—

6 “(i) REASONABLE RESTRICTIONS.—

7 Nothing in this section prevents a health  
8 insurance issuer offering group health in-  
9 surance coverage or an entity providing  
10 pharmacy benefit management services on  
11 behalf of a group health plan or group  
12 health insurance coverage from placing  
13 reasonable restrictions on the public disclo-  
14 sure of the information contained in a re-  
15 port under paragraph (1) or (2).

16 “(ii) LIMITATIONS.—A health insur-  
17 ance issuer offering group health insurance  
18 coverage or an entity providing pharmacy  
19 benefit management services on behalf of a  
20 group health plan or group health insur-  
21 ance coverage may not restrict disclosure  
22 of such reports to the Department of  
23 Health and Human Services, the Depart-  
24 ment of Labor, the Department of the  
25 Treasury, or any other Federal agency re-

1           sponsible for enforcement activities under  
2           this section for purposes of enforcement  
3           under this section or other applicable law,  
4           or to the Comptroller General of the  
5           United States in accordance with para-  
6           graph (6).

7           ~~“(4) USE AND DISCLOSURE BY PLAN SPON-~~  
8           ~~SORS.—~~

9           ~~“(A) PROHIBITION.—A plan sponsor may~~  
10          ~~not—~~

11           ~~“(i) fail or refuse to hire, or dis-~~  
12           ~~charge, any employee, or otherwise dis-~~  
13           ~~criminate against any employee with re-~~  
14           ~~spect to the compensation, terms, condi-~~  
15           ~~tions, or privileges of employment of the~~  
16           ~~employee, because of information sub-~~  
17           ~~mitted under paragraph (1) or (2) attrib-~~  
18           ~~uted to the employee or a dependent of the~~  
19           ~~employee; or~~

20           ~~“(ii) limit, segregate, or classify the~~  
21           ~~employees of the employer in any way that~~  
22           ~~would deprive or tend to deprive any em-~~  
23           ~~ployee of employment opportunities or oth-~~  
24           ~~erwise adversely affect the status of the~~  
25           ~~employee as an employee, because of infor-~~

1           mation submitted under paragraph (1) or  
2           (2) attributed to the employee or a depend-  
3           ent of the employee.

4           “(B) DISCLOSURE AND REDISCLOSURE.—

5           A plan sponsor shall not disclose the informa-  
6           tion received under paragraph (1) or (2) ex-  
7           cept—

8           “(i) to an occupational or other health  
9           researcher if the research is conducted in  
10          compliance with the regulations and pro-  
11          tections provided for under part 46 of title  
12          45, Code of Federal Regulations (or suc-  
13          cessor regulations);

14          “(ii) in response to an order of a  
15          court, except that the plan sponsor may  
16          disclose only the information expressly au-  
17          thorized by such order;

18          “(iii) to the Department of Health  
19          and Human Services, the Department of  
20          Labor, the Department of the Treasury, or  
21          other Federal agency responsible for en-  
22          forcement activities under this section; or

23          “(iv) to a contractor or agent for pur-  
24          poses of health plan administration, if such  
25          contractor or agent agrees, in writing, to



1 abide by the same use and disclosure re-  
2 strictions as the plan sponsor.

3 “(C) ~~RELATIONSHIP TO HIPAA REGULA-~~  
4 ~~TIONS.~~—With respect to the regulations pro-  
5 mulgated by the Secretary of Health and  
6 Human Services under part C of title XI of the  
7 Social Security Act and section 264 of the  
8 Health Insurance Portability and Accountability  
9 Act of 1996, subparagraph (B) does not pro-  
10 hibit a covered entity (as defined for purposes  
11 of such regulations) from any use or disclosure  
12 of health information that is authorized for the  
13 covered entity under such regulations. The pre-  
14 vious sentence does not affect the authority of  
15 such Secretary to modify such regulations.

16 “(D) ~~ENFORCEMENT.~~—

17 “(i) ~~IN GENERAL.~~—The powers, pro-  
18 cedures, and remedies provided in section  
19 207 of the Genetic Information Non-  
20 discrimination Act to a person alleging a  
21 violation of title II of such Act shall be the  
22 powers, procedures, and remedies this sub-  
23 paragraph provides for any person alleging  
24 a violation of this paragraph.

1           “(ii) PROHIBITION AGAINST RETALIA-  
2           TION.—No person shall discriminate  
3           against any individual because such indi-  
4           vidual has opposed any act or practice  
5           made unlawful by this paragraph or be-  
6           cause such individual made a charge, testi-  
7           fied, assisted, or participated in any man-  
8           ner in an investigation, proceeding, or  
9           hearing under this paragraph. The rem-  
10          edies and procedures otherwise provided  
11          for under this subparagraph shall be avail-  
12          able to aggrieved individuals with respect  
13          to violations of this clause.

14          “(5) ADDITIONAL REPORTING.—

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

1 mat, and such other formats as the Secretary,  
 2 the Secretary of Health and Human Services,  
 3 and the Secretary of the Treasury may deter-  
 4 mine. Each such report shall include, with re-  
 5 spect to the applicable group health plan, the  
 6 information described in subparagraphs (A),  
 7 (D), (E), (F), (G), and (H) of paragraph (1).

8 “(B) OPT-IN FOR GROUP HEALTH INSUR-  
 9 ANCE COVERAGE.—

10 “(i) IN GENERAL.—A plan sponsor  
 11 may, on an annual basis, beginning with  
 12 plan years beginning on or after January  
 13 1, 2025, elect to require a health insurance  
 14 issuer offering group health insurance cov-  
 15 erage to submit to such plan sponsor a re-  
 16 port in accordance with this subsection.

17 “(ii) CONTENTS OF REPORTS.—

18 “(I) COVERED GROUP HEALTH  
 19 INSURANCE COVERAGE.—In the case  
 20 of an issuer that offers covered group  
 21 health insurance coverage, a report  
 22 provided pursuant to clause (i) shall  
 23 include, with respect to the applicable  
 24 covered group health insurance cov-  
 25 erage, the information required under

1 paragraph (1) for covered group  
2 health plans.

3 “(II) OTHER GROUP HEALTH IN-  
4 SURANCE COVERAGE.—In the case of  
5 an issuer that offers group health in-  
6 surance coverage that is not covered  
7 group health insurance, a report pro-  
8 vided pursuant to clause (i) shall in-  
9 clude, with respect to the applicable  
10 group health insurance coverage, the  
11 information described in subpara-  
12 graphs (A), (D), (E), (F), and (G) of  
13 paragraph (1).

14 “(iii) APPLICATION.—For purposes of  
15 reports submitted in accordance with this  
16 subparagraph, paragraph (1) shall be ap-  
17 plied by substituting ‘group health insur-  
18 ance coverage’ or ‘health insurance issuer’,  
19 as applicable, for ‘group health plan’,  
20 ‘group plan’, and ‘plan’ where such terms  
21 appear in such paragraph.

22 “(iv) REQUIRED REPORTING FOR ALL  
23 GROUP HEALTH INSURANCE COVERAGE.—  
24 Each health insurance issuer of health in-  
25 surance coverage shall annually submit the

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

5 “(6) SUBMISSIONS TO GAO.—A health insur-  
6 ance issuer offering group health insurance coverage  
7 or an entity providing pharmacy benefit manage-  
8 ment services on behalf of a group health plan shall  
9 submit to the Comptroller General of the United  
10 States each of the first 2 reports submitted to a  
11 plan sponsor under paragraph (1) or (5) with re-  
12 spect to such coverage or plan, and other such re-  
13 ports as requested, in accordance with the privacy  
14 requirements under paragraph (3), and such other  
15 information that the Comptroller General determines  
16 necessary to carry out the study under section 2(f)  
17 of the Pharmacy Benefit Manager Reform Act.

18 “(7) STANDARD FORMATS.—

19 “(A) IN GENERAL.—Not later than June  
20 1, 2024, the Secretary, the Secretary of Labor,  
21 and the Secretary of the Treasury shall specify,  
22 through rulemaking, standard formats for  
23 health insurance issuers and entities providing  
24 pharmacy benefit management services to sub-  
25 mit reports required under this subsection.

1           “(B) LIMITED FORM OF REPORT.—The  
2           Secretary, the Secretary of Labor, and the Sec-  
3           retary of the Treasury shall define through  
4           rulemaking a limited form of the reports under  
5           paragraphs (1) and (2) required to be sub-  
6           mitted to plan sponsors who also are drug man-  
7           ufacturers, drug wholesalers, entities providing  
8           pharmacy benefit management services, or  
9           other direct participants in the drug supply  
10          chain, in order to prevent anti-competitive be-  
11          havior.

12          “(c) LIMITATIONS ON SPREAD PRICING.—

13           “(1) IN GENERAL.—For plan years beginning  
14          on or after January 1, 2025, a group health plan or  
15          health insurance issuer offering group or individual  
16          health insurance coverage shall not charge partici-  
17          pants and beneficiaries, and an entity providing  
18          pharmacy benefit management services under such a  
19          plan or coverage shall not charge the plan, issuer, or  
20          participants and beneficiaries, a price for a prescrip-  
21          tion drug that exceeds the price paid to the phar-  
22          macy for such drug, excluding penalties paid by the  
23          pharmacy (as described in paragraph (2)) to such  
24          plan, issuer, or entity.

1           “(2) ~~RULE OF CONSTRUCTION.~~—For purposes  
2 of paragraph (1), penalties paid by pharmacies in-  
3 clude only the following:

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

7           “(B) A penalty paid if the original claim  
8 payment made by the plan, issuer, or entity to  
9 the pharmacy was inconsistent with the reim-  
10 bursement terms in any contract between the  
11 pharmacy and the plan, issuer, or entity.

12           “(C) A penalty paid if the pharmacist serv-  
13 ices billed to the plan, issuer, or entity were not  
14 rendered by the pharmacy.

15           “(d) ~~FULL REBATE PASS-THROUGH TO PLAN.~~—

16           “(1) ~~IN GENERAL.~~—For plan years beginning  
17 on or after January 1, 2025, a third-party adminis-  
18 trator of a group health plan, a health insurance  
19 issuer offering group health insurance coverage, or  
20 an entity providing pharmacy benefit management  
21 services under such health plan or health insurance  
22 coverage shall—

23           “(A) remit 100 percent of rebates, fees, al-  
24 ternative discounts, and other remuneration re-  
25 ceived from any applicable entity that are re-

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

4           “(B) ensure that any contract entered into  
5           by such third-party administrator, health insur-  
6           ance issuer, or entity providing pharmacy ben-  
7           efit management services with an applicable en-  
8           tity remit 100 percent of rebates, fees, alter-  
9           native discounts, and other remuneration re-  
10          ceived to the third-party administrator, health  
11          insurance issuer, or entity providing pharmacy  
12          benefit management services.

13          “(2) FORM AND MANNER OF REMITTANCE.—

14          Such rebates, fees, alternative discounts, and other  
15          remuneration shall be—

16                 “(A) remitted to the group health plan or  
17                 group health insurance coverage in a timely  
18                 fashion after the period for which such rebates,  
19                 fees, alternative discounts, or other remunera-  
20                 tion is calculated, and in no case later than 90  
21                 days after the end of such period;

22                 “(B) fully disclosed and enumerated to the  
23                 group health plan sponsor, as described in para-  
24                 graphs (1) and (4) of subsection (b);



1           “(C) available for audit by the plan spon-  
2           sor, or a third-party designated by a plan spon-  
3           sor not less than once per plan year; and

4           “(D) returned to the issuer or entity pro-  
5           viding pharmaceutical benefit management  
6           services by the group health plan if audits by  
7           such issuer or entity indicate that the amounts  
8           received are incorrect after such amounts have  
9           been paid to the group health plan.

10          “(3) AUDIT OF REBATE CONTRACTS.—A third-  
11          party administrator of a group health plan, a health  
12          insurance issuer offering group health insurance cov-  
13          erage, or an entity providing pharmacy benefit man-  
14          agement services under such health plan or health  
15          insurance coverage shall make rebate contracts with  
16          rebate aggregators or drug manufacturers available  
17          for audit by such plan sponsor or designated third-  
18          party, subject to confidentiality agreements to pre-  
19          vent re-disclosure of such contracts.

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

23          “(5) RULE OF CONSTRUCTION.—Nothing in  
24          this subsection shall be construed to prohibit pay-  
25          ments to entities offering pharmacy benefit manage-

1 ment services for bona fide services using a fee  
2 structure not contemplated by this subsection, pro-  
3 vided that such fees are transparent to group health  
4 plans and health insurance issuers.

5 “(e) ENFORCEMENT.—

6 “(1) IN GENERAL.—The Secretary, in consulta-  
7 tion with the Secretary of Labor and the Secretary  
8 of the Treasury, shall enforce this section.

9 “(2) FAILURE TO PROVIDE TIMELY INFORMA-  
10 TION.—A health insurance issuer or an entity pro-  
11 viding pharmacy benefit management services that  
12 violates subsection (a) or fails to provide information  
13 required under subsection (b); a group health plan;  
14 health insurance issuer, or entity providing phar-  
15 macy benefit management services that violates sub-  
16 section (c); or a third-party administrator of a group  
17 health plan, a health insurance issuer offering group  
18 health insurance coverage, or an entity providing  
19 pharmacy benefit management services that violates  
20 subsection (d) shall be subject to a civil monetary  
21 penalty in the amount of \$10,000 for each day dur-  
22 ing which such violation continues or such informa-  
23 tion is not disclosed or reported.

24 “(3) FALSE INFORMATION.—A health insurance  
25 issuer, entity providing pharmacy benefit manage-

1       ment services, or drug manufacturer that knowingly  
2       provides false information under this section shall be  
3       subject to a civil money penalty in an amount not  
4       to exceed \$100,000 for each item of false informa-  
5       tion. Such civil money penalty shall be in addition to  
6       other penalties as may be prescribed by law.

7           “(4) PROCEDURE.—The provisions of section  
8       1128A of the Social Security Act, other than sub-  
9       sections (a) and (b) and the first sentence of sub-  
10      section (c)(1) of such section shall apply to civil  
11      monetary penalties under this subsection in the  
12      same manner as such provisions apply to a penalty  
13      or proceeding under section 1128A of the Social Se-  
14      curity Act.

15          “(5) WAIVERS.—The Secretary may waive pen-  
16      alties under paragraph (2), or extend the period of  
17      time for compliance with a requirement of this sec-  
18      tion, for an entity in violation of this section that  
19      has made a good-faith effort to comply with this sec-  
20      tion.

21          “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
22      tion shall be construed to permit a health insurance issuer,  
23      group health plan, or other entity to restrict disclosure to,  
24      or otherwise limit the access of, the Department of Health  
25      and Human Services to a report described in subsection

1 (b)(1) or information related to compliance with sub-  
2 section (a) by such issuer, plan, or entity.

3 “(g) DEFINITIONS.—In this section—

4 “(1) the term ‘applicable entity’ means—

5 “(A) a drug manufacturer, distributor,  
6 wholesaler, rebate aggregator (or other pur-  
7 chasing entity designed to aggregate rebates),  
8 group purchasing organization, or associated  
9 third party;

10 “(B) any subsidiary, parent, affiliate, or  
11 subcontractor of a group health plan, health in-  
12 surance issuer, entity that provides pharmacy  
13 benefit management services on behalf of such  
14 a plan or issuer, or any entity described in sub-  
15 paragraph (A); or

16 “(C) such other entity as the Secretary,  
17 the Secretary of Labor, and the Secretary of  
18 the Treasury may specify through rulemaking;

19 “(2) the term ‘covered group health insurance  
20 coverage’ means health insurance coverage offered in  
21 connection with a group health plan maintained by  
22 a large employer;

23 “(3) the term ‘covered group health plan’  
24 means a group health plan maintained by a large  
25 employer;

1           “(4) the term ‘gross spending’, with respect to  
2           prescription drug benefits under a group health plan  
3           or health insurance coverage, means the amount  
4           spent by a group health plan or health insurance  
5           issuer on prescription drug benefits, calculated be-  
6           fore the application of manufacturer rebates, fees,  
7           alternative discounts, or other remuneration;

8           “(5) the term ‘large employer’ means, in con-  
9           nection with a group health plan with respect to a  
10          calendar year and a plan year, an employer who em-  
11          ployed an average of at least 50 employees on busi-  
12          ness days during the preceding calendar year and  
13          who employs at least 1 employee on the first day of  
14          the plan year;

15          “(6) the term ‘net spending’, with respect to  
16          prescription drug benefits under a group health plan  
17          or health insurance coverage, means the amount  
18          spent by a group health plan or health insurance  
19          issuer on prescription drug benefits, calculated after  
20          the application of manufacturer rebates, fees, alter-  
21          native discounts, or other remuneration;

22          “(7) the term ‘plan sponsor’ has the meaning  
23          given such term in section 3(16)(B) of the Employee  
24          Retirement Income Security Act of 1974;

1           “(8) the term ‘remuneration’ has the meaning  
2 given such term by the Secretary, the Secretary of  
3 Labor, and the Secretary of the Treasury, through  
4 notice and comment rulemaking;

5           “(9) the term ‘small employer’ means, in con-  
6 nection with a group health plan with respect to a  
7 calendar year and a plan year, an employer who em-  
8 ployed an average of at least 1 but not more than  
9 49 employees on business days during the preceding  
10 calendar year and who employs at least 1 employee  
11 on the first day of the plan year; and

12           “(10) the term ‘wholesale acquisition cost’ has  
13 the meaning given such term in section  
14 1847A(e)(6)(B) of the Social Security Act.”; and

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

16           (A) in subsection (a)—

17           (i) in paragraph (1), by inserting  
18           “(other than section 2799A-11)” after  
19           “part D”; and

20           (ii) in paragraph (2), by inserting  
21           “(other than section 2799A-11)” after  
22           “part D”;

23           (B) in subsection (b)—

1 (i) in paragraph (1), by inserting  
 2 “(other than section 2799A-11)” after  
 3 “part D”;

4 (ii) in paragraph (2)(A), by inserting  
 5 “(other than section 2799A-11)” after  
 6 “part D”; and

7 (iii) in paragraph (2)(C)(ii), by insert-  
 8 ing “(other than section 2799A-11)” after  
 9 “part D”.

10 (b) ERISA.—

11 (1) IN GENERAL.—Subtitle B of title I of the  
 12 Employee Retirement Income Security Act of 1974  
 13 (29 U.S.C. 1021 et seq.) is amended—

14 (A) in subpart B of part 7 (29 U.S.C.  
 15 1185 et seq.), by adding at the end the fol-  
 16 lowing:

17 **“SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
 18 **MACY BENEFIT MANAGEMENT SERVICES.**

19 “(a) IN GENERAL.—For plan years beginning on or  
 20 after January 1, 2025, a group health plan (or health in-  
 21 surance issuer offering group health insurance coverage  
 22 in connection with such a plan) or an entity providing  
 23 pharmacy benefit management services on behalf of such  
 24 a plan or issuer shall not enter into a contract with an  
 25 applicable entity that limits the disclosure of information

1 to plan sponsors in such a manner that prevents the plan  
2 or issuer, or an entity providing pharmacy benefit manage-  
3 ment services on behalf of a plan or issuer, from making  
4 the reports described in subsection (b).

5 “(b) REPORTS.—

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

17 “(A) as applicable, information collected  
18 from drug manufacturers by such issuer or en-  
19 tity on the total amount of copayment assist-  
20 ance dollars paid, or copayment cards applied,  
21 that were funded by the drug manufacturer  
22 with respect to the participants and bene-  
23 ficiaries in such plan;

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



1           agement services that was billed during the re-  
2           porting period, including, with respect to each  
3           such drug during the reporting period—

4                   “(i) the brand name, generic or non-  
5                   proprietary name, and National Drug  
6                   Code;

7                   “(ii) the number of participants and  
8                   beneficiaries for whom the drug was billed  
9                   during the reporting period, the total num-  
10                  ber of prescription claims for the drug (in-  
11                  cluding original prescriptions and refills);  
12                  and the total number of dosage units of  
13                  the drug dispensed across the reporting pe-  
14                  riod;

15                  “(iii) for each claim or dosage unit de-  
16                  scribed in clause (ii); the type of dis-  
17                  pensing channel used, such as retail, mail  
18                  order, or specialty pharmacy;

19                  “(iv) the wholesale acquisition cost,  
20                  listed as cost per days supply, cost per dos-  
21                  age unit, and cost per typical course of  
22                  treatment (as applicable);

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

1 under the plan or coverage, including par-  
2 ticipant and beneficiary spending through  
3 copayments, coinsurance, and deductibles,  
4 but not including any amounts spent by  
5 participants and beneficiaries on drugs not  
6 covered under the plan or coverage or for  
7 which no claim is submitted to the plan or  
8 coverage; and

9 “(vi) for any drug for which gross  
10 spending by the plan exceeded \$10,000  
11 and that is one of the 50 prescription  
12 drugs for which the group health plan  
13 spent the most on prescription drug bene-  
14 fits during the reporting period—

15 “(I) a list of all other drugs in  
16 the same therapeutic class, including  
17 brand name drugs and biological  
18 products and generic drugs or bio-  
19 similar biological products that are in  
20 the same therapeutic class as such  
21 drug; and

22 “(II) if applicable, the rationale  
23 for preferred formulary placement of  
24 such drug in that therapeutic class;

1                   selected from a list of standard ra-  
2                   tionales established by the Secretary;

3                   “(C) a list of each therapeutic class of  
4                   drugs that were dispensed under the health  
5                   plan during the reporting period, and, with re-  
6                   spect to each such therapeutic class of drugs,  
7                   during the reporting period—

8                   “(i) total gross spending by the plan,  
9                   before rebates, fees, alternative discounts,  
10                  or other remuneration;

11                  “(ii) the number of participants and  
12                  beneficiaries who filled a prescription for a  
13                  drug in that class;

14                  “(iii) if applicable to that class, a de-  
15                  scription of the formulary tiers and utiliza-  
16                  tion management mechanisms (such as  
17                  prior authorization or step therapy) em-  
18                  ployed for drugs in that class;

19                  “(iv) the total out-of-pocket spending  
20                  by participants and beneficiaries, including  
21                  participant and beneficiary spending  
22                  through copayments, coinsurance, and  
23                  deductibles; and

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

4                   “(I) the amount received, or ex-  
5                   pected to be received, by such entity,  
6                   from an applicable entity, in rebates,  
7                   fees, alternative discounts, or other  
8                   remuneration that—

9                           “(aa) has been paid, or will  
10                           be paid, by such an applicable  
11                           entity for claims incurred during  
12                           the reporting period; or

13                           “(bb) is related to utilization  
14                           of drugs or drug spending;

15                   “(II) the total net spending by  
16                   the health plan on that class of drugs;  
17                   and

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

1                   within such therapeutic class during  
2                   the reporting period;

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

8                   “(E) the total amount received, or ex-  
9                   pected to be received, by the health plan, from  
10                  an applicable entity, in rebates, fees, alternative  
11                  discounts, and other remuneration received  
12                  from any such entities, related to utilization of  
13                  drug or drug spending under that health plan  
14                  during the reporting period;

15                  “(F) the total net spending on prescription  
16                  drugs by the health plan during the reporting  
17                  period;

18                  “(G) amounts paid directly or indirectly in  
19                  rebates, fees, or any other type of compensation  
20                  (as defined in section 408(b)(2)(B)(ii)(dd)(AA))  
21                  to brokers, consultants, advisors, or any other  
22                  individual or firm who referred the group health  
23                  plan’s business to the pharmacy benefit man-  
24                  ager; and

1           “(H) a summary document that includes  
2 such information described in subparagraphs  
3 (A) through (G) as the Secretary determines  
4 useful for plan sponsors for purposes of select-  
5 ing pharmacy benefit management services,  
6 such as an estimated net price to plan sponsor  
7 and participant or beneficiary; a cost per claim;  
8 the fee structure or reimbursement model; and  
9 estimated cost per participant or beneficiary.

10           “(2) SUPPLEMENTARY REPORTING FOR INTRA-  
11 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—

12           “(A) IN GENERAL.—A health insurance  
13 issuer offering covered group health insurance  
14 coverage or an entity providing pharmacy ben-  
15 efit management services under a covered group  
16 health plan or covered group health insurance  
17 coverage shall submit, together with the report  
18 under paragraph (1), a supplementary report  
19 every 6 months to the plan sponsor that in-  
20 eludes—

21           “(i) an explanation of any benefit de-  
22 sign parameters that encourage or require  
23 participants and beneficiaries in the plan  
24 or coverage to fill prescriptions at mail  
25 order, specialty, or retail pharmacies that

1 are wholly or partially-owned by that issuer  
2 or entity providing pharmacy benefit man-  
3 agement services under such plan or cov-  
4 erage, including mandatory mail and spe-  
5 cialty home delivery programs, retail and  
6 mail auto-refill programs, and copayment  
7 incentives funded by an entity providing  
8 pharmacy benefit management services;

9 “(ii) the percentage of total prescrip-  
10 tions charged to the plan, coverage, or par-  
11 ticipants and beneficiaries in the plan or  
12 coverage, that were dispensed by mail  
13 order, specialty, or retail pharmacies that  
14 are wholly or partially-owned by the issuer  
15 or entity providing pharmacy benefit man-  
16 agement services; and

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

23 “(I) the amounts charged, per  
24 dosage unit, per course of treatment,  
25 per 30-day supply, and per 90-day

1 supply, with respect to participants  
2 and beneficiaries in the plan or cov-  
3 erage, including amounts charged to  
4 the plan or coverage and amounts  
5 charged to the participants and bene-  
6 ficiaries;

7 “(II) the median amount charged  
8 to the plan or coverage, per dosage  
9 unit, per course of treatment, per 30-  
10 day supply, and per 90-day supply, in-  
11 cluding amounts paid by the partici-  
12 pants and beneficiaries, when the  
13 same drug is dispensed by other phar-  
14 macies that are not wholly or par-  
15 tially-owned by the issuer or entity  
16 and that are included in the pharmacy  
17 network of that plan or coverage;

18 “(III) the interquartile range of  
19 the costs, per dosage unit, per course  
20 of treatment, per 30-day supply, and  
21 per 90-day supply, including amounts  
22 paid by the participants and bene-  
23 ficiaries, when the same drug is dis-  
24 pensed by other pharmacies that are  
25 not wholly or partially-owned by the



1 issuer or entity and that are included  
2 in the pharmacy network of that plan  
3 or coverage;

4 “(IV) the lowest cost, per dosage  
5 unit, per course of treatment, per 30-  
6 day supply, and per 90-day supply,  
7 for such drug, including amounts  
8 charged to the plan or issuer and par-  
9 ticipants and beneficiaries, that is  
10 available from any pharmacy included  
11 in the network of the plan or cov-  
12 erage;

13 “(V) the net acquisition cost per  
14 dosage unit and for a 30 day-supply,  
15 and the acquisition cost per typical  
16 course of treatment, if the drug is  
17 subject to a maximum price discount;  
18 and

19 “(VI) other information with re-  
20 spect to the cost of the drug, as deter-  
21 mined by the Secretary, such as aver-  
22 age sales price, wholesale acquisition  
23 cost, and national average drug acqui-  
24 sition cost per dosage unit, per typical  
25 course of treatment, or per 30-day

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

6 “(B) PLANS AND COVERAGE OFFERED BY  
7 SMALL EMPLOYERS.—A health insurance issuer  
8 offering covered group health insurance cov-  
9 erage that is not covered group health insur-  
10 ance coverage or an entity providing pharmacy  
11 benefit management services under a group  
12 health plan that is not a covered group health  
13 plan or under group health insurance coverage  
14 that is not covered group health insurance cov-  
15 erage that conducts transactions with a wholly  
16 or partially-owned pharmacy shall submit, to-  
17 gether with the report under paragraph (1), a  
18 supplementary report every 6 months to the  
19 plan sponsor that includes the information de-  
20 scribed in clauses (i) and (ii) of subparagraph  
21 (A).

22 “(3) PRIVACY REQUIREMENTS.—

23 “(A) RELATIONSHIP TO HIPAA REGULA-  
24 TIONS.—Nothing in this section shall be con-  
25 strued to modify the requirements for the cre-

1           ation, receipt, maintenance, or transmission of  
2           protected health information under the privacy,  
3           security, breach notification, and enforcement  
4           regulations in parts 160 and 164 of title 45,  
5           Code of Federal Regulations (or successor regu-  
6           lations).

7           “(B) REQUIREMENT.—A report submitted  
8           under paragraph (1) or (2) shall contain only  
9           summary health information, as defined in sec-  
10          tion 164.504(a) of title 45, Code of Federal  
11          Regulations (or successor regulations).

12          “(C) CLARIFICATION REGARDING CERTAIN  
13          DISCLOSURES OF INFORMATION.—

14          “(i) REASONABLE RESTRICTIONS.—  
15          Nothing in this section prevents a health  
16          insurance issuer offering group health in-  
17          surance coverage or an entity providing  
18          pharmacy benefit management services on  
19          behalf of a group health plan or group  
20          health insurance coverage from placing  
21          reasonable restrictions on the public disclo-  
22          sure of the information contained in a re-  
23          port under paragraph (1) or (2).

24          “(ii) LIMITATIONS.—A health insur-  
25          ance issuer offering group health insurance

1 coverage or an entity providing pharmacy  
2 benefit management services on behalf of a  
3 group health plan or group health insur-  
4 ance coverage may not restrict disclosure  
5 of such reports to the Department of  
6 Health and Human Services, the Depart-  
7 ment of Labor, the Department of the  
8 Treasury, or any other Federal agency re-  
9 sponsible for enforcement activities under  
10 this section for purposes of enforcement  
11 under this section or other applicable law,  
12 or to the Comptroller General of the  
13 United States in accordance with para-  
14 graph (6).

15 “(4) USE AND DISCLOSURE BY PLAN SPON-  
16 SORS.—

17 “(A) PROHIBITION.—A plan sponsor may  
18 not—

19 “(i) fail or refuse to hire, or dis-  
20 charge, any employee, or otherwise dis-  
21 criminate against any employee with re-  
22 spect to the compensation, terms, condi-  
23 tions, or privileges of employment of the  
24 employee, because of information sub-  
25 mitted under paragraph (1) or (2) attrib-

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

3           ~~“(ii) limit, segregate, or classify the~~  
4           ~~employees of the employer in any way that~~  
5           ~~would deprive or tend to deprive any em-~~  
6           ~~ployee of employment opportunities or oth-~~  
7           ~~erwise adversely affect the status of the~~  
8           ~~employee as an employee, because of infor-~~  
9           ~~mation submitted under paragraph (1) or~~  
10          ~~(2) attributed to the employee or a depend-~~  
11          ~~ent of the employee.~~

12          ~~“(B) DISCLOSURE AND REDISCLOSURE.—~~

13          ~~A plan sponsor shall not disclose the informa-~~  
14          ~~tion received under paragraph (1) or (2) ex-~~  
15          ~~cept—~~

16                 ~~“(i) to an occupational or other health~~  
17                 ~~researcher if the research is conducted in~~  
18                 ~~compliance with the regulations and pro-~~  
19                 ~~tections provided for under part 46 of title~~  
20                 ~~45, Code of Federal Regulations (or sue-~~  
21                 ~~cessor regulations);~~

22                 ~~“(ii) in response to an order of a~~  
23                 ~~court, except that the plan sponsor may~~  
24                 ~~disclose only the information expressly au-~~  
25                 ~~thorized by such order;~~

1           “(iii) to the Department of Health  
2           and Human Services, the Department of  
3           Labor, the Department of the Treasury, or  
4           other Federal agency responsible for en-  
5           forcement activities under this section; or

6           “(iv) to a contractor or agent for pur-  
7           poses of health plan administration, if such  
8           contractor or agent agrees, in writing, to  
9           abide by the same use and disclosure re-  
10          strictions as the plan sponsor.

11          “(C) RELATIONSHIP TO HIPAA REGULA-  
12          TIONS.—With respect to the regulations pro-  
13          mulgated by the Secretary of Health and  
14          Human Services under part C of title XI of the  
15          Social Security Act (42 U.S.C. 1320d et seq.)  
16          and section 264 of the Health Insurance Port-  
17          ability and Accountability Act of 1996 (42  
18          U.S.C. 1320d–2), subparagraph (B) does not  
19          prohibit a covered entity (as defined for pur-  
20          poses of such regulations) from any use or dis-  
21          closure of health information that is authorized  
22          for the covered entity under such regulations.  
23          The previous sentence does not affect the au-  
24          thority of such Secretary to modify such regula-  
25          tions.

1                   “(D) ENFORCEMENT.—

2                   “(i) IN GENERAL.—The powers, pro-  
3                   cedures, and remedies provided in section  
4                   207 of the Genetic Information Non-  
5                   discrimination Act (42 U.S.C. 2000ff-6) to  
6                   a person alleging a violation of title II of  
7                   such Act shall be the powers, procedures,  
8                   and remedies this subparagraph provides  
9                   for any person alleging a violation of this  
10                  paragraph.

11                  “(ii) PROHIBITION AGAINST RETALIA-  
12                  TION.—No person shall discriminate  
13                  against any individual because such indi-  
14                  vidual has opposed any act or practice  
15                  made unlawful by this paragraph or be-  
16                  cause such individual made a charge, testi-  
17                  fied, assisted, or participated in any man-  
18                  ner in an investigation, proceeding, or  
19                  hearing under this paragraph. The rem-  
20                  edies and procedures otherwise provided  
21                  for under this subparagraph shall be avail-  
22                  able to aggrieved individuals with respect  
23                  to violations of this clause.

24                  “(5) ADDITIONAL REPORTING.—

1           “(A) REPORTING WITH RESPECT TO  
2           GROUP HEALTH PLANS OFFERED BY SMALL  
3           EMPLOYERS.—For plan years beginning on or  
4           after January 1, 2025, not less frequently than  
5           annually, an entity providing pharmacy benefit  
6           management services on behalf of a group  
7           health plan that is not a covered group health  
8           plan shall submit to the plan sponsor of such  
9           group health plan a report in accordance with  
10          this paragraph, and make such report available  
11          to the plan sponsor in a machine-readable for-  
12          mat, and such other formats as the Secretary,  
13          the Secretary of Health and Human Services,  
14          and the Secretary of Labor may determine.  
15          Each such report shall include, with respect to  
16          the applicable group health plan, the informa-  
17          tion described in subparagraphs (A), (D), (E),  
18          (F), (G), and (H) of paragraph (1).

19          “(B) OPT-IN FOR GROUP HEALTH INSUR-  
20          ANCE COVERAGE.—

21                 “(i) IN GENERAL.—A plan sponsor  
22                 may, on an annual basis, beginning with  
23                 plan years beginning on or after January  
24                 1, 2025, elect to require a health insurance  
25                 issuer offering group health insurance cov-



1 erage to submit to such plan sponsor a re-  
2 port in accordance with this subsection.

3 “(ii) CONTENTS OF REPORTS.—

4 “(I) COVERED GROUP HEALTH  
5 INSURANCE COVERAGE.—In the case  
6 of an issuer that offers covered group  
7 health insurance coverage, a report  
8 provided pursuant to clause (i) shall  
9 include, with respect to the applicable  
10 covered group health insurance cov-  
11 erage, the information required under  
12 paragraph (1) for covered group  
13 health plans.

14 “(II) OTHER GROUP HEALTH IN-  
15 SURANCE COVERAGE.—In the case of  
16 an issuer that offers group health in-  
17 surance coverage that is not covered  
18 group health insurance, a report pro-  
19 vided pursuant to clause (i) shall in-  
20 clude, with respect to the applicable  
21 group health insurance coverage, the  
22 information described in subpara-  
23 graphs (A), (D), (E), (F), and (G) of  
24 paragraph (1).

1           “(iii) APPLICATION.—For purposes of  
2 reports submitted in accordance with this  
3 subparagraph, paragraph (1) shall be ap-  
4 plied by substituting ‘group health insur-  
5 ance coverage’ or ‘health insurance issuer’,  
6 as applicable, for ‘group health plan’,  
7 ‘group plan’, and ‘plan’ where such terms  
8 appear in such paragraph.

9           “(iv) REQUIRED REPORTING FOR ALL  
10 GROUP HEALTH INSURANCE COVERAGE.—  
11 Each health insurance issuer of health in-  
12 surance coverage shall annually submit the  
13 information described in paragraph (1)(H),  
14 regardless of whether the plan sponsor  
15 made the election described in clause (i)  
16 for the applicable year.

17           “(6) SUBMISSIONS TO GAO.—A health insur-  
18 ance issuer offering group health insurance coverage  
19 or an entity providing pharmacy benefit manage-  
20 ment services on behalf of a group health plan shall  
21 submit to the Comptroller General of the United  
22 States each of the first 2 reports submitted to a  
23 plan sponsor under paragraph (1) or (5) with re-  
24 spect to such coverage or plan, and other such re-  
25 ports as requested, in accordance with the privacy

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

5 “(7) STANDARD FORMATS.—

6 “(A) IN GENERAL.—Not later than June  
7 1, 2024, the Secretary, the Secretary of Health  
8 and Human Services, and the Secretary of the  
9 Treasury shall specify, through rulemaking,  
10 standard formats for health insurance issuers  
11 and entities providing pharmacy benefit man-  
12 agement services to submit reports required  
13 under this subsection.

14 “(B) LIMITED FORM OF REPORT.—The  
15 Secretary, the Secretary of Health and Human  
16 Services, and the Secretary of the Treasury  
17 shall define through rulemaking a limited form  
18 of the reports under paragraphs (1) and (2) re-  
19 quired to be submitted to plan sponsors who  
20 also are drug manufacturers, drug wholesalers,  
21 entities providing pharmacy benefit manage-  
22 ment services, or other direct participants in  
23 the drug supply chain, in order to prevent anti-  
24 competitive behavior.

25 “(c) LIMITATIONS ON SPREAD PRICING.—

1           “(1) IN GENERAL.—For plan years beginning  
2           on or after January 1, 2025, a group health plan or  
3           health insurance issuer offering group health insur-  
4           ance coverage shall not charge participants and  
5           beneficiaries, and an entity providing pharmacy ben-  
6           efit management services under such a plan or cov-  
7           erage shall not charge the plan, issuer, or partici-  
8           pants and beneficiaries, a price for a prescription  
9           drug that exceeds the price paid to the pharmacy for  
10          such drug, excluding penalties paid by the pharmacy  
11          (as described in paragraph (2)) to such plan, issuer,  
12          or entity.

13           “(2) RULE OF CONSTRUCTION.—For purposes  
14          of paragraph (1), penalties paid by pharmacies in-  
15          clude only the following:

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

19                   “(B) A penalty paid if the original claim  
20                   payment made by the plan, issuer, or entity to  
21                   the pharmacy was inconsistent with the reim-  
22                   bursement terms in any contract between the  
23                   pharmacy and the plan, issuer, or entity.

1           “(C) A penalty paid if the pharmacist serv-  
2           ices billed to the plan, issuer, or entity were not  
3           rendered by the pharmacy.

4           “~~(d) FULL REBATE PASS-THROUGH TO PLAN.—~~

5           “~~(1) IN GENERAL.—~~For plan years beginning  
6           on or after January 1, 2025, a third-party adminis-  
7           trator of a group health plan, a health insurance  
8           issuer offering group health insurance coverage, or  
9           an entity providing pharmacy benefit management  
10          services under such health plan or health insurance  
11          coverage shall—

12           “~~(A)~~ remit 100 percent of rebates, fees, al-  
13          ternative discounts, and other applicable remun-  
14          eration received from any applicable entity  
15          that are related to utilization of drugs under  
16          such health plan or health insurance coverage,  
17          to the group health plan; and

18           “~~(B)~~ ensure that any contract entered into  
19          by such third-party administrator, health insur-  
20          ance issuer, or entity providing pharmacy ben-  
21          efit management services with an applicable en-  
22          tity remit 100 percent of rebates, fees, alter-  
23          native discounts, and other remuneration re-  
24          ceived to the third-party administrator, health

1 insurance issuer, or entity providing pharmacy  
2 benefit management services:

3 ~~“(2) FORM AND MANNER OF REMITTANCE.—~~

4 Such rebates, fees, alternative discounts, and other  
5 remuneration shall be—

6 “(A) remitted to the group health plan or  
7 group health insurance coverage in a timely  
8 fashion after the period for which such rebates,  
9 fees, alternative discounts, or other remunera-  
10 tion is calculated, and in no case later than 90  
11 days after the end of such period;

12 “(B) fully disclosed and enumerated to the  
13 group health plan sponsor, as described in para-  
14 graphs (1) and (4) of subsection (b);

15 “(C) available for audit by the plan spon-  
16 sor, or a third-party designated by a plan spon-  
17 sor not less than once per plan year; and

18 “(D) returned to the issuer or entity pro-  
19 viding pharmaceutical benefit management  
20 services by the group health plan if audits by  
21 such issuer or entity indicate that the amounts  
22 received are incorrect after such amounts have  
23 been paid to the group health plan.

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

1 insurance issuer offering group health insurance cov-  
2 erage, or an entity providing pharmacy benefit man-  
3 agement services under such health plan or health  
4 insurance coverage shall make rebate contracts with  
5 rebate aggregators or drug manufacturers available  
6 for audit by such plan sponsor or designated third-  
7 party, subject to confidentiality agreements to pre-  
8 vent re-disclosure of such contracts.

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

12 “(5) RULE OF CONSTRUCTION.—Nothing in  
13 this subsection shall be construed to prohibit pay-  
14 ments to entities offering pharmacy benefit manage-  
15 ment services for bona fide services using a fee  
16 structure not contemplated by this subsection, pro-  
17 vided that such fees are transparent to group health  
18 plans and health insurance issuers.

19 “(e) ENFORCEMENT.—

20 “(1) IN GENERAL.—The Secretary, in consulta-  
21 tion with the Secretary of Health and Human Serv-  
22 ices and the Secretary of the Treasury, shall enforce  
23 this section.

24 “(2) FAILURE TO PROVIDE TIMELY INFORMA-  
25 TION.—A health insurance issuer or an entity pro-

1       viding pharmacy benefit management services that  
2       violates subsection (a) or fails to provide information  
3       required under subsection (b); a group health plan,  
4       health insurance issuer, or entity providing phar-  
5       macy benefit management services that violates sub-  
6       section (c); or a third-party administrator of a group  
7       health plan, a health insurance issuer offering group  
8       health insurance coverage, or an entity providing  
9       pharmacy benefit management services that violates  
10      subsection (d) shall be subject to a civil monetary  
11      penalty in the amount of \$10,000 for each day dur-  
12      ing which such violation continues or such informa-  
13      tion is not disclosed or reported.

14           “(3) FALSE INFORMATION.—A health insurance  
15      issuer, entity providing pharmacy benefit manage-  
16      ment services, or drug manufacturer that knowingly  
17      provides false information under this section shall be  
18      subject to a civil money penalty in an amount not  
19      to exceed \$100,000 for each item of false informa-  
20      tion. Such civil money penalty shall be in addition to  
21      other penalties as may be prescribed by law.

22           “(4) PROCEDURE.—The provisions of section  
23      1128A of the Social Security Act, other than sub-  
24      sections (a) and (b) and the first sentence of sub-  
25      section (c)(1) of such section shall apply to civil



1 monetary penalties under this subsection in the  
 2 same manner as such provisions apply to a penalty  
 3 or proceeding under section 1128A of the Social Se-  
 4 curity Act.

5 “(5) WAIVERS.—The Secretary may waive pen-  
 6 alties under paragraph (2), or extend the period of  
 7 time for compliance with a requirement of this sec-  
 8 tion, for an entity in violation of this section that  
 9 has made a good-faith effort to comply with this sec-  
 10 tion.

11 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
 12 tion shall be construed to permit a health insurance issuer,  
 13 group health plan, or other entity to restrict disclosure to,  
 14 or otherwise limit the access of, the Department of Labor  
 15 to a report described in subsection (b)(1) or information  
 16 related to compliance with subsection (a) by such issuer,  
 17 plan, or entity.

18 “(g) DEFINITIONS.—In this section—

19 “(1) the term ‘applicable entity’ means—

20 “(A) a drug manufacturer, distributor,  
 21 wholesaler, rebate aggregator (or other pur-  
 22 chasing entity designed to aggregate rebates),  
 23 group purchasing organization, or associated  
 24 third party;

1           “(B) any subsidiary, parent, affiliate, or  
2           subcontractor of a group health plan, health in-  
3           surance issuer, entity that provides pharmacy  
4           benefit management services on behalf of such  
5           a plan or issuer, or any entity described in sub-  
6           paragraph (A); or

7           “(C) such other entity as the Secretary,  
8           the Secretary of Health and Human Services,  
9           and the Secretary of the Treasury may specify  
10          through rulemaking;

11          “(2) the term ‘covered group health insurance  
12          coverage’ means health insurance coverage offered in  
13          connection with a group health plan maintained by  
14          a large employer;

15          “(3) the term ‘covered group health plan’  
16          means a group health plan maintained by a large  
17          employer;

18          “(4) the term ‘gross 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 be-  
23          fore the application of manufacturer rebates, fees,  
24          alternative discounts, or other remuneration;

1           “(5) the term ‘large employer’ means, in con-  
2           nection with a group health plan with respect to a  
3           calendar year and a plan year, an employer who em-  
4           ployed an average of at least 50 employees on busi-  
5           ness days during the preceding calendar year and  
6           who employs at least 1 employee on the first day of  
7           the plan year;

8           “(6) the term ‘net spending’, with respect to  
9           prescription drug benefits under a group health plan  
10          or health insurance coverage, means the amount  
11          spent by a group health plan or health insurance  
12          issuer on prescription drug benefits, calculated after  
13          the application of manufacturer rebates, fees, alter-  
14          native discounts, or other remuneration;

15          “(7) the term ‘plan sponsor’ has the meaning  
16          given such term in section 3(16)(B);

17          “(8) the term ‘remuneration’ has the meaning  
18          given such term by the Secretary, the Secretary of  
19          Health and Human Services, and the Secretary of  
20          the Treasury, through notice and comment rule-  
21          making;

22          “(9) the term ‘small employer’ means, in con-  
23          nection with a group health plan with respect to a  
24          calendar year and a plan year, an employer who em-  
25          ployed an average of at least 1 but not more than

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

4 “(10) the term ‘wholesale acquisition cost’ has  
 5 the meaning given such term in section  
 6 1847A(e)(6)(B) of the Social Security Act (42  
 7 U.S.C. 1395w-3a(e)(6)(B)).”; and

8 (B) in section 502(b)(3) (29 U.S.C.  
 9 1132(b)(3)), by inserting “(other than section  
 10 726)” after “part 7”.

11 (2) CLERICAL AMENDMENT.—The table of con-  
 12 tents in section 1 of the Employee Retirement In-  
 13 come Security Act of 1974 (29 U.S.C. 1001 et seq.)  
 14 is amended by inserting after the item relating to  
 15 section 725 the following new item:

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

16 (c) INTERNAL REVENUE CODE.—

17 (1) IN GENERAL.—Subchapter B of chapter  
 18 100 of the Internal Revenue Code of 1986 is amend-  
 19 ed by adding at the end the following:

20 **“SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
 21 **MACY BENEFIT MANAGEMENT SERVICES.**

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

1 half of such a plan shall not enter into a contract with  
2 an applicable entity that limits the disclosure of informa-  
3 tion to plan sponsors in such a manner that prevents the  
4 plan, or an entity providing pharmacy benefit management  
5 services on behalf of a plan, from making the reports de-  
6 scribed in subsection (b).

7 “(b) REPORTS.—

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

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

1           “(B) a list of each drug covered by such  
2 plan or entity providing pharmacy benefit man-  
3 agement services that was billed during the re-  
4 porting period, including, with respect to each  
5 such drug during the reporting period—

6           “(i) the brand name, generic or non-  
7 proprietary name, and National Drug  
8 Code;

9           “(ii) the number of participants and  
10 beneficiaries for whom the drug was billed  
11 during the reporting period, the total num-  
12 ber of prescription claims for the drug (in-  
13 cluding original prescriptions and refills);  
14 and the total number of dosage units of  
15 the drug dispensed across the reporting pe-  
16 riod;

17           “(iii) for each claim or dosage unit de-  
18 scribed in clause (ii), the type of dis-  
19 pensing channel used, such as retail, mail  
20 order, or specialty pharmacy;

21           “(iv) the wholesale acquisition cost,  
22 listed as cost per days supply, cost per dos-  
23 age unit, and cost per typical course of  
24 treatment (as applicable);

1           “(v) the total out-of-pocket spending  
2           by participants and beneficiaries on such  
3           drug after application of any benefits  
4           under the plan, including participant and  
5           beneficiary spending through copayments,  
6           coinsurance, and deductibles, but not in-  
7           cluding any amounts spent by participants  
8           and beneficiaries on drugs not covered  
9           under the plan or for which no claim is  
10          submitted to the plan; and

11          “(vi) for any drug for which gross  
12          spending by the plan exceeded \$10,000  
13          and that is one of the 50 prescription  
14          drugs for which the group health plan  
15          spent the most on prescription drug bene-  
16          fits during the reporting period—

17                 “(I) a list of all other drugs in  
18                 the same therapeutic class, including  
19                 brand name drugs and biological  
20                 products and generic drugs or bio-  
21                 similar biological products that are in  
22                 the same therapeutic class as such  
23                 drug; and

24                 “(II) if applicable, the rationale  
25                 for preferred formulary placement of

1           such drug in that therapeutic class,  
2           selected from a list of standard ra-  
3           tionales established by the Secretary;

4           “(C) a list of each therapeutic class of  
5           drugs that were dispensed under the health  
6           plan during the reporting period, and, with re-  
7           spect to each such therapeutic class of drugs,  
8           during the reporting period—

9           “(i) total gross spending by the plan,  
10          before rebates, fees, alternative discounts,  
11          or other remuneration;

12          “(ii) the number of participants and  
13          beneficiaries who filled a prescription for a  
14          drug in that class;

15          “(iii) if applicable to that class, a de-  
16          scription of the formulary tiers and utiliza-  
17          tion management mechanisms (such as  
18          prior authorization or step therapy) em-  
19          ployed for drugs in that class;

20          “(iv) the total out-of-pocket spending  
21          by participants and beneficiaries, including  
22          participant and beneficiary spending  
23          through copayments, coinsurance, and  
24          deductibles; and



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

4                   “(I) the amount received, or ex-  
5                   pected to be received, by such entity,  
6                   from an applicable entity, in rebates,  
7                   fees, alternative discounts, or other  
8                   remuneration that—

9                           “(aa) has been paid, or will  
10                           be paid, by such an applicable  
11                           entity for claims incurred during  
12                           the reporting period; or

13                           “(bb) is related to utilization  
14                           of drugs or drug spending;

15                   “(II) the total net spending by  
16                   the health plan on that class of drugs;  
17                   and

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

1           within such therapeutic class during  
2           the reporting period;

3           ~~“(D) total gross spending on prescription~~  
4           ~~drugs by the plan during the reporting period,~~  
5           ~~before rebates, fees, alternative discounts, or~~  
6           ~~other remuneration provided by an applicable~~  
7           ~~entity;~~

8           ~~“(E) the total amount received, or ex-~~  
9           ~~pected to be received, by the health plan, from~~  
10          ~~an applicable entity, in rebates, fees, alternative~~  
11          ~~discounts, and other remuneration received~~  
12          ~~from any such entities, related to utilization of~~  
13          ~~drug or drug spending under that health plan~~  
14          ~~during the reporting period;~~

15          ~~“(F) the total net spending on prescription~~  
16          ~~drugs by the health plan during the reporting~~  
17          ~~period;~~

18          ~~“(G) amounts paid directly or indirectly in~~  
19          ~~rebates, fees, or any other type of compensation~~  
20          ~~(as defined in section 408(b)(2)(B)(ii)(dd)(AA)~~  
21          ~~of the Employee Retirement Income Security~~  
22          ~~Act of 1974 (29 U.S.C.~~  
23          ~~1108(b)(2)(B)(ii)(dd)(A))) to brokers, consult-~~  
24          ~~ants, advisors, or any other individual or firm~~

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

3 “(H) a summary document that includes  
4 such information described in subparagraphs  
5 (A) through (G) as the Secretary determines  
6 useful for plan sponsors for purposes of select-  
7 ing pharmacy benefit management services,  
8 such as an estimated net price to plan sponsor  
9 and participant or beneficiary; a cost per claim,  
10 the fee structure or reimbursement model, and  
11 estimated cost per participant or beneficiary.

12 “(2) SUPPLEMENTARY REPORTING FOR INTRA-  
13 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—

14 “(A) IN GENERAL.—An entity providing  
15 pharmacy benefit management services under a  
16 covered group health plan shall submit, to-  
17 gether with the report under paragraph (1), a  
18 supplementary report every 6 months to the  
19 plan sponsor that includes—

20 “(i) an explanation of any benefit de-  
21 sign parameters that encourage or require  
22 participants and beneficiaries in the plan  
23 to fill prescriptions at mail order, specialty,  
24 or retail pharmacies that are wholly or  
25 partially-owned by that entity providing

1 pharmacy benefit management services  
2 under such plan, including mandatory mail  
3 and specialty home delivery programs, re-  
4 tail and mail auto-refill programs, and co-  
5 payment incentives funded by an entity  
6 providing pharmacy benefit management  
7 services;

8 “(ii) the percentage of total prescrip-  
9 tions charged to the plan or participants  
10 and beneficiaries in the plan, that were  
11 dispensed by mail order, specialty, or retail  
12 pharmacies that are wholly or partially-  
13 owned by the entity providing pharmacy  
14 benefit management services; and

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

21 “(I) the amounts charged, per  
22 dosage unit, per course of treatment,  
23 per 30-day supply, and per 90-day  
24 supply, with respect to participants  
25 and beneficiaries in the plan, includ-

1 ing amounts charged to the plan and  
2 amounts charged to the participants  
3 and beneficiaries;

4 “(II) the median amount charged  
5 to the plan, per dosage unit, per  
6 course of treatment, per 30-day sup-  
7 ply, and per 90-day supply, including  
8 amounts paid by the participants and  
9 beneficiaries, when the same drug is  
10 dispensed by other pharmacies that  
11 are not wholly or partially-owned by  
12 the entity and that are included in the  
13 pharmacy network of that plan;

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 entity and that are included in the  
23 pharmacy network of that plan;

24 “(IV) the lowest cost, per dosage  
25 unit, per course of treatment, per 30-

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

7 “(V) the net acquisition cost per  
8 dosage unit and for a 30 day-supply,  
9 and the acquisition cost per typical  
10 course of treatment, if the drug is  
11 subject to a maximum price discount;  
12 and

13 “(VI) other information with re-  
14 spect to the cost of the drug, as deter-  
15 mined by the Secretary, such as aver-  
16 age sales price, wholesale acquisition  
17 cost, and national average drug acqui-  
18 sition cost per dosage unit, per typical  
19 course of treatment, or per 30-day  
20 supply, for such drug, including  
21 amounts charged to the plan and par-  
22 ticipants and beneficiaries among all  
23 pharmacies included in the network of  
24 the plan.

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

11          “(3) PRIVACY REQUIREMENTS.—

12                 “(A) RELATIONSHIP TO HIPAA REGULA-  
13                 TIONS.—Nothing in this section shall be con-  
14                 strued to modify the requirements for the ere-  
15                 ation, receipt, maintenance, or transmission of  
16                 protected health information under the privacy,  
17                 security, breach notification, and enforcement  
18                 regulations in parts 160 and 164 of title 45,  
19                 Code of Federal Regulations (or successor regu-  
20                 lations).

21                 “(B) REQUIREMENT.—A report submitted  
22                 under paragraph (1) or (2) shall contain only  
23                 summary health information, as defined in sec-  
24                 tion 164.504(a) of title 45, Code of Federal  
25                 Regulations (or successor regulations).

1                   “(C) CLARIFICATION REGARDING CERTAIN  
2 DISCLOSURES OF INFORMATION.—

3                   “(i) REASONABLE RESTRICTIONS.—

4                   Nothing in this section prevents an entity  
5                   providing pharmacy benefit management  
6                   services on behalf of a group health plan  
7                   from placing reasonable restrictions on the  
8                   public disclosure of the information con-  
9                   tained in a report under paragraph (1) or  
10                  (2).

11                  “(ii) LIMITATIONS.—An entity pro-  
12                  viding pharmacy benefit management serv-  
13                  ices on behalf of a group health plan or  
14                  group health insurance coverage may not  
15                  restrict disclosure of such reports to the  
16                  Department of Health and Human Serv-  
17                  ices, the Department of Labor, the Depart-  
18                  ment of the Treasury, or any other Federal  
19                  agency responsible for enforcement activi-  
20                  ties under this section for purposes of en-  
21                  forcement under this section or other ap-  
22                  plicable law, or to the Comptroller General  
23                  of the United States in accordance with  
24                  paragraph (6).



1           ~~“(4) USE AND DISCLOSURE BY PLAN SPON-~~  
2           ~~SORS.—~~

3           ~~“(A) PROHIBITION.—A plan sponsor may~~  
4           ~~not—~~

5                   ~~“(i) fail or refuse to hire, or dis-~~  
6                   ~~charge, any employee, or otherwise dis-~~  
7                   ~~criminate against any employee with re-~~  
8                   ~~spect to the compensation, terms, condi-~~  
9                   ~~tions, or privileges of employment of the~~  
10                  ~~employee, because of information sub-~~  
11                  ~~mitted under paragraph (1) or (2) attrib-~~  
12                  ~~uted to the employee or a dependent of the~~  
13                  ~~employee; or~~

14                   ~~“(ii) limit, segregate, or classify the~~  
15                   ~~employees of the employer in any way that~~  
16                   ~~would deprive or tend to deprive any em-~~  
17                   ~~ployee of employment opportunities or oth-~~  
18                   ~~erwise adversely affect the status of the~~  
19                   ~~employee as an employee, because of infor-~~  
20                   ~~mation submitted under paragraph (1) or~~  
21                   ~~(2) attributed to the employee or a depend-~~  
22                   ~~ent of the employee.~~

23           ~~“(B) DISCLOSURE AND REDISCLOSURE.—~~  
24           ~~A plan sponsor shall not disclose the informa-~~

1           tion received under paragraph (1) or (2) ex-  
2           cept—

3                   “(i) to an occupational or other health  
4                   researcher if the research is conducted in  
5                   compliance with the regulations and pro-  
6                   tections provided for under part 46 of title  
7                   45, Code of Federal Regulations (or suc-  
8                   cessor regulations);

9                   “(ii) in response to an order of a  
10                  court, except that the plan sponsor may  
11                  disclose only the information expressly au-  
12                  thorized by such order;

13                  “(iii) to the Department of Health  
14                  and Human Services, the Department of  
15                  Labor, the Department of the Treasury, or  
16                  other Federal agency responsible for en-  
17                  forcement activities under this section; or

18                  “(iv) to a contractor or agent for pur-  
19                  poses of health plan administration, if such  
20                  contractor or agent agrees, in writing, to  
21                  abide by the same use and disclosure re-  
22                  strictions as the plan sponsor.

23                  “(C) RELATIONSHIP TO HIPAA REGULA-  
24                  TIONS.—With respect to the regulations pro-  
25                  mulgated by the Secretary of Health and

1 Human Services under part C of title XI of the  
2 Social Security Act (42 U.S.C. 1320d et seq.)  
3 and section 264 of the Health Insurance Port-  
4 ability and Accountability Act of 1996 (42  
5 U.S.C. 1320d-2), subparagraph (B) does not  
6 prohibit a covered entity (as defined for pur-  
7 poses of such regulations) from any use or dis-  
8 closure of health information that is authorized  
9 for the covered entity under such regulations.  
10 The previous sentence does not affect the au-  
11 thority of such Secretary to modify such regula-  
12 tions.

13 “(D) ENFORCEMENT.—

14 “(i) IN GENERAL.—The powers, pro-  
15 cedures, and remedies provided in section  
16 207 of the Genetic Information Non-  
17 discrimination Act (42 U.S.C. 2000ff-6) to  
18 a person alleging a violation of title II of  
19 such Act shall be the powers, procedures,  
20 and remedies this subparagraph provides  
21 for any person alleging a violation of this  
22 paragraph.

23 “(ii) PROHIBITION AGAINST RETALIA-  
24 TION.—No person shall discriminate  
25 against any individual because such indi-

1           vidual has opposed any act or practice  
2           made unlawful by this paragraph or be-  
3           cause such individual made a charge, testi-  
4           fied, assisted, or participated in any man-  
5           ner in an investigation, proceeding, or  
6           hearing under this paragraph. The rem-  
7           edies and procedures otherwise provided  
8           for under this subparagraph shall be avail-  
9           able to aggrieved individuals with respect  
10          to violations of this clause.

11           ~~“(5) REPORTING WITH RESPECT TO GROUP~~  
12          ~~HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—~~  
13          For plan years beginning on or after January 1,  
14          2025, not less frequently than annually, an entity  
15          providing pharmacy benefit management services on  
16          behalf of a group health plan that is not a covered  
17          group health plan shall submit to the plan sponsor  
18          of such group health plan a report in accordance  
19          with this paragraph, and make such report available  
20          to the plan sponsor in a machine-readable format.  
21          Each such report shall include, with respect to the  
22          applicable group health plan, the information de-  
23          scribed in subparagraphs (A), (D), (E), (F), (G),  
24          and (H) of paragraph (1).

1           “(6) SUBMISSIONS TO GAO.—An entity pro-  
2           viding pharmacy benefit management services on be-  
3           half of a group health plan shall submit to the  
4           Comptroller General of the United States each of  
5           the first 2 reports submitted to a plan sponsor under  
6           paragraph (1) or (5) with respect to such plan, and  
7           other such reports as requested, in accordance with  
8           the privacy requirements under paragraph (3), and  
9           such other information that the Comptroller General  
10          determines necessary to carry out the study under  
11          section 2(f) of the Pharmacy Benefit Manager Re-  
12          form Act.

13           “(7) STANDARD FORMATS.—

14           “(A) IN GENERAL.—Not later than June  
15          1, 2024, the Secretary, the Secretary of Health  
16          and Human Services, and the Secretary of  
17          Labor shall specify, through rulemaking, stand-  
18          ard formats for health insurance issuers and  
19          entities providing pharmacy benefit manage-  
20          ment services to submit reports required under  
21          this subsection.

22           “(B) LIMITED FORM OF REPORT.—The  
23          Secretary, the Secretary of Health and Human  
24          Services, and the Secretary of Labor shall de-  
25          fine through rulemaking a limited form of the

1 reports under paragraphs (1) and (2) required  
2 to be submitted to plan sponsors who also are  
3 drug manufacturers, drug wholesalers, entities  
4 providing pharmacy benefit management serv-  
5 ices, or other direct participants in the drug  
6 supply chain, in order to prevent anti-competi-  
7 tive behavior.

8 “(c) LIMITATIONS ON SPREAD PRICING.—

9 “(1) IN GENERAL.—A group health plan shall  
10 not charge participants and beneficiaries, and an en-  
11 tity providing pharmacy benefit management serv-  
12 ices under such a plan shall not charge the plan or  
13 participants and beneficiaries, a price for a prescrip-  
14 tion drug that exceeds the price paid to the phar-  
15 macy for such drug, excluding penalties paid by the  
16 pharmacy (as described in paragraph (2)) to such  
17 plan or entity.

18 “(2) RULE OF CONSTRUCTION.—For purposes  
19 of paragraph (1), penalties paid by pharmacies in-  
20 clude only the following:

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

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

1 the pharmacy was inconsistent with the reim-  
 2 bursement terms in any contract between the  
 3 pharmacy and the plan or entity.

4 “(C) A penalty paid if the pharmacist serv-  
 5 ices billed to the plan or entity were not ren-  
 6 dered by the pharmacy.

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

8 “(1) IN GENERAL.—For plan years beginning  
 9 on or after January 1, 2025, a third-party adminis-  
 10 trator of a group health plan or an entity providing  
 11 pharmacy benefit management services under such  
 12 health plan shall—

13 “(A) remit 100 percent of rebates, fees, al-  
 14 ternative discounts, and other remuneration re-  
 15 ceived from any applicable entity that are re-  
 16 lated to utilization of drugs under such health  
 17 plan; to the group health plan; and

18 “(B) ensure that any contract entered into  
 19 by such third-party administrator or entity pro-  
 20 viding pharmacy benefit management services  
 21 with an applicable entity remit 100 percent of  
 22 rebates, fees, alternative discounts, and other  
 23 remuneration received to the third-party admin-  
 24 istrator or entity providing pharmacy benefit  
 25 management services.

1           “(2) FORM AND MANNER OF REMITTANCE.—

2           Such rebates, fees, alternative discounts, and other  
3           remuneration shall be—

4                   “(A) remitted to the group health plan in  
5                   a timely fashion after the period for which such  
6                   rebates, fees, alternative discounts, or other re-  
7                   muneration is calculated, and in no case later  
8                   than 90 days after the end of such period;

9                   “(B) fully disclosed and enumerated to the  
10                  group health plan sponsor, as described in para-  
11                  graphs (1) and (4) of subsection (b);

12                  “(C) available for audit by the plan spon-  
13                  sor, or a third-party designated by a plan spon-  
14                  sor not less than once per plan year; and

15                  “(D) returned to the issuer or entity pro-  
16                  viding pharmaceutical benefit management  
17                  services by the group health plan if audits by  
18                  such entity indicate that the amounts received  
19                  are incorrect after such amounts have been paid  
20                  to the group health plan.

21           “(3) AUDIT OF REBATE CONTRACTS.—A third-  
22           party administrator of a group health plan or an en-  
23           tity providing pharmacy benefit management serv-  
24           ices under such health plan shall make rebate con-  
25           tracts with rebate aggregators or drug manufactur-



1 ers available for audit by such plan sponsor or des-  
2 ignated third-party, subject to confidentiality agree-  
3 ments to prevent re-disclosure of such contracts.

4 “(4) AUDITORS.—The applicable plan sponsor  
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.

14 “(e) ENFORCEMENT.—

15 “(1) IN GENERAL.—The Secretary, in consulta-  
16 tion with the Secretary of Labor and the Secretary  
17 of Health and Human Services, shall enforce this  
18 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 or entity providing pharmacy benefit management  
25 services that violates subsection (c); or a third-party

1 administrator of a group health plan or an entity  
2 providing pharmacy benefit management services  
3 that violates subsection (d) shall be subject to a civil  
4 monetary penalty in the amount of \$10,000 for each  
5 day during which such violation continues or such  
6 information is not disclosed or reported.

7 “(3) FALSE INFORMATION.—An entity pro-  
8 viding pharmacy benefit management services, or  
9 drug manufacturer that knowingly provides false in-  
10 formation under this section shall be subject to a  
11 civil money penalty in an amount not to exceed  
12 \$100,000 for each item of false information. Such  
13 civil money penalty shall be in addition to other pen-  
14 alties as may be prescribed by law.

15 “(4) PROCEDURE.—The provisions of section  
16 1128A of the Social Security Act, other than sub-  
17 sections (a) and (b) and the first sentence of sub-  
18 section (c)(1) of such section shall apply to civil  
19 monetary penalties under this subsection in the  
20 same manner as such provisions apply to a penalty  
21 or proceeding under section 1128A of the Social Se-  
22 curity Act.

23 “(5) WAIVERS.—The Secretary may waive pen-  
24 alties under paragraph (2), or extend the period of  
25 time for compliance with a requirement of this sec-

1       tion; for an entity in violation of this section that  
 2       has made a good-faith effort to comply with this sec-  
 3       tion.

4       “(f) RULE OF CONSTRUCTION.—Nothing in this sec-  
 5       tion shall be construed to permit a group health plan or  
 6       other entity to restrict disclosure to, or otherwise limit the  
 7       access of, the Department of the Treasury to a report de-  
 8       scribed in subsection (b)(1) or information related to com-  
 9       pliance with subsection (a) by such plan or entity.

10       “(g) DEFINITIONS.—In this section—

11               “(1) the term ‘applicable entity’ means—

12                       “(A) a drug manufacturer, distributor,  
 13                       wholesaler, rebate aggregator (or other pur-  
 14                       chasing entity designed to aggregate rebates),  
 15                       group purchasing organization, or associated  
 16                       third party;

17                       “(B) any subsidiary, parent, affiliate, or  
 18                       subcontractor of a group health plan, health in-  
 19                       surance issuer, entity that provides pharmacy  
 20                       benefit management services on behalf of such  
 21                       a plan or issuer, or any entity described in sub-  
 22                       paragraph (A); or

23                       “(C) such other entity as the Secretary,  
 24                       the Secretary of Health and Human Services,

1           and the Secretary of Labor may specify through  
2           rulemaking;

3           “(2) the term ‘covered group health insurance  
4           coverage’ means health insurance coverage offered in  
5           connection with a group health plan maintained by  
6           a large employer;

7           “(3) the term ‘covered group health plan’  
8           means a group health plan maintained by a large  
9           employer;

10          “(4) the term ‘gross spending’, with respect to  
11          prescription drug benefits under a group health plan  
12          or health insurance coverage, means the amount  
13          spent by a group health plan or health insurance  
14          issuer on prescription drug benefits, calculated be-  
15          fore the application of manufacturer rebates, fees,  
16          alternative discounts, or other remuneration;

17          “(5) the term ‘large 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 50 employees on busi-  
21          ness days during the preceding calendar year and  
22          who employs at least 1 employee on the first day of  
23          the plan year;

24          “(6) the term ‘net spending’, with respect to  
25          prescription drug benefits under a group health plan

1 or health insurance coverage, means the amount  
2 spent by a group health plan or health insurance  
3 issuer on prescription drug benefits, calculated after  
4 the application of manufacturer rebates, fees, alter-  
5 native discounts, or other remuneration;

6 “(7) the term ‘plan sponsor’ has the meaning  
7 given such term in section 3(16)(B) of the Employee  
8 Retirement Income Security Act of 1974 (29 U.S.C.  
9 1002(16)(B));

10 “(8) the term ‘remuneration’ has the meaning  
11 given such term by the Secretary, the Secretary of  
12 Labor, and the Secretary of Health and Human  
13 Services, through notice and comment rulemaking;

14 “(9) the term ‘small employer’ means, in con-  
15 nection with a group health plan with respect to a  
16 calendar year and a plan year, an employer who em-  
17 ployed an average of at least 1 but not more than  
18 49 employees on business days during the preceding  
19 calendar year and who employs at least 1 employee  
20 on the first day of the plan year; and

21 “(10) the term ‘wholesale acquisition cost’ has  
22 the meaning given such term in section  
23 1847A(e)(6)(B) of the Social Security Act (42  
24 U.S.C. ~~1395w-3a(c)(6)(B)~~.”.

1           (2) CLERICAL AMENDMENT.—The table of sec-  
 2           tions for subchapter B of chapter 100 of the Inter-  
 3           nal Revenue Code of 1986 is amended by adding at  
 4           the end the following new item:

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

5           (d) FUNDING.—

6           (1) For purposes of carrying out the amend-  
 7           ments made by subsection (a), there are appro-  
 8           priated to the Centers for Medicare & Medicaid  
 9           Services, out of amounts in the Treasury not other-  
 10          wise appropriated, \$80,000,000 for fiscal year 2024.

11          (2) For purposes of carrying out the amend-  
 12          ments made by subsection (b), there are appro-  
 13          priated to the Department of Labor, out of amounts  
 14          in the Treasury not otherwise appropriated,  
 15          \$43,750,000 for fiscal year 2024.

16          (e) ASPE STUDY.—The Assistant Secretary for  
 17          Planning and Evaluation of the Department of Health and  
 18          Human Services shall conduct or commission a study on  
 19          how the United States health care market would be im-  
 20          pacted by potential regulatory changes disallowing manu-  
 21          facturer rebates in the manner and to the extent allowed  
 22          on the date of enactment of this Act, with a focus on the  
 23          impact to stakeholders in the commercial insurance mar-  
 24          ket, and, not later than 1 year after the date of enactment

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

4 (1) The impact on the impact of making no  
5 such regulatory changes, as well as potential behav-  
6 ioral changes by plan sponsors, members, and phar-  
7 maceutical manufacturers, such as tighter  
8 formularies, changes to price concessions, changes in  
9 utilization, if such regulatory changes are made.

10 (2) The mechanics needed in the pharma-  
11 ceutical supply chain (whether existing or not) to  
12 move a manufacturer rebate to the point of sale.

13 (3) The feasibility of a partial point-of-sale  
14 manufacturer rebate versus a full point-of-sale man-  
15 ufacturer rebate.

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

18 (5) Possible behavioral changes by other third  
19 parties in the pharmaceutical supply chain including  
20 drug manufacturer, distributor, wholesaler, rebate  
21 aggregators, pharmacy services administrative orga-  
22 nizations, or group purchasing organizations.

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

1           (7) Alternative price negotiation mechanisms,  
2 including the impact of the Act of June 19, 1936  
3 (commonly known as the “Robinson–Patman Act”;  
4 49 Stat. 1526, chapter 592; 15 U.S.C. 13a et seq.);  
5 and the amendments made by that Act, on drug  
6 pricing negotiations.

7           (8) The impact on pharmacies, including phar-  
8 macy rebates, pharmacy fees, and dispensing chan-  
9 nels.

10 (f) GAO STUDY.—

11           (1) IN GENERAL.—Not later than January 1,  
12 2029, the Comptroller General of the United States  
13 shall report to Congress on—

14           (A) pharmacy networks of group health  
15 plans, health insurance issuers, and entities  
16 providing pharmacy benefit management serv-  
17 ices under such group health plan or group or  
18 individual health insurance coverage, including  
19 networks that have pharmacies that are under  
20 common ownership (in whole or part) with  
21 group health plans, health insurance issuers, or  
22 entities providing pharmacy benefit manage-  
23 ment services or pharmacy benefit administra-  
24 tive services under group health plan or group  
25 or individual health insurance coverage;



1           (B) as it relates to pharmacy networks  
2 that include pharmacies under common owner-  
3 ship described in subparagraph (A)—

4           (i) whether such networks are de-  
5 signed to encourage participants and bene-  
6 ficiaries of a plan or coverage to use such  
7 pharmacies over other network pharmacies  
8 for specific services or drugs; and if so, the  
9 reasons the networks give for encouraging  
10 use of such pharmacies; and

11           (ii) whether such pharmacies are used  
12 by participants and beneficiaries dispropor-  
13 tionately more in the aggregate or for spe-  
14 cific services or drugs compared to other  
15 network pharmacies;

16           (C) whether group health plans and health  
17 insurance issuers offering group or individual  
18 health insurance coverage have options to elect  
19 different network pricing arrangements in the  
20 marketplace with entities that provide phar-  
21 macy benefit management services; the preva-  
22 lence of electing such different network pricing  
23 arrangements;

24           (D) pharmacy network design parameters  
25 that encourage participants and beneficiaries in

1 the plan or coverage to fill prescriptions at mail  
2 order, specialty, or retail pharmacies that are  
3 wholly or partially-owned by that issuer or enti-  
4 ty; and

5 (E) the degree to which mail order, spe-  
6 cialty, or retail pharmacies that dispense pre-  
7 scription drugs to participants and beneficiaries  
8 in a group health plan or health insurance cov-  
9 erage that are under common ownership (in  
10 whole or part) with group health plans, health  
11 insurance issuers, or entities providing phar-  
12 macy benefit management services or pharmacy  
13 benefit administrative services under group  
14 health plan or group or individual health insur-  
15 ance coverage receive reimbursement that is  
16 greater than the median price charged to the  
17 group health plan or health insurance issuer  
18 when the same drug is dispensed to participants  
19 and beneficiaries in the plan or coverage by  
20 other pharmacies included in the pharmacy net-  
21 work of that plan, issuer, or entity that are not  
22 wholly or partially owned by the health insur-  
23 ance issuer or entity providing pharmacy ben-  
24 efit management services.

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

4                   (A) information that would allow for iden-  
5                   tification of a specific individual, plan sponsor,  
6                   health insurance issuer, plan, or entity pro-  
7                   viding pharmacy benefit management services;  
8                   or

9                   (B) commercial or financial information  
10                  that is privileged or confidential.

11           (3) DEFINITIONS.—In this subsection, the  
12           terms “group health plan”, “health insurance cov-  
13           erage”, and “health insurance issuer” have the  
14           meanings given such terms in section 2791 of the  
15           Public Health Service Act (42 U.S.C. 300gg–91).

16 **SECTION 1. SHORT TITLE.**

17           *This Act may be cited as the “Pharmacy Benefit Man-*  
18 *ager Reform Act”.*

19 **SEC. 2. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
20 **MACY BENEFIT MANAGEMENT SERVICES.**

21           (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of  
22 *the Public Health Service Act (42 U.S.C. 300gg et seq.) is*  
23 *amended—*

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

1 **“SEC. 2799A-11. OVERSIGHT OF ENTITIES THAT PROVIDE**  
2 **PHARMACY BENEFIT MANAGEMENT SERV-**  
3 **ICES.**

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

12               “(1) *not limit the disclosure of information to*  
13 *plan sponsors in such a manner that prevents the*  
14 *plan or issuer, or an entity providing pharmacy ben-*  
15 *efit management services on behalf of a plan or*  
16 *issuer, from making the reports described in sub-*  
17 *section (b); and*

18               “(2) *provide the group health plan or health in-*  
19 *surance issuer offering group health insurance cov-*  
20 *erage, or an entity providing pharmacy benefit man-*  
21 *agement services on behalf of a plan or issuer, rel-*  
22 *evant information necessary to make the reports de-*  
23 *scribed in subsection (b).*

24       “(b) *REPORTS.*—

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

1        *enactment of the Pharmacy Benefit Manager Reform*  
2        *Act, not less frequently than annually, an entity pro-*  
3        *viding pharmacy benefit management services on be-*  
4        *half of a covered group health plan or group health*  
5        *insurance coverage (regardless of whether such cov-*  
6        *erage is covered group health insurance coverage as*  
7        *defined in subsection (g)(3)) shall submit to the plan*  
8        *sponsor of such covered group health plan or issuer of*  
9        *such health insurance coverage a report in accordance*  
10       *with this subsection and make such report available*  
11       *to the plan sponsor or issuer in plain language, in*  
12       *a machine-readable format, and, as the Secretary, the*  
13       *Secretary of Labor, and the Secretary of the Treasury*  
14       *may determine, other formats. Each such report shall*  
15       *include, with respect to the covered group health plan*  
16       *or health insurance coverage—*

17                *“(A) as applicable, information collected*  
18                *from drug manufacturers by such entity on the*  
19                *total amount of copayment assistance dollars*  
20                *paid, or copayment cards applied, that were*  
21                *funded by such drug manufacturers with respect*  
22                *to the participants and beneficiaries in such*  
23                *plan or coverage;*

24                *“(B) a list of each drug covered by the plan,*  
25                *coverage, or entity providing pharmacy benefit*

1           *management services for which a claim was filed*  
2           *during the reporting period, including, with re-*  
3           *spect to each such drug during the reporting pe-*  
4           *riod—*

5                     “(i) *the brand name, generic or non-*  
6                     *proprietary name, and National Drug Code;*

7                     “(ii) *the number of participants and*  
8                     *beneficiaries for whom a claim for the drug*  
9                     *was filed during the reporting period, the*  
10                    *total number of prescription claims for the*  
11                    *drug (including original prescriptions and*  
12                    *refills), and the total number of dosage*  
13                    *units of the drug for which a claim was*  
14                    *filed across the reporting period;*

15                    “(iii) *for each claim or dosage unit de-*  
16                    *scribed in clause (ii), the type of dispensing*  
17                    *channel used, such as retail, mail order, or*  
18                    *specialty pharmacy;*

19                    “(iv) *the wholesale acquisition cost,*  
20                    *listed as cost per days’ supply and cost per*  
21                    *dosage unit;*

22                    “(v) *the total out-of-pocket spending by*  
23                    *participants and beneficiaries on such drug*  
24                    *after application of any benefits under the*  
25                    *plan or coverage—*

1           “(I) including copayments, coin-  
2           surance, and deductibles; and

3           “(II) not including any amounts  
4           spent by participants and beneficiaries  
5           on drugs not covered under the plan or  
6           coverage or for which no claim is sub-  
7           mitted to the plan or coverage; and

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

12           “(I) a list of all other drugs in the  
13           same therapeutic class (as defined by  
14           the Secretary, the Secretary of Labor,  
15           and the Secretary of the Treasury), in-  
16           cluding brand name drugs and biologi-  
17           cal products and generic drugs or bio-  
18           similar biological products that are in  
19           the same therapeutic class as such  
20           drug;

21           “(II) if applicable, the rationale  
22           for preferred formulary placement of  
23           such drug in that therapeutic class, se-  
24           lected from a list of standard ration-  
25           ales established by the Secretary, the

1                    *Secretary of Labor, and the Secretary*  
2                    *of the Treasury, in consultation with*  
3                    *stakeholders; and*

4                    *“(III) any change in formulary*  
5                    *placement compared to the prior plan*  
6                    *year;*

7                    *“(C) a list of each therapeutic class of drugs*  
8                    *for which a claim was filed under the group*  
9                    *health plan or health insurance coverage during*  
10                   *the reporting period, and, with respect to each*  
11                   *such therapeutic class (as defined as described in*  
12                   *subparagraph (B)(vi)(I)) of drugs, during the re-*  
13                   *porting period—*

14                   *“(i) total gross spending by the plan or*  
15                   *by the issuer offering such coverage;*

16                   *“(ii) the number of participants and*  
17                   *beneficiaries who filled a prescription for a*  
18                   *drug in that class;*

19                   *“(iii) if applicable to that class, a de-*  
20                   *scription of the formulary tiers and utiliza-*  
21                   *tion management mechanisms (such as*  
22                   *prior authorization or step therapy) em-*  
23                   *ployed for drugs in that class;*

24                   *“(iv) the total out-of-pocket spending*  
25                   *by participants and beneficiaries on drugs*



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

3                   “(I) *including copayments, coin-*  
4                   *surance, and deductibles; and*

5                   “(II) *not including any amounts*  
6                   *spent by participants and beneficiaries*  
7                   *on drugs not covered under the plan or*  
8                   *coverage or for which no claim is sub-*  
9                   *mitted to the plan or issuer; and*

10                  “(v) *for each therapeutic class under*  
11                  *which 3 or more drugs are included on the*  
12                  *formulary of such plan or coverage—*

13                   “(I) *the amount received, or ex-*  
14                   *pected to be received, by such entity,*  
15                   *from applicable entities, in rebates,*  
16                   *fees, alternative discounts, or other re-*  
17                   *muneration—*

18                           “(aa) *for claims incurred*  
19                           *during the reporting period; or*

20                           “(bb) *that is related to utili-*  
21                           *zation of drugs or drug spending;*

22                   “(II) *the total net spending by the*  
23                   *plan or by the issuer with respect to*  
24                   *such coverage on that class of drugs;*  
25                   *and*

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

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

12                  “(E) the total amount received, or expected  
13                  to be received, by the group health plan or health  
14                  insurance issuer, from applicable entities, in re-  
15                  bates, fees, alternative discounts, and other remun-  
16                  eration received from such entities, related to  
17                  utilization of drugs or drug spending under that  
18                  group health plan or health insurance coverage  
19                  during the reporting period;

20                  “(F) the total net spending on prescription  
21                  drugs by the group health plan or health insur-  
22                  ance issuer with respect to the coverage during  
23                  the reporting period;

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

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

5                     *“(i) referral of the group health plan’s*  
6                     *or health insurance issuer’s business to the*  
7                     *pharmacy benefit manager;*

8                     *“(ii) consideration of the entity pro-*  
9                     *viding pharmacy benefit management serv-*  
10                    *ices by the group health plan or health in-*  
11                    *surance issuer; or*

12                    *“(iii) the retention of the entity by the*  
13                    *group health plan or health insurance*  
14                    *issuer;*

15                    *“(H)(i) an explanation of any benefit de-*  
16                    *sign parameters that encourage or require par-*  
17                    *ticipants and beneficiaries in the plan or cov-*  
18                    *erage to fill prescriptions at mail order, spe-*  
19                    *cialty, or retail pharmacies that are affiliated*  
20                    *with or under common ownership with the entity*  
21                    *providing pharmacy benefit management services*  
22                    *on behalf of such plan or coverage, including*  
23                    *mandatory mail and specialty home delivery*  
24                    *programs, retail and mail auto-refill programs,*  
25                    *and cost-sharing assistance incentives funded by*

1           *an entity providing pharmacy benefit manage-*  
2           *ment services;*

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

10           “(iii) *a list of all drugs dispensed by such*  
11           *affiliated pharmacy or pharmacy under common*  
12           *ownership and charged to the plan, issuer, or*  
13           *participants and beneficiaries of the plan or cov-*  
14           *erage, during the applicable period, and, with*  
15           *respect to each drug—*

16           “(I)(aa) *the amount charged, per dos-*  
17           *age unit, per 30-day supply, and per 90-*  
18           *day supply, with respect to participants*  
19           *and beneficiaries in the plan or coverage, to*  
20           *the plan or issuer; and*

21           “(bb) *the amount charged, per dosage*  
22           *unit, per 30-day supply, and per 90-day*  
23           *supply to participants and beneficiaries;*

24           “(II) *the median amount charged to*  
25           *the plan or issuer, per dosage unit, per 30-*

1            *day supply, and per 90-day supply, includ-*  
2            *ing amounts paid by the participants and*  
3            *beneficiaries, when the same drug is dis-*  
4            *persed by other pharmacies that are not af-*  
5            *filiated with or under common ownership*  
6            *with the entity and that are included in the*  
7            *pharmacy network of that plan or coverage;*

8            *“(III) the interquartile range of the*  
9            *costs, per dosage unit, per 30-day supply,*  
10           *and per 90-day supply, including amounts*  
11           *paid by the participants and beneficiaries,*  
12           *when the same drug is dispensed by other*  
13           *pharmacies that are not affiliated with or*  
14           *under common ownership with the entity*  
15           *and that are included in the pharmacy net-*  
16           *work of that plan or coverage;*

17           *“(IV) the lowest cost, per dosage unit,*  
18           *per 30-day supply, and per 90-day supply,*  
19           *for such drug, including amounts charged to*  
20           *the plan and participants and beneficiaries,*  
21           *that is available from any pharmacy in-*  
22           *cluded in the network of the plan or cov-*  
23           *erage;*

24           *“(V) the net acquisition cost per dosage*  
25           *unit, per 30-day supply, and per 90-day*

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

3            *“(VI) other information with respect to*  
4            *the cost of the drug, as determined by the*  
5            *Secretary, the Secretary of Labor, and the*  
6            *Secretary of the Treasury, such as average*  
7            *sales price, wholesale acquisition cost, and*  
8            *national average drug acquisition cost per*  
9            *dosage unit or per 30-day supply, for such*  
10           *drug, including amounts charged to the*  
11           *plan or issuer and participants and bene-*  
12           *ficiaries among all pharmacies included in*  
13           *the network of the plan or coverage;*

14           *“(I) a summary document for plan sponsors*  
15           *or issuers that includes the information described*  
16           *in subparagraphs (A) through (H) that the Sec-*  
17           *retary, the Secretary of Labor, and the Secretary*  
18           *of the Treasury determine useful to plan spon-*  
19           *sors and health insurance issuers for purposes of*  
20           *selecting pharmacy benefit management services,*  
21           *such as an estimated net price to plan sponsor*  
22           *and participant or beneficiary, a cost per claim,*  
23           *the fee structure or reimbursement model, and es-*  
24           *timated cost per participant or beneficiary; and*

1           “(J) a summary document for participants  
2           or beneficiaries, which shall be made available to  
3           participants or beneficiaries upon request to the  
4           plan sponsor, that contains the information de-  
5           scribed in subparagraphs (D) through (G) that  
6           the Secretary, the Secretary of Labor, and the  
7           Secretary of the Treasury determine useful to  
8           participants or beneficiaries in better under-  
9           standing their plan or benefits, except that such  
10          summary document for participants or bene-  
11          ficiaries shall contain only aggregate informa-  
12          tion.

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

24          “(3) ADDITIONAL REPORTING.—

1           “(A) *REPORTING WITH RESPECT TO GROUP*  
2           *HEALTH PLANS OFFERED BY SMALL EMPLOY-*  
3           *ERS.—For plan years beginning on or after the*  
4           *date that is 30 months after the date of enact-*  
5           *ment of the Pharmacy Benefit Manager Reform*  
6           *Act, not less frequently than annually, an entity*  
7           *providing pharmacy benefit management services*  
8           *on behalf of a group health plan that is not a*  
9           *covered group health plan shall submit to the*  
10           *plan sponsor of such group health plan a report*  
11           *in accordance with this paragraph, and make*  
12           *such report available to the plan sponsor in a*  
13           *machine-readable format, and such other formats*  
14           *as the Secretary, the Secretary of Labor, and the*  
15           *Secretary of the Treasury may specify. Each*  
16           *such report shall include, with respect to the ap-*  
17           *plicable group health plan—*

18                   “(i) *the information described in sub-*  
19                   *paragraphs (D), (E), (F), and (G) of para-*  
20                   *graph (1);*

21                   “(ii) *as applicable, information col-*  
22                   *lected from drug manufacturers by such*  
23                   *plan on the total amount of copayment as-*  
24                   *sistance dollars paid, or copayment cards*  
25                   *applied, that were funded by applicable*



1 *drug manufacturers with respect to the par-*  
2 *ticipants and beneficiaries in such plan, ex-*  
3 *cept that such information shall not iden-*  
4 *tify any drug manufacturer; and*

5 *“(iii) a summary document that in-*  
6 *cludes the information described in clauses*  
7 *(i) and (ii) that the Secretary, the Sec-*  
8 *retary of Labor, and the Secretary of the*  
9 *Treasury determine useful for plan sponsors*  
10 *for purposes of selecting pharmacy benefit*  
11 *management services, provided that such*  
12 *summary documents include only aggregate*  
13 *information.*

14 *“(B) OPT-IN FOR GROUP HEALTH INSUR-*  
15 *ANCE COVERAGE.—*

16 *“(i) IN GENERAL.—A plan sponsor of*  
17 *group health insurance coverage offered in*  
18 *connection with a group health plan may,*  
19 *on an annual basis, for plan years begin-*  
20 *ning on or after the date that is 30 months*  
21 *after the date of enactment of the Pharmacy*  
22 *Benefit Manager Reform Act, elect to re-*  
23 *quire an entity providing pharmacy benefit*  
24 *management services on behalf of a health*  
25 *insurance issuer offering group health in-*

1            *surance coverage to submit to such plan*  
2            *sponsor a report in accordance with this*  
3            *subsection.*

4            “(ii) *CONTENTS OF REPORTS.—*

5                    “(I) *COVERED GROUP HEALTH IN-*  
6                    *SURANCE COVERAGE.—In the case of*  
7                    *an entity providing pharmacy benefit*  
8                    *management services on behalf of an*  
9                    *issuer that offers covered group health*  
10                   *insurance coverage, a report provided*  
11                   *pursuant to clause (i) shall include,*  
12                   *with respect to the applicable covered*  
13                   *group health insurance coverage, the*  
14                   *information required under paragraph*  
15                   *(1) for covered group health plans.*

16                   “(II) *OTHER GROUP HEALTH IN-*  
17                   *SURANCE COVERAGE.—In the case of*  
18                   *an entity providing pharmacy benefit*  
19                   *management services on behalf of an*  
20                   *issuer that offers group health insur-*  
21                   *ance coverage that is not covered group*  
22                   *health insurance, a report provided*  
23                   *pursuant to clause (i) shall include,*  
24                   *with respect to the applicable group*  
25                   *health insurance coverage—*

1           “(aa) the information de-  
2           scribed in subparagraphs (D),  
3           (E), (F), and (G) of paragraph  
4           (1); and

5           “(bb) as applicable, informa-  
6           tion collected from drug manufac-  
7           turers by such issuer or entity on  
8           the total amount of copayment as-  
9           sistance dollars paid, or copay-  
10          ment cards applied, that were  
11          funded by applicable drug manu-  
12          facturers with respect to the par-  
13          ticipants and beneficiaries in such  
14          plan, except that such information  
15          shall not identify any drug manu-  
16          facturer.

17           “(iii) *REQUIRED REPORTING FOR COV-*  
18          *ERED GROUP HEALTH INSURANCE COV-*  
19          *ERAGE.—Each health insurance issuer that*  
20          *offers covered group health insurance cov-*  
21          *erage shall annually submit to the plan*  
22          *sponsor the information described in para-*  
23          *graph (1)(I), regardless of whether the plan*  
24          *sponsor made the election described in*  
25          *clause (i) for the applicable year.*

1                   “(iv) *REQUIRED REPORTING FOR*  
2                   *OTHER GROUP HEALTH INSURANCE COV-*  
3                   *ERAGE.—Each health insurance issuer that*  
4                   *offers group health insurance coverage that*  
5                   *is not covered group health insurance shall*  
6                   *annually submit a summary document that*  
7                   *includes such information described in*  
8                   *items (aa) and (bb) of clause (ii)(II) as the*  
9                   *Secretary and the Secretary of Labor deter-*  
10                  *mine useful for plan sponsors for purposes*  
11                  *of selecting pharmacy benefit management*  
12                  *services, provided that such summary docu-*  
13                  *ments include only aggregate information.*

14                  “(4) *PRIVACY REQUIREMENTS.—*

15                  “(A) *RELATIONSHIP TO HIPAA REGULA-*  
16                  *TIONS.—Nothing in this section shall be con-*  
17                  *strued to modify the requirements for the cre-*  
18                  *ation, receipt, maintenance, or transmission of*  
19                  *protected health information under the HIPAA*  
20                  *privacy regulations, as defined in section*  
21                  *1180(b)(3) of the Social Security Act.*

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

1            *tion 164.504(a) of title 45, Code of Federal Regu-*  
2            *lations (or successor regulations).*

3            “(C) *CLARIFICATION REGARDING CERTAIN*  
4            *DISCLOSURES OF INFORMATION.—*

5            “(i) *REASONABLE RESTRICTIONS.—*  
6            *Nothing in this section prevents a health in-*  
7            *surance issuer offering group health insur-*  
8            *ance coverage or an entity providing phar-*  
9            *macy benefit management services on behalf*  
10           *of a group health plan or health insurance*  
11           *issuer offering group health insurance cov-*  
12           *erage from placing reasonable restrictions*  
13           *(as the Secretary, the Secretary of Labor,*  
14           *and the Secretary of the Treasury may de-*  
15           *termine) on the public disclosure of the in-*  
16           *formation contained in a report under*  
17           *paragraph (1) or (3).*

18           “(ii) *LIMITATIONS.—A health insur-*  
19           *ance issuer offering group health insurance*  
20           *coverage or an entity providing pharmacy*  
21           *benefit management services on behalf of a*  
22           *group health plan or health insurance issuer*  
23           *offering group health insurance coverage*  
24           *may not restrict disclosure of such reports*  
25           *to the Department of Health and Human*

1           *Services, the Department of Labor, the De-*  
2           *partment of the Treasury, or any other Fed-*  
3           *eral agency responsible for enforcement ac-*  
4           *tivities under this section for purposes of*  
5           *enforcement under this section or other ap-*  
6           *plicable law, or to the Comptroller General*  
7           *of the United States in accordance with*  
8           *paragraph (6).*

9           “(5) *USE AND DISCLOSURE BY PLAN SPON-*  
10          *SORS.—*

11           “(A) *PROHIBITION.—A plan sponsor may*  
12          *not—*

13            “(i) *fail or refuse to hire, or discharge,*  
14            *any employee, or otherwise discriminate*  
15            *against any employee with respect to the*  
16            *compensation, terms, conditions, or privi-*  
17            *leges of employment of the employee, because*  
18            *of information submitted under paragraph*  
19            *(1) or (3) attributed to the employee or a*  
20            *dependent of the employee; or*

21            “(ii) *limit, segregate, or classify the*  
22            *employees of the employer in any way that*  
23            *would deprive or tend to deprive any em-*  
24            *ployee of employment opportunities or oth-*  
25            *erwise adversely affect the status of the em-*

1            *ployee as an employee, because of informa-*  
2            *tion submitted under paragraph (1) or (3)*  
3            *attributed to the employee or a dependent of*  
4            *the employee.*

5            “(B) *DISCLOSURE AND REDISCLOSURE.—A*  
6            *plan sponsor shall not disclose the information*  
7            *received under paragraph (1) or (3) except—*

8                    *“(i) to an occupational or other health*  
9                    *researcher if the research is conducted in*  
10                   *compliance with the regulations and protec-*  
11                   *tions provided for under part 46 of title 45,*  
12                   *Code of Federal Regulations (or successor*  
13                   *regulations);*

14                   *“(ii) in response to an order of a court,*  
15                   *except that the plan sponsor may disclose*  
16                   *only the information expressly authorized*  
17                   *by such order;*

18                   *“(iii) to the Department of Health and*  
19                   *Human Services, the Department of Labor,*  
20                   *the Department of the Treasury, or other*  
21                   *Federal agency responsible for enforcement*  
22                   *activities under this section; or*

23                   *“(iv) to a contractor or agent for pur-*  
24                   *poses of health plan administration, if such*  
25                   *contractor or agent agrees, in writing, and*

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

4           “(C) *RELATIONSHIP TO HIPAA REGULA-*  
5           *TIONS.—With respect to the HIPAA privacy reg-*  
6           *ulations, as defined in section 1180(b)(3) of the*  
7           *Social Security Act, subparagraph (B) does not*  
8           *prohibit a covered entity (as defined for purposes*  
9           *of such regulations promulgated under section*  
10           *264 of the Health Insurance Portability and Ac-*  
11           *countability Act of 1996) from any use or disclo-*  
12           *sure of health information that is authorized for*  
13           *the covered entity under such regulations. The*  
14           *previous sentence does not affect the authority of*  
15           *such Secretary to modify such regulations.*

16           “(D) *WRITTEN NOTICE.—Plan sponsors of*  
17           *group health plans and group health insurance*  
18           *coverage shall provide to each employee written*  
19           *notice informing the employee of the requirement*  
20           *for health insurance issuers or entities providing*  
21           *pharmacy benefit management services on behalf*  
22           *of the plan or coverage to submit reports to plan*  
23           *sponsors under paragraphs (1) and (3), as appli-*  
24           *cable, which may include incorporating such no-*  
25           *tification in plan documents provided to the em-*



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

3            *“(E) ENFORCEMENT.—*

4                    *“(i) IN GENERAL.—The powers, proce-*  
5                    *dures, and remedies provided in section 207*  
6                    *of the Genetic Information Nondiscrimina-*  
7                    *tion Act to a person alleging a violation of*  
8                    *title II of such Act shall be the powers, pro-*  
9                    *cedures, and remedies this subparagraph*  
10                   *provides for any person alleging a violation*  
11                   *of this paragraph.*

12                   *“(ii) PROHIBITION AGAINST RETALIA-*  
13                   *TION.—No person shall discriminate*  
14                   *against any individual because such indi-*  
15                   *vidual has opposed any act or practice*  
16                   *made unlawful by this paragraph or be-*  
17                   *cause such individual made a charge, testi-*  
18                   *fied, assisted, or participated in any man-*  
19                   *ner in an investigation, proceeding, or hear-*  
20                   *ing under this paragraph. The remedies and*  
21                   *procedures otherwise provided for under this*  
22                   *subparagraph shall be available to aggrieved*  
23                   *individuals with respect to violations of this*  
24                   *clause.*

1           “(6) *SUBMISSIONS TO GAO.*—A health insurance  
2           *issuer offering group health insurance coverage or an*  
3           *entity providing pharmacy benefit management serv-*  
4           *ices on behalf of a group health plan shall submit,*  
5           *upon request, to the Comptroller General of the*  
6           *United States each of the first 2 reports submitted to*  
7           *a plan sponsor under paragraph (1) or (3) with re-*  
8           *spect to such coverage or plan, and other such reports*  
9           *as requested, in accordance with the privacy require-*  
10           *ments under paragraph (4), and such other informa-*  
11           *tion that the Comptroller General determines nec-*  
12           *essary to carry out the study under section 2(f) of the*  
13           *Pharmacy Benefit Manager Reform Act.*

14           “(7) *STANDARD FORMATS.*—

15           “(A) *IN GENERAL.*—Not later than June 1,  
16           2024, the Secretary, the Secretary of Labor, and  
17           the Secretary of the Treasury shall specify,  
18           through rulemaking, standard formats for enti-  
19           ties providing pharmacy benefit management  
20           services to submit reports required under this  
21           subsection. Such secretaries may provide for sep-  
22           arate standard formats for reports to plan spon-  
23           sors of group health plans and reports to plan  
24           sponsors of group health insurance coverage of-  
25           fered in connection with a group health plan.

1           “(B) *FORM OF REPORT.*—*The Secretary, the*  
2           *Secretary of Labor, and the Secretary of the*  
3           *Treasury shall define through rulemaking a form*  
4           *of the reports under paragraphs (1) and (3) re-*  
5           *quired to be submitted to plan sponsors who also*  
6           *are drug manufacturers, drug wholesalers, enti-*  
7           *ties providing pharmacy benefit management*  
8           *services, or other direct participants in the drug*  
9           *supply chain, in the case that such secretaries*  
10          *determine that changes to the standard format*  
11          *are necessary to prevent anticompetitive behav-*  
12          *ior.*

13          “(c) *LIMITATIONS ON SPREAD PRICING.*—

14                 “(1) *IN GENERAL.*—*For plan years beginning on*  
15                 *or after the date that is 30 months after the date of*  
16                 *enactment of the Pharmacy Benefit Manager Reform*  
17                 *Act, a group health plan or health insurance issuer*  
18                 *offering group or individual health insurance cov-*  
19                 *erage shall ensure that the amount required to be*  
20                 *paid by a participant, beneficiary, or enrollee for a*  
21                 *prescription drug covered under the plan or coverage,*  
22                 *and a third-party administrator or an entity pro-*  
23                 *viding pharmacy benefit management services on be-*  
24                 *half of such a plan or coverage shall ensure that the*  
25                 *total amount required to be paid by the plan or issuer*

1       *and participant, beneficiary, or enrollee for a pre-*  
2       *scription drug covered under the plan or coverage,*  
3       *does not exceed the price paid to the pharmacy, ex-*  
4       *cluding penalties paid by the pharmacy (as described*  
5       *in paragraph (2)) to such plan, issuer, or entity.*

6               “(2) *RULE OF CONSTRUCTION.—For purposes of*  
7       *paragraph (1), penalties paid by pharmacies include*  
8       *only the following:*

9                       “(A) *A penalty paid if an original claim*  
10                      *for a prescription drug was submitted fraudu-*  
11                      *lently by the pharmacy to the plan, issuer, or en-*  
12                      *tity.*

13                     “(B) *A penalty paid if the original claim*  
14                      *payment made by the plan, issuer, or entity to*  
15                      *the pharmacy was inconsistent with the reim-*  
16                      *bursement terms in any contract between the*  
17                      *pharmacy and the plan, issuer, or entity.*

18                     “(C) *A penalty paid if the pharmacist serv-*  
19                      *ices for which a claim was filed with the plan,*  
20                      *issuer, or entity were not rendered by the phar-*  
21                      *macy.*

22               “(d) *FULL REBATE PASS-THROUGH TO PLAN OR*  
23       *HEALTH INSURANCE ISSUER.—*

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

1 *enactment of the Pharmacy Benefit Manager Reform*  
2 *Act, a third-party administrator of a group health*  
3 *plan or an entity providing pharmacy benefit man-*  
4 *agement services on behalf of a group health plan or*  
5 *health insurance issuer offering group health insur-*  
6 *ance coverage shall—*

7 *“(A) remit 100 percent of rebates, fees, al-*  
8 *ternative discounts, and other remuneration re-*  
9 *ceived from any applicable entity that are re-*  
10 *lated to utilization of drugs under such group*  
11 *health plan or health insurance coverage, to the*  
12 *group health plan or health insurance issuer of-*  
13 *fering group health insurance coverage; and*

14 *“(B) ensure that any contract entered into,*  
15 *by such third-party administrator or entity pro-*  
16 *viding pharmacy benefit management services on*  
17 *behalf of such a plan or coverage, with rebate*  
18 *aggregators (or other purchasing entity designed*  
19 *to aggregate rebates), applicable group pur-*  
20 *chasing organizations, or any subsidiary, par-*  
21 *ent, affiliate, or subcontractor of the plan, entity,*  
22 *rebate aggregator (or other purchasing entity de-*  
23 *signed to aggregate rebates), or applicable group*  
24 *purchasing organization remit 100 percent of re-*  
25 *bates, fees, alternative discounts, and other remu-*

1            *neration received that are related to utilization*  
2            *of drugs under such group health plan or health*  
3            *insurance coverage, to the third-party adminis-*  
4            *trator or entity providing pharmacy benefit*  
5            *management services.*

6            *“(2) FORM AND MANNER OF REMITTANCE.—With*  
7            *respect to such rebates, fees, alternative discounts, and*  
8            *other remuneration—*

9                    *“(A) the rebates, fees, alternative discounts,*  
10                   *and other remuneration under paragraph (1)(A)*  
11                   *shall be—*

12                            *“(i) remitted—*

13                                    *“(I) on a quarterly basis, to the*  
14                                    *group health plan or the group health*  
15                                    *insurance issuer, not later than 90*  
16                                    *days after the end of each quarter; or*

17                                    *“(II) in the case of an under-*  
18                                    *payment in a remittance for a prior*  
19                                    *quarter, as soon as practicable, but not*  
20                                    *later than 90 days after notice of the*  
21                                    *underpayment is first given;*

22                                    *“(ii) fully disclosed and enumerated to*  
23                                    *the group health plan or health insurance*  
24                                    *issuer, as described in paragraphs (1) and*  
25                                    *(3) of subsection (b); and*

1           “(iii) returned to the issuer or entity  
2           providing pharmacy benefit management  
3           services on behalf of the group health plan  
4           if an audit by a plan sponsor, or a third  
5           party designated by a plan sponsor, indi-  
6           cates that the amounts received are incor-  
7           rect after such amounts have been paid to  
8           the group health plan or health insurance  
9           issuer;

10           “(B) the rebates, fees, alternative discounts,  
11           and other remuneration under paragraph (1)(B)  
12           shall be remitted in accordance with such proce-  
13           dures as the Secretary, Secretary of Labor, and  
14           Secretary of the Treasury establish; and

15           “(C) the records of such rebates, fees, alter-  
16           native discounts, and other remuneration shall  
17           be available for audit by the plan sponsor,  
18           issuer, or a third party designated by a plan  
19           sponsor, not less than once per plan year.

20           “(3) AUDIT OF REBATE CONTRACTS.—A third-  
21           party administrator of a group health plan, a health  
22           insurance issuer offering group health insurance cov-  
23           erage, or an entity providing pharmacy benefit man-  
24           agement services on behalf of such group health plan  
25           or health insurance coverage shall make rebate con-

1        *tracts with rebate aggregators or drug manufacturers*  
2        *available for audit by the plan sponsor or designated*  
3        *third party, subject to reasonable restrictions (as de-*  
4        *termined by the Secretary, the Secretary of Labor,*  
5        *and the Secretary of the Treasury) on confidentiality*  
6        *to prevent re-disclosure of such contracts.*

7                *“(4) AUDITORS.—Audits carried out under para-*  
8        *graphs (2)(C) and (3) shall be performed by an audi-*  
9        *tor selected by the applicable plan sponsor.*

10                *“(5) RULE OF CONSTRUCTION.—Nothing in this*  
11        *subsection shall be construed to—*

12                        *“(A) prohibit payments to entities offering*  
13        *pharmacy benefit management services for bona*  
14        *fide services using a fee structure not described*  
15        *in this subsection, provided that such fees are*  
16        *transparent to group health plans and health in-*  
17        *surance issuers;*

18                        *“(B) require a third-party administrator of*  
19        *a group health plan or an entity providing*  
20        *pharmacy benefit management services on behalf*  
21        *of a group health plan or health insurance issuer*  
22        *offering health insurance coverage to remit bona*  
23        *fide service fees to group health plans or health*  
24        *insurance issuers; or*



1           “(C) *limit the ability of a group health*  
2           *plan or health insurance issuer to pass through*  
3           *rebates, fees, alternative discounts, and other re-*  
4           *muneration to the participant or beneficiary.*

5           “(e) *ENFORCEMENT.*—

6           “(1) *IN GENERAL.*—*The Secretary shall enforce*  
7           *this section.*

8           “(2) *VIOLATIONS.*—*A group health plan, a health*  
9           *insurance issuer, or an entity providing pharmacy*  
10           *benefit management services that violates subsection*  
11           *(a); an entity providing pharmacy benefit manage-*  
12           *ment services that fails to provide information re-*  
13           *quired under subsection (b); a group health plan,*  
14           *health insurance issuer, or entity providing phar-*  
15           *macy benefit management services that violates sub-*  
16           *section (c); or a third-party administrator of a group*  
17           *health plan, a health insurance issuer, or an entity*  
18           *providing pharmacy benefit management services that*  
19           *violates subsection (d) shall be subject to a civil mone-*  
20           *tary penalty in the amount of \$10,000 for each day*  
21           *during which such violation continues or such infor-*  
22           *mation is not disclosed or reported.*

23           “(3) *FALSE INFORMATION.*—*A group health*  
24           *plan, a health insurance issuer, an entity providing*  
25           *pharmacy benefit management services, or a third-*

1        *party administrator that knowingly provides false in-*  
2        *formation under this section shall be subject to a civil*  
3        *money penalty in an amount not to exceed \$100,000*  
4        *for each item of false information. Such civil money*  
5        *penalty shall be in addition to other penalties as may*  
6        *be prescribed by law.*

7                *“(4) PROCEDURE.—The provisions of section*  
8        *1128A of the Social Security Act, other than sub-*  
9        *section (a) and (b) and the first sentence of subsection*  
10        *(c)(1) of such section shall apply to civil monetary*  
11        *penalties under this subsection in the same manner as*  
12        *such provisions apply to a penalty or proceeding*  
13        *under section 1128A of the Social Security Act.*

14                *“(5) WAIVERS.—The Secretary may waive pen-*  
15        *alties under paragraph (2), or extend the period of*  
16        *time for compliance with a requirement of this sec-*  
17        *tion, for an entity in violation of this section that has*  
18        *made a good-faith effort to comply with this section.*

19                *“(f) RULE OF CONSTRUCTION.—Nothing in this sec-*  
20        *tion shall be construed to permit a health insurance issuer,*  
21        *group health plan, entity providing pharmacy benefit man-*  
22        *agement services on behalf of a group health plan or health*  
23        *insurance issuer, or other entity to restrict disclosure to,*  
24        *or otherwise limit the access of, the Secretary of Health and*  
25        *Human Services, the Secretary of Labor, or the Secretary*

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

4 “(g) *DEFINITIONS.—In this section—*

5 “(1) *the term ‘applicable entity’ means—*

6 “(A) *an applicable group purchasing orga-*  
7 *nization, drug manufacturer, distributor, whole-*  
8 *saler, rebate aggregator (or other purchasing en-*  
9 *tity designed to aggregate rebates), 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 a*  
15 *plan or issuer, or any entity described in sub-*  
16 *paragraph (A); or*

17 “(C) *such other entity as the Secretary, the*  
18 *Secretary of Labor, and the Secretary of the*  
19 *Treasury may specify through rulemaking;*

20 “(2) *the term ‘applicable group purchasing orga-*  
21 *nization’ means a group purchasing organization*  
22 *that is affiliated with or under common ownership*  
23 *with an entity providing pharmacy benefit manage-*  
24 *ment services;*

1           “(3) the term ‘covered group health insurance  
2 coverage’ means health insurance coverage offered in  
3 connection with a group health plan maintained by  
4 a large employer;

5           “(4) the term ‘covered group health plan’ means  
6 a group health plan maintained by a large employer;

7           “(5) the term ‘gross spending’, with respect to  
8 prescription drug benefits under a group health plan  
9 or health insurance coverage, means the amount spent  
10 by a group health plan or health insurance issuer on  
11 prescription drug benefits, calculated before the appli-  
12 cation of rebates, fees, alternative discounts, or other  
13 remuneration;

14           “(6) the term ‘large employer’ means, in connec-  
15 tion with a group health plan with respect to a cal-  
16 endar year and a plan year, an employer who em-  
17 ployed an average of at least 50 employees on busi-  
18 ness days during the preceding calendar year and  
19 who employs at least 1 employee on the first day of  
20 the plan year;

21           “(7) the term ‘net spending’, with respect to pre-  
22 scription drug benefits under a group health plan or  
23 health insurance coverage, means the amount spent by  
24 a group health plan or health insurance issuer on  
25 prescription drug benefits, calculated after the appli-

1 *cation of rebates, fees, alternative discounts, or other*  
2 *remuneration;*

3 “(8) the term ‘plan sponsor’ has the meaning  
4 given such term in section 3(16)(B) of the *Employee*  
5 *Retirement Income Security Act of 1974;*

6 “(9) the term ‘remuneration’ has the meaning  
7 given such term by the Secretary, the Secretary of  
8 Labor, and the Secretary of the Treasury, through  
9 rulemaking, which shall be reevaluated by such secre-  
10 taries every 5 years; and

11 “(10) the term ‘wholesale acquisition cost’ has  
12 the meaning given such term in section  
13 1847A(c)(6)(B) of the *Social Security Act.*”;

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

15 (A) in subsection (a)—

16 (i) in paragraph (1), by inserting  
17 “(other than section 2799A-11)” after “part  
18 D”; and

19 (ii) in paragraph (2), by inserting  
20 “(other than section 2799A-11)” after “part  
21 D”;

22 (B) in subsection (b)—

23 (i) in paragraph (1), by inserting  
24 “(other than section 2799A-11)” after “part  
25 D”;

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

4                   (iii) in paragraph (2)(C)(ii), by in-  
 5                   serting “(other than section 2799A–11)”  
 6                   after “part D”; and

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

9                   “(d) *ENTITIES PROVIDING PHARMACY BENEFIT MAN-*  
 10 *AGEMENT SERVICES.*—Beginning 2 years after the date of  
 11 *enactment of the Pharmacy Benefit Manager Reform Act,*  
 12 *entities providing pharmacy benefit management services*  
 13 *shall report to plan sponsors of group health plans or group*  
 14 *health insurance coverage information required under para-*  
 15 *graphs (4), (5), (6), (7)(A)(iii), and (7)(B) of subsection*  
 16 *(a).”.*

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

19                   (1) *IN GENERAL.*—Subtitle B of title I of the  
 20 *Employee Retirement Income Security Act of 1974*  
 21 *(29 U.S.C. 1021 et seq.) is amended—*

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

1 **“SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
2 **MACY BENEFIT MANAGEMENT SERVICES.**

3       “(a) *IN GENERAL.*—*For plan years beginning on or*  
4 *after the date that is 30 months after the date of enactment*  
5 *of the Pharmacy Benefit Manager Reform Act, a group*  
6 *health plan (or health insurance issuer offering group*  
7 *health insurance coverage in connection with such a plan)*  
8 *or an entity providing pharmacy benefit management serv-*  
9 *ices on behalf of such a plan or issuer shall not enter into*  
10 *a contract with an applicable entity unless such applicable*  
11 *entity agrees to—*

12               “(1) *not limit the disclosure of information to*  
13 *plan sponsors in such a manner that prevents the*  
14 *plan or issuer, or an entity providing pharmacy ben-*  
15 *efit management services on behalf of a plan or*  
16 *issuer, from making the reports described in sub-*  
17 *section (b); and*

18               “(2) *provide the group health plan or health in-*  
19 *surance issuer offering group health insurance cov-*  
20 *erage, or an entity providing pharmacy benefit man-*  
21 *agement services on behalf of a plan or issuer, rel-*  
22 *evant information necessary to make the reports de-*  
23 *scribed in subsection (b).*

24       “(b) *REPORTS.*—

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

1        *enactment of the Pharmacy Benefit Manager Reform*  
2        *Act, not less frequently than annually, an entity pro-*  
3        *viding pharmacy benefit management services on be-*  
4        *half of a covered group health plan or group health*  
5        *insurance coverage (regardless of whether such cov-*  
6        *erage is covered group health insurance coverage as*  
7        *defined in subsection (g)(3)) shall submit to the plan*  
8        *sponsor of such covered group health plan or issuer of*  
9        *such health insurance coverage a report in accordance*  
10       *with this subsection and make such report available*  
11       *to the plan sponsor or issuer in plain language, in*  
12       *a machine-readable format, and, as the Secretary, the*  
13       *Secretary of Health and Human Services, and the*  
14       *Secretary of the Treasury may determine, other for-*  
15       *mats. Each such report shall include, with respect to*  
16       *the covered group health plan or health insurance cov-*  
17       *erage—*

18                *“(A) as applicable, information collected*  
19                *from drug manufacturers by such entity on the*  
20                *total amount of copayment assistance dollars*  
21                *paid, or copayment cards applied, that were*  
22                *funded by such drug manufacturers with respect*  
23                *to the participants and beneficiaries in such*  
24                *plan or coverage;*



1           “(B) a list of each drug covered by the plan,  
2 coverage, or entity providing pharmacy benefit  
3 management services for which a claim was filed  
4 during the reporting period, including, with re-  
5 spect to each such drug during the reporting pe-  
6 riod—

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

9           “(ii) the number of participants and  
10 beneficiaries for whom a claim for the drug  
11 was filed during the reporting period, the  
12 total number of prescription claims for the  
13 drug (including original prescriptions and  
14 refills), and the total number of dosage  
15 units of the drug for which a claim was  
16 filed across the reporting period;

17           “(iii) for each claim or dosage unit de-  
18 scribed in clause (ii), the type of dispensing  
19 channel used, such as retail, mail order, or  
20 specialty pharmacy;

21           “(iv) the wholesale acquisition cost,  
22 listed as cost per days’ supply and cost per  
23 dosage unit;

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

1           *after application of any benefits under the*  
2           *plan or coverage—*

3                     “(I) *including copayments, coin-*  
4                     *surance, and deductibles; and*

5                     “(II) *not including any amounts*  
6                     *spent by participants and beneficiaries*  
7                     *on drugs not covered under the plan or*  
8                     *coverage or for which no claim is sub-*  
9                     *mitted to the plan or coverage; and*

10                    “(vi) *for each of the 50 prescription*  
11                    *drugs with the highest gross spending under*  
12                    *the group health plan or health insurance*  
13                    *coverage during the reporting period—*

14                    “(I) *a list of all other drugs in the*  
15                    *same therapeutic class (as defined by*  
16                    *the Secretary, the Secretary of Health*  
17                    *and Human Services, and the Sec-*  
18                    *retary of the Treasury), including*  
19                    *brand name drugs and biological prod-*  
20                    *ucts and generic drugs or biosimilar*  
21                    *biological products that are in the*  
22                    *same therapeutic class as such drug;*

23                    “(II) *if applicable, the rationale*  
24                    *for preferred formulary placement of*  
25                    *such drug in that therapeutic class, se-*

1                   lected from a list of standard ration-  
2                   ales established by the Secretary, the  
3                   Secretary of Health and Human Serv-  
4                   ices, and the Secretary of the Treasury,  
5                   in consultation with stakeholders; and

6                   “*(III) any change in formulary*  
7                   *placement compared to the prior plan*  
8                   *year;*

9                   “*(C) a list of each therapeutic class (as de-*  
10                  *defined as described in subparagraph (B)(vi)(I)) of*  
11                  *drugs for which a claim was filed under the*  
12                  *group health plan or health insurance coverage*  
13                  *during the reporting period, and, with respect to*  
14                  *each such therapeutic class of drugs, during the*  
15                  *reporting period—*

16                  “*(i) total gross spending by the plan or*  
17                  *by the issuer offering such coverage;*

18                  “*(ii) the number of participants and*  
19                  *beneficiaries who filled a prescription for a*  
20                  *drug in that class;*

21                  “*(iii) if applicable to that class, a de-*  
22                  *scription of the formulary tiers and utiliza-*  
23                  *tion management mechanisms (such as*  
24                  *prior authorization or step therapy) em-*  
25                  *ployed for drugs in that class;*

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

5                   “(I) including copayments, coin-  
6 surance, and deductibles; and

7                   “(II) not including any amounts  
8 spent by participants and beneficiaries  
9 on drugs not covered under the plan or  
10 coverage or for which no claim is sub-  
11 mitted to the plan or issuer; and

12           “(v) for each therapeutic class under  
13 which 3 or more drugs are included on the  
14 formulary of such plan or coverage—

15                   “(I) the amount received, or ex-  
16 pected to be received, by such entity,  
17 from applicable entities, in rebates,  
18 fees, alternative discounts, or other re-  
19 munerations—

20                   “(aa) for claims incurred  
21 during the reporting period; or

22                   “(bb) that is related to utili-  
23 zation of drugs or drug spending;

24                   “(II) the total net spending by the  
25 plan or by the issuer with respect to

1           *such coverage on that class of drugs;*  
2           *and*

3                   “(III) *the average net spending*  
4                   *per 30-day supply and per 90-day*  
5                   *supply by the plan or by the issuer*  
6                   *with respect to such coverage and its*  
7                   *participants and beneficiaries, among*  
8                   *all drugs within the therapeutic class*  
9                   *for which a claim was filed during the*  
10                  *reporting period;*

11                  “(D) *total gross spending on prescription*  
12                  *drugs by the plan or coverage during the report-*  
13                  *ing period;*

14                  “(E) *the total amount received, or expected*  
15                  *to be received, by the group health plan or health*  
16                  *insurance issuer, from applicable entities, in re-*  
17                  *bates, fees, alternative discounts, and other remu-*  
18                  *neration received from such entities, related to*  
19                  *utilization of drugs or drug spending under that*  
20                  *group health plan or health insurance coverage*  
21                  *during the reporting period;*

22                  “(F) *the total net spending on prescription*  
23                  *drugs by the group health plan or health insur-*  
24                  *ance issuer with respect to the coverage during*  
25                  *the reporting period;*

1           “(G) amounts paid directly or indirectly in  
2 rebates, fees, or any other type of compensation  
3 (as defined in section 408(b)(2)(B)(ii)(dd)(AA))  
4 to brokers, consultants, advisors, or any other in-  
5 dividual or firm for—

6           “(i) referral of the group health plan’s  
7 or health insurance issuer’s business to the  
8 pharmacy benefit manager;

9           “(ii) consideration of the entity pro-  
10 viding pharmacy benefit management serv-  
11 ices by the group health plan or health in-  
12 surance issuer; or

13           “(iii) the retention of the entity by the  
14 group health plan or health insurance  
15 issuer;

16           “(H)(i) an explanation of any benefit de-  
17 sign parameters that encourage or require par-  
18 ticipants and beneficiaries in the plan or cov-  
19 erage to fill prescriptions at mail order, spe-  
20 cialty, or retail pharmacies that are affiliated  
21 with or under common ownership with the entity  
22 providing pharmacy benefit management services  
23 on behalf of such plan or coverage, including  
24 mandatory mail and specialty home delivery  
25 programs, retail and mail auto-refill programs,

1           *and cost-sharing assistance incentives funded by*  
2           *an entity providing pharmacy benefit manage-*  
3           *ment services;*

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

11          “(iii) *a list of all drugs dispensed by such*  
12          *affiliated pharmacy or pharmacy under common*  
13          *ownership and charged to the plan, issuer, or*  
14          *participants and beneficiaries of the plan or cov-*  
15          *erage, during the applicable period, and, with*  
16          *respect to each drug—*

17                 “(I)(aa) *the amount charged, per dos-*  
18                 *age unit, per 30-day supply, and per 90-*  
19                 *day supply, with respect to participants*  
20                 *and beneficiaries in the plan or coverage, to*  
21                 *the plan or issuer; and*

22                 “(bb) *the amount charged, per dosage*  
23                 *unit, per 30-day supply, and per 90-day*  
24                 *supply to participants and beneficiaries;*

1           “(II) the median amount charged to  
2 the plan or issuer, per dosage unit, per 30-  
3 day supply, and per 90-day supply, includ-  
4 ing amounts paid by the participants and  
5 beneficiaries, when the same drug is dis-  
6 pensed by other pharmacies that are not af-  
7 filiated with or under common ownership  
8 with the entity and that are included in the  
9 pharmacy network of that plan or coverage;

10           “(III) the interquartile range of the  
11 costs, per dosage unit, per 30-day supply,  
12 and per 90-day supply, including amounts  
13 paid by the participants and beneficiaries,  
14 when the same drug is dispensed by other  
15 pharmacies that are not affiliated with or  
16 under common ownership with the entity  
17 and that are included in the pharmacy net-  
18 work of that plan or coverage;

19           “(IV) the lowest cost, per dosage unit,  
20 per 30-day supply, and per 90-day supply,  
21 for such drug, including amounts charged to  
22 the plan and participants and beneficiaries,  
23 that is available from any pharmacy in-  
24 cluded in the network of the plan or cov-  
25 erage;



1           “(V) *the net acquisition cost per dosage*  
2           *unit, per 30-day supply, and per 90-day*  
3           *supply, if the drug is subject to a maximum*  
4           *price discount; and*

5           “(VI) *other information with respect to*  
6           *the cost of the drug, as determined by the*  
7           *Secretary, the Secretary of Health and*  
8           *Human Services, and the Secretary of the*  
9           *Treasury, such as average sales price,*  
10          *wholesale acquisition cost, and national av-*  
11          *erage drug acquisition cost per dosage unit*  
12          *or per 30-day supply, for such drug, includ-*  
13          *ing amounts charged to the plan or issuer*  
14          *and participants and beneficiaries among*  
15          *all pharmacies included in the network of*  
16          *the plan or coverage;*

17          “(I) *a summary document for plan sponsors*  
18          *or issuers that includes the information described*  
19          *in subparagraphs (A) through (H) that the Sec-*  
20          *retary, the Secretary of Health and Human*  
21          *Services, and the Secretary of the Treasury de-*  
22          *termine useful to plan sponsors and health in-*  
23          *surance issuers for purposes of selecting phar-*  
24          *macy benefit management services, such as an*  
25          *estimated net price to plan sponsor and partici-*

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

4            *“(J) a summary document for participants*  
5            *or beneficiaries, which shall be made available to*  
6            *participants or beneficiaries upon request to the*  
7            *plan sponsor, that contains the information de-*  
8            *scribed in subparagraphs (D) through (G) that*  
9            *the Secretary, the Secretary of Health and*  
10           *Human Services, and the Secretary of the Treas-*  
11           *ury determine useful to participants or bene-*  
12           *ficiaries in better understanding their plan or*  
13           *benefits, except that such summary document for*  
14           *participants or beneficiaries shall contain only*  
15           *aggregate information.*

16           *“(2) REGULATIONS.—Not later than 2 years*  
17           *after the date of enactment of the Pharmacy Benefit*  
18           *Manager Reform Act, the Secretary, the Secretary of*  
19           *Health and Human Services, and the Secretary of the*  
20           *Treasury shall, through notice and comment rule-*  
21           *making, promulgate final regulations to implement*  
22           *the requirements of this subsection. In promulgating*  
23           *such regulations, the Secretary, the Secretary of*  
24           *Health and Human Services, and the Secretary of the*  
25           *Treasury shall, to the extent practicable, align the re-*

1        *porting requirements under this subsection with the*  
2        *reporting requirements under section 725.*

3            *“(3) ADDITIONAL REPORTING.—*

4                    *“(A) REPORTING WITH RESPECT TO GROUP*  
5                    *HEALTH PLANS OFFERED BY SMALL EMPLOY-*  
6                    *ERS.—For plan years beginning on or after the*  
7                    *date that is 30 months after the date of enact-*  
8                    *ment of the Pharmacy Benefit Manager Reform*  
9                    *Act, not less frequently than annually, an entity*  
10                   *providing pharmacy benefit management services*  
11                   *on behalf of a group health plan that is not a*  
12                   *covered group health plan shall submit to the*  
13                   *plan sponsor of such group health plan a report*  
14                   *in accordance with this paragraph, and make*  
15                   *such report available to the plan sponsor in a*  
16                   *machine-readable format, and such other formats*  
17                   *as the Secretary, the Secretary of Health and*  
18                   *Human Services, and the Secretary of the Treas-*  
19                   *ury may specify. Each such report shall include,*  
20                   *with respect to the applicable group health*  
21                   *plan—*

22                            *“(i) the information described in sub-*  
23                            *paragraphs (D), (E), (F), and (G) of para-*  
24                            *graph (1);*

1           “(ii) as applicable, information col-  
2           lected from drug manufacturers by such  
3           plan on the total amount of copayment as-  
4           sistance dollars paid, or copayment cards  
5           applied, that were funded by applicable  
6           drug manufacturers with respect to the par-  
7           ticipants and beneficiaries in such plan, ex-  
8           cept that such information shall not iden-  
9           tify any drug manufacturer; and

10           “(iii) a summary document that in-  
11           cludes the information described in clauses  
12           (i) and (ii) that the Secretary, the Sec-  
13           retary of Health and Human Services, and  
14           the Secretary of the Treasury determine use-  
15           ful to plan sponsors for purposes of selecting  
16           pharmacy benefit management services, pro-  
17           vided that such summary documents include  
18           only aggregate information.

19           “(B) *OPT-IN FOR GROUP HEALTH INSUR-*  
20           *ANCE COVERAGE.—*

21           “(i) *IN GENERAL.—*A plan sponsor of  
22           group health insurance coverage offered in  
23           connection with a group health plan may,  
24           on an annual basis, for plan years begin-  
25           ning on or after the date that is 30 months

1           *after the date of enactment of the Pharmacy*  
2           *Benefit Manager Reform Act, elect to re-*  
3           *quire an entity providing pharmacy benefit*  
4           *management services on behalf of a health*  
5           *insurance issuer offering group health in-*  
6           *surance coverage to submit to such plan*  
7           *sponsor a report in accordance with this*  
8           *subsection.*

9                   “(ii) CONTENTS OF REPORTS.—

10                           “(I) COVERED GROUP HEALTH IN-

11                           *SURANCE COVERAGE.—In the case of*  
12                           *an entity providing pharmacy benefit*  
13                           *management services on behalf of an*  
14                           *issuer that offers covered group health*  
15                           *insurance coverage, a report provided*  
16                           *pursuant to clause (i) shall include,*  
17                           *with respect to the applicable covered*  
18                           *group health insurance coverage, the*  
19                           *information required under paragraph*  
20                           *(1) for covered group health plans.*

21                           “(II) OTHER GROUP HEALTH IN-

22                           *SURANCE COVERAGE.—In the case of*  
23                           *an entity providing pharmacy benefit*  
24                           *management services on behalf of an*  
25                           *issuer that offers group health insur-*

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

6                    *“(aa) the information de-*  
7                    *scribed in subparagraphs (D),*  
8                    *(E), (F), and (G) of paragraph*  
9                    *(1); and*

10                    *“(bb) as applicable, informa-*  
11                    *tion collected from drug manufac-*  
12                    *turers by such issuer or entity on*  
13                    *the total amount of copayment as-*  
14                    *sistance dollars paid, or copay-*  
15                    *ment cards applied, that were*  
16                    *funded by applicable drug manu-*  
17                    *facturers with respect to the par-*  
18                    *ticipants and beneficiaries in such*  
19                    *plan, except that such information*  
20                    *shall not identify any drug manu-*  
21                    *facturer.*

22                    *“(iii) REQUIRED REPORTING FOR COV-*  
23                    *ERED GROUP HEALTH INSURANCE COV-*  
24                    *ERAGE.—Each health insurance issuer that*  
25                    *offers covered group health insurance cov-*

1            *erage shall annually submit to the plan*  
2            *sponsor the information described in para-*  
3            *graph (1)(I), regardless of whether the plan*  
4            *sponsor made the election described in*  
5            *clause (i) for the applicable year.*

6            *“(iv) REQUIRED REPORTING FOR*  
7            *OTHER GROUP HEALTH INSURANCE COV-*  
8            *ERAGE.—Each health insurance issuer that*  
9            *offers group health insurance coverage that*  
10           *is not covered group health insurance shall*  
11           *annually submit a summary document that*  
12           *includes such information described in*  
13           *items (aa) and (bb) of clause (ii)(II) as the*  
14           *Secretary and the Secretary of Health and*  
15           *Human Services determine useful for plan*  
16           *sponsors for purposes of selecting pharmacy*  
17           *benefit management services, provided that*  
18           *such summary documents include only ag-*  
19           *gregate information.*

20           *“(4) PRIVACY REQUIREMENTS.—*

21           *“(A) RELATIONSHIP TO HIPAA REGULA-*  
22           *TIONS.—Nothing in this section shall be con-*  
23           *strued to modify the requirements for the cre-*  
24           *ation, receipt, maintenance, or transmission of*  
25           *protected health information under the HIPAA*

1 *privacy regulations, as defined in section*  
2 *1180(b)(3) of the Social Security Act (42 U.S.C.*  
3 *1320d–9(b)(3)).*

4 “(B) *REQUIREMENT.*—*A report submitted*  
5 *under paragraph (1) or (3) shall contain only*  
6 *summary health information, as defined in sec-*  
7 *tion 164.504(a) of title 45, Code of Federal Regu-*  
8 *lations (or successor regulations).*

9 “(C) *CLARIFICATION REGARDING CERTAIN*  
10 *DISCLOSURES OF INFORMATION.*—

11 “(i) *REASONABLE RESTRICTIONS.*—  
12 *Nothing in this section prevents a health in-*  
13 *surance issuer offering group health insur-*  
14 *ance coverage or an entity providing phar-*  
15 *macy benefit management services on behalf*  
16 *of a group health plan or health insurance*  
17 *issuer offering group health insurance cov-*  
18 *erage from placing reasonable restrictions*  
19 *(as the Secretary, the Secretary of Health*  
20 *and Human Services, and the Secretary of*  
21 *the Treasury may determine) on the public*  
22 *disclosure of the information contained in a*  
23 *report under paragraph (1) or (3).*

24 “(ii) *LIMITATIONS.*—*A health insur-*  
25 *ance issuer offering group health insurance*



1           *coverage or an entity providing pharmacy*  
2           *benefit management services on behalf of a*  
3           *group health plan or health insurance issuer*  
4           *offering group health insurance coverage*  
5           *may not restrict disclosure of such reports*  
6           *to the Department of Health and Human*  
7           *Services, the Department of Labor, the De-*  
8           *partment of the Treasury, or any other Fed-*  
9           *eral agency responsible for enforcement ac-*  
10           *tivities under this section for purposes of*  
11           *enforcement under this section or other ap-*  
12           *plicable law, or to the Comptroller General*  
13           *of the United States in accordance with*  
14           *paragraph (6).*

15           “(5) *USE AND DISCLOSURE BY PLAN SPON-*  
16           *SORS.—*

17                   “(A) *PROHIBITION.—A plan sponsor may*  
18           *not—*

19                           “(i) *fail or refuse to hire, or discharge,*  
20                           *any employee, or otherwise discriminate*  
21                           *against any employee with respect to the*  
22                           *compensation, terms, conditions, or privi-*  
23                           *leges of employment of the employee, because*  
24                           *of information submitted under paragraph*

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

3           “(ii) limit, segregate, or classify the  
4           employees of the employer in any way that  
5           would deprive or tend to deprive any em-  
6           ployee of employment opportunities or oth-  
7           erwise adversely affect the status of the em-  
8           ployee as an employee, because of informa-  
9           tion submitted under paragraph (1) or (3)  
10          attributed to the employee or a dependent of  
11          the employee.

12          “(B) *DISCLOSURE AND REDISCLOSURE.*—A  
13          plan sponsor shall not disclose the information  
14          received under paragraph (1) or (3) except—

15               “(i) to an occupational or other health  
16               researcher if the research is conducted in  
17               compliance with the regulations and protec-  
18               tions provided for under part 46 of title 45,  
19               Code of Federal Regulations (or successor  
20               regulations);

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

1           “(iii) to the Department of Health and  
2           Human Services, the Department of Labor,  
3           the Department of the Treasury, or other  
4           Federal agency responsible for enforcement  
5           activities under this section; or

6           “(iv) to a contractor or agent for pur-  
7           poses of health plan administration, if such  
8           contractor or agent agrees, in writing, and  
9           as a term of the contract, to abide by the  
10          same use and disclosure restrictions as the  
11          plan sponsor.

12          “(C) *RELATIONSHIP TO HIPAA REGULA-*  
13          *TIONS.—With respect to HIPAA privacy regula-*  
14          *tions, as defined in section 1180(b)(3) of the So-*  
15          *cial Security Act (42 U.S.C. 1320d–9(b)(3)),*  
16          *subparagraph (B) does not prohibit a covered en-*  
17          *tity (as defined for purposes of such regulations*  
18          *promulgated under section 264 of the Health In-*  
19          *surance Portability and Accountability Act of*  
20          *1996 (42 U.S.C. 1320d–2)) from any use or dis-*  
21          *closure of health information that is authorized*  
22          *for the covered entity under such regulations.*  
23          *The previous sentence does not affect the author-*  
24          *ity of such Secretary to modify such regulations.*

1           “(D) *WRITTEN NOTICE.*—*Plan sponsors of*  
2 *group health plans and group health insurance*  
3 *coverage shall provide to each employee written*  
4 *notice informing the employee of the requirement*  
5 *for health insurance issuers or entities providing*  
6 *pharmacy benefit management services on behalf*  
7 *of the plan or coverage to submit reports to plan*  
8 *sponsors under paragraphs (1) and (3), as appli-*  
9 *cable, which may include incorporating such no-*  
10 *tification in plan documents provided to the em-*  
11 *ployee, an employee handbook provided to the*  
12 *employee, or individual notification.*

13           “(E) *ENFORCEMENT.*—

14           “(i) *IN GENERAL.*—*The powers, proce-*  
15 *dures, and remedies provided in section 207*  
16 *of the Genetic Information Nondiscrimina-*  
17 *tion Act (42 U.S.C. 2000ff–6) to a person*  
18 *alleging a violation of title II of such Act*  
19 *shall be the powers, procedures, and rem-*  
20 *edies this subparagraph provides for any*  
21 *person alleging a violation of this para-*  
22 *graph.*

23           “(ii) *PROHIBITION AGAINST RETALIA-*  
24 *TION.*—*No person shall discriminate*  
25 *against any individual because such indi-*

1            *vidual has opposed any act or practice*  
2            *made unlawful by this paragraph or be-*  
3            *cause such individual made a charge, testi-*  
4            *fied, assisted, or participated in any man-*  
5            *ner in an investigation, proceeding, or hear-*  
6            *ing under this paragraph. The remedies and*  
7            *procedures otherwise provided for under this*  
8            *subparagraph shall be available to aggrieved*  
9            *individuals with respect to violations of this*  
10           *clause.*

11            *“(6) SUBMISSIONS TO GAO.—A health insurance*  
12            *issuer offering group health insurance coverage or an*  
13            *entity providing pharmacy benefit management serv-*  
14            *ices on behalf of a group health plan shall submit,*  
15            *upon request, to the Comptroller General of the*  
16            *United States each of the first 2 reports submitted to*  
17            *a plan sponsor under paragraph (1) or (3) with re-*  
18            *spect to such coverage or plan, and other such reports*  
19            *as requested, in accordance with the privacy require-*  
20            *ments under paragraph (4), and such other informa-*  
21            *tion that the Comptroller General determines nec-*  
22            *essary to carry out the study under section 2(f) of the*  
23            *Pharmacy Benefit Manager Reform Act.*

24            *“(7) STANDARD FORMATS.—*

1           “(A) *IN GENERAL.*—Not later than June 1,  
2           2024, the Secretary, the Secretary of Health and  
3           Human Services, and the Secretary of the Treas-  
4           ury shall specify, through rulemaking, standard  
5           formats for entities providing pharmacy benefit  
6           management services to submit reports required  
7           under this subsection. Such secretaries may pro-  
8           vide for separate standard formats for reports to  
9           plan sponsors of group health plans and reports  
10          to plan sponsors of group health insurance cov-  
11          erage offered in connection with a group health  
12          plan.

13          “(B) *FORM OF REPORT.*—The Secretary, the  
14          Secretary of Health and Human Services, and  
15          the Secretary of the Treasury shall define  
16          through rulemaking a form of the reports under  
17          paragraphs (1) and (3) required to be submitted  
18          to plan sponsors who also are drug manufactur-  
19          ers, drug wholesalers, entities providing phar-  
20          macy benefit management services, or other di-  
21          rect participants in the drug supply chain, in  
22          the case that such secretaries determine that  
23          changes to the standard format are necessary to  
24          prevent anticompetitive behavior.

25          “(c) *LIMITATIONS ON SPREAD PRICING.*—

1           “(1) *IN GENERAL.*—*For plan years beginning on*  
2           *or after the date that is 30 months after the date of*  
3           *enactment of the Pharmacy Benefit Manager Reform*  
4           *Act, a group health plan or health insurance issuer*  
5           *offering group health insurance coverage shall ensure*  
6           *that the amount required to be paid by a participant*  
7           *or beneficiary for a prescription drug covered under*  
8           *the plan or coverage, and a third-party administrator*  
9           *or an entity providing pharmacy benefit management*  
10           *services on behalf of such a plan or coverage shall en-*  
11           *sure that the total amount required to be paid by the*  
12           *plan or issuer and participant or beneficiary for a*  
13           *prescription drug covered under the plan or coverage,*  
14           *does not exceed the price paid to the pharmacy, ex-*  
15           *cluding penalties paid by the pharmacy (as described*  
16           *in paragraph (2)) to such plan, issuer, or entity.*

17           “(2) *RULE OF CONSTRUCTION.*—*For purposes of*  
18           *paragraph (1), penalties paid by pharmacies include*  
19           *only the following:*

20                   “(A) *A penalty paid if an original claim*  
21                   *for a prescription drug was submitted fraudu-*  
22                   *lently by the pharmacy to the plan, issuer, or en-*  
23                   *tity.*

24                   “(B) *A penalty paid if the original claim*  
25                   *payment made by the plan, issuer, or entity to*

1           *the pharmacy was inconsistent with the reim-*  
2           *bursement terms in any contract between the*  
3           *pharmacy and the plan, issuer, or entity.*

4           “(C) *A penalty paid if the pharmacist serv-*  
5           *ices for which a claim was filed with the plan,*  
6           *issuer, or entity were not rendered by the phar-*  
7           *macy.*

8           “(d) *FULL REBATE PASS-THROUGH TO PLAN OR*  
9           *HEALTH INSURANCE ISSUER.—*

10           “(1) *IN GENERAL.—For plan years beginning on*  
11           *or after the date that is 30 months after the date of*  
12           *enactment of the Pharmacy Benefit Manager Reform*  
13           *Act, a third-party administrator of a group health*  
14           *plan or an entity providing pharmacy benefit man-*  
15           *agement services on behalf of a group health plan or*  
16           *health insurance issuer offering group health insur-*  
17           *ance coverage shall—*

18           “(A) *remit 100 percent of rebates, fees, al-*  
19           *ternative discounts, and other remuneration re-*  
20           *ceived from any applicable entity that are re-*  
21           *lated to utilization of drugs under such group*  
22           *health plan or health insurance coverage, to the*  
23           *group health plan or health insurance issuer of-*  
24           *fering group health insurance coverage; and*



1           “(B) ensure that any contract entered into,  
2           by such third-party administrator or entity pro-  
3           viding pharmacy benefit management services on  
4           behalf of such a plan or coverage, with rebate  
5           aggregators (or other purchasing entity designed  
6           to aggregate rebates), applicable group pur-  
7           chasing organizations, or any subsidiary, par-  
8           ent, affiliate, or subcontractor of the plan, entity,  
9           rebate aggregator (or other purchasing entity de-  
10          signed to aggregate rebates), or applicable group  
11          purchasing organization remit 100 percent of re-  
12          bates, fees, alternative discounts, and other remu-  
13          neration received that are related to utilization  
14          of drugs under such group health plan or health  
15          insurance coverage, to the third-party adminis-  
16          trator or entity providing pharmacy benefit  
17          management services.

18           “(2) *FORM AND MANNER OF REMITTANCE.*—With  
19          respect to such rebates, fees, alternative discounts, and  
20          other remuneration—

21           “(A) the rebates, fees, alternative discounts,  
22          and other remuneration under paragraph (1)(A)  
23          shall be—

24           “(i) remitted—

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

5                   “(II) in the case of an under-  
6                   payment in a remittance for a prior  
7                   quarter, as soon as practicable, but not  
8                   later than 90 days after notice of the  
9                   underpayment is first given;

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

14                  “(iii) returned to the issuer or entity  
15                  providing pharmacy benefit management  
16                  services on behalf of the group health plan  
17                  if an audit by a plan sponsor, or a third  
18                  party designated by a plan sponsor, indi-  
19                  cates that the amounts received are incor-  
20                  rect after such amounts have been paid to  
21                  the group health plan or health insurance  
22                  issuer;

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

1           *dures as the Secretary, Secretary of Health and*  
2           *Human Services, and Secretary of the Treasury*  
3           *establish; and*

4           “(C) *the records of such rebates, fees, alter-*  
5           *native discounts, and other remuneration shall*  
6           *be available for audit by the plan sponsor,*  
7           *issuer, or a third party designated by a plan*  
8           *sponsor, not less than once per plan year.*

9           “(3) *AUDIT OF REBATE CONTRACTS.—A third-*  
10          *party administrator of a group health plan, a health*  
11          *insurance issuer offering group health insurance cov-*  
12          *erage, or an entity providing pharmacy benefit man-*  
13          *agement services on behalf of such group health plan*  
14          *or health insurance coverage shall make rebate con-*  
15          *tracts with rebate aggregators or drug manufacturers*  
16          *available for audit by the plan sponsor or designated*  
17          *third party, subject to reasonable restrictions (as de-*  
18          *termined by the Secretary, the Secretary of Health*  
19          *and Human Services, and the Secretary of the Treas-*  
20          *ury) on confidentiality to prevent re-disclosure of*  
21          *such contracts.*

22          “(4) *AUDITORS.—Audits carried out under para-*  
23          *graphs (2)(C) and (3) shall be performed by an audi-*  
24          *tor selected by the applicable plan sponsor.*

1           “(5) *RULE OF CONSTRUCTION.*—*Nothing in this*  
2           *subsection shall be construed to—*

3                   “(A) *prohibit payments to entities offering*  
4                   *pharmacy benefit management services for bona*  
5                   *fide services using a fee structure not described*  
6                   *in this subsection, provided that such fees are*  
7                   *transparent to group health plans and health in-*  
8                   *surance issuers;*

9                   “(B) *require a third-party administrator of*  
10                   *a group health plan or an entity providing*  
11                   *pharmacy benefit management services on behalf*  
12                   *of a group health plan or health insurance issuer*  
13                   *offering group health insurance coverage to remit*  
14                   *bona fide service fees to the group health plans*  
15                   *or health insurance issuers; or*

16                   “(C) *limit the ability of a group health*  
17                   *plan or health insurance issuer to pass through*  
18                   *rebates, fees, alternative discounts, and other re-*  
19                   *muneration to the participant or beneficiary.*

20           “(e) *ENFORCEMENT.*—

21                   “(1) *IN GENERAL.*—*The Secretary shall enforce*  
22                   *this section.*

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

1       (a); an entity providing pharmacy benefit manage-  
2       ment services that fails to provide information re-  
3       quired under subsection (b); a group health plan,  
4       health insurance issuer, or entity providing phar-  
5       macy benefit management services that violates sub-  
6       section (c); or a third-party administrator of a group  
7       health plan, a health insurance issuer, or an entity  
8       providing pharmacy benefit management services that  
9       violates subsection (d) shall be subject to a civil mone-  
10      etary penalty in the amount of \$10,000 for each day  
11      during which such violation continues or such infor-  
12      mation is not disclosed or reported.

13           “(3) *FALSE INFORMATION.*—A group health  
14      plan, a health insurance issuer, an entity providing  
15      pharmacy benefit management services, or a third-  
16      party administrator that knowingly provides false in-  
17      formation under this section shall be subject to a civil  
18      money penalty in an amount not to exceed \$100,000  
19      for each item of false information. Such civil money  
20      penalty shall be in addition to other penalties as may  
21      be prescribed by law.

22           “(4) *PROCEDURE.*—The Secretary shall impose  
23      civil monetary penalties under this subsection in the  
24      same manner and according to the same procedures

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

3               “(5) *WAIVERS.*—*The Secretary may waive pen-*  
4       *alties under paragraph (2), or extend the period of*  
5       *time for compliance with a requirement of this sec-*  
6       *tion, for an entity in violation of this section that has*  
7       *made a good-faith effort to comply with this section.*

8               “(f) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
9       *tion shall be construed to permit a health insurance issuer,*  
10       *group health plan, entity providing pharmacy benefit man-*  
11       *agement services on behalf of a group health plan or health*  
12       *insurance issuer, or other entity to restrict disclosure to,*  
13       *or otherwise limit the access of, the Secretary of Labor, the*  
14       *Secretary of Health and Human Services, or the Secretary*  
15       *of the Treasury to a report described in subsection (b)(1)*  
16       *or information related to compliance with subsections (a),*  
17       *(b), (c), or (d) by such issuer, plan, or entity.*

18               “(g) *DEFINITIONS.*—*In this section—*

19                       “(1) *the term ‘applicable entity’ means—*

20                               “(A) *an applicable group purchasing orga-*  
21       *nization, drug manufacturer, distributor, whole-*  
22       *saler, rebate aggregator (or other purchasing en-*  
23       *tity designed to aggregate rebates), or associated*  
24       *third party;*

1           “(B) any subsidiary, parent, affiliate, or  
2           subcontractor of a group health plan, health in-  
3           surance issuer, entity that provides pharmacy  
4           benefit management services on behalf of such a  
5           plan or issuer, or any entity described in sub-  
6           paragraph (A); or

7           “(C) such other entity as the Secretary, the  
8           Secretary of Health and Human Services, and  
9           the Secretary of the Treasury may specify  
10          through rulemaking;

11          “(2) the term ‘applicable group purchasing orga-  
12          nization’ means a group purchasing organization  
13          that is affiliated with or under common ownership  
14          with an entity providing pharmacy benefit manage-  
15          ment services;

16          “(3) the term ‘covered group health insurance  
17          coverage’ means health insurance coverage offered in  
18          connection with a group health plan maintained by  
19          a large employer;

20          “(4) the term ‘covered group health plan’ means  
21          a group health plan maintained by a large employer;

22          “(5) the term ‘gross spending’, with respect to  
23          prescription drug benefits under a group health plan  
24          or health insurance coverage, means the amount spent  
25          by a group health plan or health insurance issuer on

1       *prescription drug benefits, calculated before the appli-*  
2       *cation of rebates, fees, alternative discounts, or other*  
3       *remuneration;*

4               “(6) the term ‘large employer’ means, in connec-

5       *tion with a group health plan with respect to a cal-*  
6       *endar year and a plan year, an employer who em-*  
7       *ployed an average of at least 50 employees on busi-*  
8       *ness days during the preceding calendar year and*  
9       *who employs at least 1 employee on the first day of*  
10       *the plan year;*

11              “(7) the term ‘net spending’, with respect to pre-

12       *scription drug benefits under a group health plan or*  
13       *health insurance coverage, means the amount spent by*  
14       *a group health plan or health insurance issuer on*  
15       *prescription drug benefits, calculated after the appli-*  
16       *cation of rebates, fees, alternative discounts, or other*  
17       *remuneration;*

18              “(8) the term ‘plan sponsor’ has the meaning

19       *given such term in section 3(16)(B);*

20              “(9) the term ‘remuneration’ has the meaning

21       *given such term by the Secretary, the Secretary of*  
22       *Health and Human Services, and the Secretary of the*  
23       *Treasury, through rulemaking, which shall be reevalu-*  
24       *ated by such secretaries every 5 years; and*



1           “(10) the term ‘wholesale acquisition cost’ has  
2 the meaning given such term in section  
3 1847A(c)(6)(B) of the Social Security Act (42 U.S.C.  
4 1395w–3a(c)(6)(B)).”; and

5           (B) in section 502(b)(3) (29 U.S.C.  
6 1132(b)(3)), by inserting “(other than section  
7 726)” after “part 7”.

8           (2) CLERICAL AMENDMENT.—The table of con-  
9 tents in section 1 of the Employee Retirement Income  
10 Security Act of 1974 (29 U.S.C. 1001 et seq.) is  
11 amended by inserting after the item relating to sec-  
12 tion 725 the following new item:

“Sec. 726. Oversight of entities that provide pharmacy benefit manage-  
ment services.”.

13           (3) ADDITIONAL REPORTING REQUIREMENT.—  
14 Section 725 of the Employee Retirement Income Secu-  
15 rity Act of 1974 (29 U.S.C. 1185n) is amended by  
16 adding at the end the following:

17           “(d) ENTITIES PROVIDING PHARMACY BENEFIT MAN-  
18 AGEMENT SERVICES.—Beginning 2 years after the date of  
19 enactment of the Pharmacy Benefit Manager Reform Act,  
20 entities providing pharmacy benefit management services  
21 shall report to plan sponsors of group health plans informa-  
22 tion required under paragraphs (4), (5), (6), (7)(A)(iii),  
23 and (7)(B) of subsection (a).”.

24           (c) INTERNAL REVENUE CODE OF 1986.—

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

4           **“SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
5                                   **MACY BENEFIT MANAGEMENT SERVICES.**

6           “(a) *IN GENERAL.*—For plan years beginning on or  
7           after the date that is 30 months after the date of enactment  
8           of the Pharmacy Benefit Manager Reform Act, a group  
9           health plan or an entity providing pharmacy benefit man-  
10          agement services on behalf of such a plan shall not enter  
11          into a contract with an applicable entity unless such appli-  
12          cable entity agrees to—

13                 “(1) not limit the disclosure of information to  
14                 plan sponsors in such a manner that prevents the  
15                 plan, or an entity providing pharmacy benefit man-  
16                 agement services on behalf of a plan, from making the  
17                 reports described in subsection (b); and

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

22          “(b) *REPORTS.*—

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

1     *Act, not less frequently than annually, an entity pro-*  
2     *viding pharmacy benefit management services on be-*  
3     *half of a covered group health plan shall submit to the*  
4     *plan sponsor of such covered group health plan a re-*  
5     *port in accordance with this subsection and make*  
6     *such report available to the plan sponsor in plain*  
7     *language, in a machine-readable format, and, as the*  
8     *Secretary, the Secretary of Labor, and the Secretary*  
9     *of Health and Human Services may determine, other*  
10    *formats. Each such report shall include, with respect*  
11    *to the covered group health plan—*

12            “(A) as applicable, information collected  
13            from drug manufacturers by such entity on the  
14            total amount of copayment assistance dollars  
15            paid, or copayment cards applied, that were  
16            funded by such drug manufacturers with respect  
17            to the participants and beneficiaries in such  
18            plan;

19            “(B) a list of each drug covered by the plan  
20            or entity providing pharmacy benefit manage-  
21            ment services for which a claim was filed during  
22            the reporting period, including, with respect to  
23            each such drug during the reporting period—

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

1           “(ii) the number of participants and  
2 beneficiaries for whom a claim for the drug  
3 was filed during the reporting period, the  
4 total number of prescription claims for the  
5 drug (including original prescriptions and  
6 refills), and the total number of dosage  
7 units of the drug for which a claim was  
8 filed across the reporting period;

9           “(iii) for each claim or dosage unit de-  
10 scribed in clause (ii), the type of dispensing  
11 channel used, such as retail, mail order, or  
12 specialty pharmacy;

13           “(iv) the wholesale acquisition cost,  
14 listed as cost per days’ supply and cost per  
15 dosage unit;

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

20                   “(I) including copayments, coin-  
21 surance, and deductibles; and

22                   “(II) not including any amounts  
23 spent by participants and beneficiaries  
24 on drugs not covered under the plan or

1                   *for which no claim is submitted to the*  
2                   *plan; and*

3                   “(vi) *for each of the 50 prescription*  
4                   *drugs with the highest gross spending under*  
5                   *the group health plan during the reporting*  
6                   *period—*

7                                 “(I) *a list of all other drugs in the*  
8                                 *same therapeutic class (as defined by*  
9                                 *the Secretary, the Secretary of Labor,*  
10                                *and the Secretary of Health and*  
11                                *Human Services), including brand*  
12                                *name drugs and biological products*  
13                                *and generic drugs or biosimilar bio-*  
14                                *logical products that are in the same*  
15                                *therapeutic class as such drug;*

16                               “(II) *if applicable, the rationale*  
17                                *for preferred formulary placement of*  
18                                *such drug in that therapeutic class, se-*  
19                                *lected from a list of standard ration-*  
20                                *ales established by the Secretary, the*  
21                                *Secretary of Labor, and the Secretary*  
22                                *of Health and Human Services, in*  
23                                *consultation with stakeholders; and*

1                   “(III) any change in formulary  
2                   placement compared to the prior plan  
3                   year;

4                   “(C) a list of each therapeutic class (as de-  
5                   fined as described in subparagraph (B)(vi)(I)) of  
6                   drugs for which a claim was filed under the  
7                   group health plan during the reporting period,  
8                   and, with respect to each such therapeutic class  
9                   of drugs, during the reporting period—

10                   “(i) total gross spending by the plan;

11                   “(ii) the number of participants and  
12                   beneficiaries who filled a prescription for a  
13                   drug in that class;

14                   “(iii) if applicable to that class, a de-  
15                   scription of the formulary tiers and utiliza-  
16                   tion management mechanisms (such as  
17                   prior authorization or step therapy) em-  
18                   ployed for drugs in that class;

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

23                   “(I) including copayments, coin-  
24                   surance, and deductibles; and

1           “(II) not including any amounts  
2           spent by participants and beneficiaries  
3           on drugs not covered under the plan or  
4           for which no claim is submitted to the  
5           plan; and

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

9                   “(I) the amount received, or ex-  
10                  pected to be received, by such entity,  
11                  from applicable entities, in rebates,  
12                  fees, alternative discounts, or other re-  
13                  muneration—

14                           “(aa) for claims incurred  
15                           during the reporting period; or

16                                   “(bb) that is related to utili-  
17                                   zation of drugs or drug spending;

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

20                                   “(III) the average net spending  
21                                   per 30-day supply and per 90-day  
22                                   supply by the plan and its partici-  
23                                   pants and beneficiaries, among all  
24                                   drugs within the therapeutic class for

1                   *which a claim was filed during the re-*  
2                   *porting period;*

3                   “(D) *total gross spending on prescription*  
4                   *drugs by the plan during the reporting period;*

5                   “(E) *the total amount received, or expected*  
6                   *to be received, by the group health plan, from ap-*  
7                   *licable entities, in rebates, fees, alternative dis-*  
8                   *counts, and other remuneration received from*  
9                   *such entities, related to utilization of drugs or*  
10                  *drug spending under that group health plan dur-*  
11                  *ing the reporting period;*

12                  “(F) *the total net spending on prescription*  
13                  *drugs by the group health plan during the re-*  
14                  *porting period;*

15                  “(G) *amounts paid directly or indirectly in*  
16                  *rebates, fees, or any other type of compensation*  
17                  *(as defined in section 408(b)(2)(B)(ii)(dd)(AA)*  
18                  *of the Employee Retirement Income Security Act*  
19                  *of 1974 (29 U.S.C. 1108(b)(2)(B)(ii)(dd)(A))) to*  
20                  *brokers, consultants, advisors, or any other indi-*  
21                  *vidual or firm for—*

22                  “(i) *referral of the group health plan’s*  
23                  *business to the pharmacy benefit manager;*



1           “(ii) consideration of the entity pro-  
2           viding pharmacy benefit management serv-  
3           ices by the group health plan; or

4           “(iii) the retention of the entity by the  
5           group health plan;

6           “(H)(i) an explanation of any benefit de-  
7           sign parameters that encourage or require par-  
8           ticipants and beneficiaries in the plan to fill  
9           prescriptions at mail order, specialty, or retail  
10          pharmacies that are affiliated with or under  
11          common ownership with the entity providing  
12          pharmacy benefit management services on behalf  
13          of such plan, including mandatory mail and  
14          specialty home delivery programs, retail and  
15          mail auto-refill programs, and cost-sharing as-  
16          sistance incentives funded by an entity providing  
17          pharmacy benefit management services;

18          “(ii) the percentage of total prescriptions  
19          charged to the plan or participants and bene-  
20          ficiaries in the plan, that were dispensed by mail  
21          order, specialty, or retail pharmacies that are af-  
22          filiated with or under common ownership with  
23          the entity providing pharmacy benefit manage-  
24          ment services; and

1           “(iii) a list of all drugs dispensed by such  
2           affiliated pharmacy or pharmacy under common  
3           ownership and charged to the plan, or partici-  
4           pants and beneficiaries of the plan, during the  
5           applicable period, and, with respect to each  
6           drug—

7                   “(I)(aa) the amount charged, per dos-  
8                   age unit, per 30-day supply, and per 90-  
9                   day supply, with respect to participants  
10                  and beneficiaries in the plan, to the plan;  
11                  and

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

15                  “(II) the median amount charged to  
16                  the plan, per dosage unit, per 30-day sup-  
17                  ply, and per 90-day supply, including  
18                  amounts paid by the participants and bene-  
19                  ficiaries, when the same drug is dispensed  
20                  by other pharmacies that are not affiliated  
21                  with or under common ownership with the  
22                  entity and that are included in the phar-  
23                  macy network of that plan;

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

1           *and per 90-day supply, including amounts*  
2           *paid by the participants and beneficiaries,*  
3           *when the same drug is dispensed by other*  
4           *pharmacies that are not affiliated with or*  
5           *under common ownership with the entity*  
6           *and that are included in the pharmacy net-*  
7           *work of that plan;*

8           *“(IV) the lowest cost, per dosage unit,*  
9           *per 30-day supply, and per 90-day supply,*  
10          *for such drug, including amounts charged to*  
11          *the plan and participants and beneficiaries,*  
12          *that is available from any pharmacy in-*  
13          *cluded in the network of the plan;*

14          *“(V) the net acquisition cost per dosage*  
15          *unit, per 30-day supply, and per 90-day*  
16          *supply, if the drug is subject to a maximum*  
17          *price discount; and*

18          *“(VI) other information with respect to*  
19          *the cost of the drug, as determined by the*  
20          *Secretary, the Secretary of Labor, and the*  
21          *Secretary of Health and Human Services,*  
22          *such as average sales price, wholesale acqui-*  
23          *sition cost, and national average drug ac-*  
24          *quisition cost per dosage unit or per 30-day*  
25          *supply, for such drug, including amounts*

1           *charged to the plan and participants and*  
2           *beneficiaries among all pharmacies included*  
3           *in the network of the plan;*

4           “(I) a summary document for plan sponsors  
5           *that includes the information described in sub-*  
6           *paragraphs (A) through (H) that the Secretary,*  
7           *the Secretary of Labor, and the Secretary of*  
8           *Health and Human Services determine useful to*  
9           *plan sponsors for purposes of selecting pharmacy*  
10          *benefit management services, such as an esti-*  
11          *mated net price to plan sponsor and participant*  
12          *or beneficiary, a cost per claim, the fee structure*  
13          *or reimbursement model, and estimated cost per*  
14          *participant or beneficiary; and*

15          “(J) a summary document for participants  
16          *or beneficiaries, which shall be made available to*  
17          *participants or beneficiaries upon request to the*  
18          *plan sponsor, that contains the information de-*  
19          *scribed in subparagraphs (D) through (G) that*  
20          *the Secretary, the Secretary of Labor, and the*  
21          *Secretary of Health and Human Services deter-*  
22          *mine useful to participants or beneficiaries in*  
23          *better understanding their plan or benefits, ex-*  
24          *cept that such summary document for partici-*

1            *pants or beneficiaries shall contain only aggregate information.*  
2

3            “(2) *REGULATIONS.—Not later than 2 years*  
4 *after the date of enactment of the Pharmacy Benefit*  
5 *Manager Reform Act, the Secretary, the Secretary of*  
6 *Labor, and the Secretary of Health and Human Services*  
7 *shall, through notice and comment rulemaking,*  
8 *promulgate final regulations to implement the re-*  
9 *quirements of this subsection. In promulgating such*  
10 *regulations, the Secretary, the Secretary of Labor,*  
11 *and the Secretary of Health and Human Services*  
12 *shall, to the extent practicable, align the reporting re-*  
13 *quirements under this subsection with the reporting*  
14 *requirements under section 9825.*

15            “(3) *ADDITIONAL REPORTING.—For plan years*  
16 *beginning on or after the date that is 30 months after*  
17 *the date of enactment of the Pharmacy Benefit Man-*  
18 *ager Reform Act, not less frequently than annually,*  
19 *an entity providing pharmacy benefit management*  
20 *services on behalf of a group health plan that is not*  
21 *a covered group health plan shall submit to the plan*  
22 *sponsor of such group health plan a report in accord-*  
23 *ance with this paragraph, and make such report*  
24 *available to the plan sponsor in a machine-readable*  
25 *format, and such other formats as the Secretary, the*

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

5                *“(A) the information described in subpara-*  
6                *graphs (D), (E), (F), and (G) of paragraph (1);*

7                *“(B) as applicable, information collected*  
8                *from drug manufacturers by such plan on the*  
9                *total amount of copayment assistance dollars*  
10                *paid, or copayment cards applied, that were*  
11                *funded by applicable drug manufacturers with*  
12                *respect to the participants and beneficiaries in*  
13                *such plan, except that such information shall not*  
14                *identify any drug manufacturer; and*

15                *“(C) a summary document that includes*  
16                *that information described in subparagraphs (A)*  
17                *and (B) that the Secretary, the Secretary of*  
18                *Labor, and the Secretary of Health and Human*  
19                *Services determine useful for plan sponsors for*  
20                *purposes of selecting pharmacy benefit manage-*  
21                *ment services, provided that such summary docu-*  
22                *ments include only aggregate information.*

23                *“(4) PRIVACY REQUIREMENTS.—*

24                *“(A) RELATIONSHIP TO HIPAA REGULA-*  
25                *TIONS.—Nothing in this section shall be con-*

1            *strued to modify the requirements for the cre-*  
2            *ation, receipt, maintenance, or transmission of*  
3            *protected health information under the HIPAA*  
4            *privacy regulations, as defined in section*  
5            *1180(b)(3) of the Social Security Act (42 U.S.C.*  
6            *1320d–9(b)(3)).*

7            “(B) *REQUIREMENT.*—*A report submitted*  
8            *under paragraph (1) or (3) shall contain only*  
9            *summary health information, as defined in sec-*  
10           *tion 164.504(a) of title 45, Code of Federal Regu-*  
11           *lations (or successor regulations).*

12           “(C) *CLARIFICATION REGARDING CERTAIN*  
13           *DISCLOSURES OF INFORMATION.*—

14           “(i) *REASONABLE RESTRICTIONS.*—  
15           *Nothing in this section prevents an entity*  
16           *providing pharmacy benefit management*  
17           *services on behalf of a group health plan*  
18           *from placing reasonable restrictions (as the*  
19           *Secretary, the Secretary of Labor, and the*  
20           *Secretary of Health and Human Services*  
21           *may determine) on the public disclosure of*  
22           *the information contained in a report under*  
23           *paragraph (1) or (3).*

24           “(ii) *LIMITATIONS.*—*An entity pro-*  
25           *viding pharmacy benefit management serv-*

1            *ices on behalf of a group health plan may*  
2            *not restrict disclosure of such reports to the*  
3            *Department of Health and Human Services,*  
4            *the Department of Labor, the Department of*  
5            *the Treasury, or any other Federal agency*  
6            *responsible 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 United*  
10           *States in accordance with paragraph (6).*

11            “(5) *USE AND DISCLOSURE BY PLAN SPON-*  
12            *SORS.—*

13            “(A) *PROHIBITION.—A plan sponsor may*  
14            *not—*

15            “(i) *fail or refuse to hire, or discharge,*  
16            *any employee, or otherwise discriminate*  
17            *against any employee with respect to the*  
18            *compensation, terms, conditions, or privi-*  
19            *leges of employment of the employee, because*  
20            *of information submitted under paragraph*  
21            *(1) or (3) attributed to the employee or a*  
22            *dependent of the employee; or*

23            “(ii) *limit, segregate, or classify the*  
24            *employees of the employer in any way that*  
25            *would deprive or tend to deprive any em-*



1            *ployee of employment opportunities or oth-*  
2            *erwise adversely affect the status of the em-*  
3            *ployee as an employee, because of informa-*  
4            *tion submitted under paragraph (1) or (3)*  
5            *attributed to the employee or a dependent of*  
6            *the employee.*

7            *“(B) DISCLOSURE AND REDISCLOSURE.—A*  
8            *plan sponsor shall not disclose the information*  
9            *received under paragraph (1) or (3) except—*

10            *“(i) to an occupational or other health*  
11            *researcher if the research is conducted in*  
12            *compliance with the regulations and protec-*  
13            *tions provided for under part 46 of title 45,*  
14            *Code of Federal Regulations (or successor*  
15            *regulations);*

16            *“(ii) in response to an order of a court,*  
17            *except that the plan sponsor may disclose*  
18            *only the information expressly authorized*  
19            *by such order;*

20            *“(iii) to the Department of Health and*  
21            *Human Services, the Department of Labor,*  
22            *the Department of the Treasury, or other*  
23            *Federal agency responsible for enforcement*  
24            *activities under this section; or*

1           “(iv) to a contractor or agent for pur-  
2           poses of health plan administration, if such  
3           contractor or agent agrees, in writing, and  
4           as a term of the contract, to abide by the  
5           same use and disclosure restrictions as the  
6           plan sponsor.

7           “(C) *RELATIONSHIP TO HIPAA REGULA-*  
8           *TIONS.*—With respect to the HIPAA privacy reg-  
9           ulations, as defined in section 1180(b)(3) of the  
10          Social Security Act (42 U.S.C. 1320d–9(b)(3)),  
11          subparagraph (B) does not prohibit a covered en-  
12          tity (as defined for purposes of such regulations  
13          promulgated under section 264 of the Health In-  
14          surance Portability and Accountability Act of  
15          1996 (42 U.S.C. 1320d–2)) from any use or dis-  
16          closure of health information that is authorized  
17          for the covered entity under such regulations.  
18          The previous sentence does not affect the author-  
19          ity of such Secretary to modify such regulations.

20          “(D) *WRITTEN NOTICE.*—Plan sponsors of  
21          group health plans shall provide to each em-  
22          ployee written notice informing the employee of  
23          the requirement for entities providing pharmacy  
24          benefit management services to submit reports to  
25          plan sponsors under paragraphs (1) and (3), as

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

5 “(E) ENFORCEMENT.—

6 “(i) IN GENERAL.—The powers, proce-  
7 dures, and remedies provided in section 207  
8 of the Genetic Information Nondiscrimina-  
9 tion Act (42 U.S.C. 2000ff-6) to a person  
10 alleging a violation of title II of such Act  
11 shall be the powers, procedures, and rem-  
12 edies this subparagraph provides for any  
13 person alleging a violation of this para-  
14 graph.

15 “(ii) PROHIBITION AGAINST RETALIA-  
16 TION.—No person shall discriminate  
17 against any individual because such indi-  
18 vidual has opposed any act or practice  
19 made unlawful by this paragraph or be-  
20 cause such individual made a charge, testi-  
21 fied, assisted, or participated in any man-  
22 ner in an investigation, proceeding, or hear-  
23 ing under this paragraph. The remedies and  
24 procedures otherwise provided for under this  
25 subparagraph shall be available to aggrieved

1                   *individuals with respect to violations of this*  
2                   *clause.*

3                   “(6) *SUBMISSIONS TO GAO.*—*An entity pro-*  
4                   *viding pharmacy benefit management services on be-*  
5                   *half of a group health plan shall submit, upon re-*  
6                   *quest, to the Comptroller General of the United States*  
7                   *each of the first 2 reports submitted to a plan sponsor*  
8                   *under paragraph (1) or (3) with respect to such plan,*  
9                   *and other such reports as requested, in accordance*  
10                   *with the privacy requirements under paragraph (4),*  
11                   *and such other information that the Comptroller Gen-*  
12                   *eral determines necessary to carry out the study*  
13                   *under section 2(f) of the Pharmacy Benefit Manager*  
14                   *Reform Act.*

15                   “(7) *STANDARD FORMATS.*—

16                   “(A) *IN GENERAL.*—*Not later than June 1,*  
17                   *2024, the Secretary, the Secretary of Health and*  
18                   *Human Services, and the Secretary of Labor*  
19                   *shall specify, through rulemaking, standard for-*  
20                   *mats for entities providing pharmacy benefit*  
21                   *management services to submit reports required*  
22                   *under this subsection. Such secretaries may pro-*  
23                   *vide for separate standard formats for reports to*  
24                   *plan sponsors of group health plans and reports*  
25                   *to plan sponsors of group health insurance cov-*

1            *erage offered in connection with a group health*  
2            *plan.*

3            *“(B) FORM.—The Secretary, the Secretary*  
4            *of Health and Human Services, and the Sec-*  
5            *retary of Labor shall define through rulemaking*  
6            *a form of the reports under paragraphs (1) and*  
7            *(3) required to be submitted to plan sponsors*  
8            *who also are drug manufacturers, drug whole-*  
9            *salers, entities providing pharmacy benefit man-*  
10           *agement services, or other direct participants in*  
11           *the drug supply chain, in the case that such sec-*  
12           *retaries determine that changes to the standard*  
13           *format are necessary to prevent anticompetitive*  
14           *behavior.*

15           *“(c) LIMITATIONS ON SPREAD PRICING.—*

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

1        *eficiary for a prescription drug covered under the*  
2        *plan, does not exceed the price paid to the pharmacy,*  
3        *excluding penalties paid by the pharmacy (as de-*  
4        *scribed in paragraph (2)) to such plan or entity.*

5                *“(2) RULE OF CONSTRUCTION.—For purposes of*  
6        *paragraph (1), penalties paid by pharmacies include*  
7        *only the following:*

8                *“(A) A penalty paid if an original claim*  
9        *for a prescription drug was submitted fraudu-*  
10        *lently by the pharmacy to the plan or entity.*

11                *“(B) A penalty paid if the original claim*  
12        *payment made by the plan or entity to the phar-*  
13        *macy was inconsistent with the reimbursement*  
14        *terms in any contract between the pharmacy and*  
15        *the plan or entity.*

16                *“(C) A penalty paid if the pharmacist serv-*  
17        *ices for which a claim was filed with the plan*  
18        *or entity were not rendered by the pharmacy.*

19                *“(d) FULL REBATE PASS-THROUGH TO PLAN.—*

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

1        *agement services on behalf of a group health plan*  
2        *shall—*

3                *“(A) remit 100 percent of rebates, fees, al-*  
4                *ternative discounts, and other remuneration re-*  
5                *ceived from any applicable entity that are re-*  
6                *lated to utilization of drugs under such plan, to*  
7                *the group health plan; and*

8                *“(B) ensure that any contract entered into,*  
9                *by such third-party administrator or entity pro-*  
10                *viding pharmacy benefit management services on*  
11                *behalf of such a plan, with rebate aggregators (or*  
12                *other purchasing entity designed to aggregate re-*  
13                *bates), applicable group purchasing organiza-*  
14                *tions, or any subsidiary, parent, affiliate, or*  
15                *subcontractor of the plan, entity, rebate*  
16                *aggregator (or other purchasing entity designed*  
17                *to aggregate rebates), or applicable group pur-*  
18                *chasing organization remit 100 percent of re-*  
19                *bates, fees, alternative discounts, and other remu-*  
20                *neration received that are related to utilization*  
21                *of drugs under such plan, to the third-party ad-*  
22                *ministrator or entity providing pharmacy ben-*  
23                *efit management services.*

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

4                   “(A) *the rebates, fees, alternative discounts,*  
5                   *and other remuneration under paragraph (1)(A)*  
6                   *shall be—*

7                           “(i) *remitted—*

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

11                                   “(II) *in the case of an under-*  
12                                   *payment in a remittance for a prior*  
13                                   *quarter, as soon as practicable, but not*  
14                                   *later than 90 days after notice of the*  
15                                   *underpayment is first given;*

16                                   “(ii) *fully disclosed and enumerated to*  
17                                   *the group health plan, as described in para-*  
18                                   *graphs (1) and (3) of subsection (b); and*

19                                   “(iii) *returned to the entity providing*  
20                                   *pharmacy benefit management services on*  
21                                   *behalf of the group health plan if an audit*  
22                                   *by a plan sponsor, or a third party des-*  
23                                   *ignated by a plan sponsor, indicates that*  
24                                   *the amounts received are incorrect after*



1           *such amounts have been paid to the group*  
2           *health plan;*

3           “(B) *the rebates, fees, alternative discounts,*  
4           *and other remuneration under paragraph (1)(B)*  
5           *shall be remitted in accordance with such proce-*  
6           *dures as the Secretary, Secretary of Health and*  
7           *Human Services, and Secretary of Labor estab-*  
8           *lish; and*

9           “(C) *the records of such rebates, fees, alter-*  
10           *native discounts, and other remuneration shall*  
11           *be available for audit by the plan sponsor, or a*  
12           *third party designated by a plan sponsor, not*  
13           *less than once per plan year.*

14           “(3) *AUDIT OF REBATE CONTRACTS.—A third-*  
15           *party administrator of a group health plan or an en-*  
16           *tity providing pharmacy benefit management services*  
17           *on behalf of such group health plan shall make rebate*  
18           *contracts with rebate aggregators or drug manufac-*  
19           *turers available for audit by the plan sponsor or des-*  
20           *ignated third party, subject to reasonable restrictions*  
21           *(as determined by the Secretary, the Secretary of*  
22           *Labor, and the Secretary of Health and Human Serv-*  
23           *ices) on confidentiality to prevent re-disclosure of*  
24           *such contracts.*

1           “(4) *AUDITORS.*—Audits carried out under para-  
2           graphs (2)(C) and (3) shall be performed by an audi-  
3           tor selected by the applicable plan sponsor.

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

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

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

16                  “(C) limit the ability of a group health  
17                  plan to pass through rebates, fees, alternative  
18                  discounts, and other remuneration to the partici-  
19                  pant or beneficiary.

20           “(e) *ENFORCEMENT.*—

21                   “(1) *IN GENERAL.*—The Secretary shall enforce  
22                   this section.

23                   “(2) *VIOLATIONS.*—A group health plan or an  
24                   entity providing pharmacy benefit management serv-  
25                   ices that violates subsection (a); an entity providing

1     *pharmacy benefit management services that fails to*  
2     *provide information required under subsection (b); a*  
3     *group health plan or entity providing pharmacy ben-*  
4     *efit management services that violates subsection (c);*  
5     *or a third-party administrator of a group health plan*  
6     *or an entity providing pharmacy benefit management*  
7     *services that violates subsection (d) shall be subject to*  
8     *a civil monetary penalty in the amount of \$10,000*  
9     *for each day during which such violation continues or*  
10    *such information is not disclosed or reported.*

11           “(3) *FALSE INFORMATION.*—*A group health*  
12    *plan, an entity providing pharmacy benefit manage-*  
13    *ment services, or a third-party administrator that*  
14    *knowingly provides false information under this sec-*  
15    *tion shall be subject to a civil money penalty in an*  
16    *amount not to exceed \$100,000 for each item of false*  
17    *information. Such civil money penalty shall be in ad-*  
18    *dition to other penalties as may be prescribed by law.*

19           “(4) *PROCEDURE.*—*The provisions of section*  
20    *1128A of the Social Security Act, other than sub-*  
21    *section (a) and (b) and the first sentence of subsection*  
22    *(c)(1) of such section shall apply to civil monetary*  
23    *penalties under this subsection in the same manner as*  
24    *such provisions apply to a penalty or proceeding*  
25    *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 has*  
5           *made a good-faith effort to comply with this section.*

6           “(f) *RULE OF CONSTRUCTION.*—*Nothing in this sec-*  
7           *tion shall be construed to permit a group health plan, entity*  
8           *providing pharmacy benefit management services on behalf*  
9           *of a group health plan, or other entity to restrict disclosure*  
10          *to, or otherwise limit the access of, the Secretary of the*  
11          *Treasury to a report described in subsection (b)(1) or infor-*  
12          *mation related to compliance with subsections (a), (b), (c),*  
13          *or (d) by such plan or entity.*

14          “(g) *DEFINITIONS.*—*In this section—*

15                  “(1) *the term ‘applicable entity’ means—*

16                          “(A) *an applicable group purchasing orga-*  
17                          *nization, drug manufacturer, distributor, whole-*  
18                          *saler, rebate aggregator (or other purchasing en-*  
19                          *tity designed to aggregate rebates), 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 a*

1            *plan or issuer, or any entity described in sub-*  
2            *paragraph (A); or*

3            *“(C) such other entity as the Secretary, the*  
4            *Secretary of Health and Human Services, and*  
5            *the Secretary of Labor may specify through rule-*  
6            *making;*

7            *“(2) the term ‘applicable group purchasing orga-*  
8            *nization’ means a group purchasing organization*  
9            *that is affiliated with or under common ownership*  
10           *with an entity providing pharmacy benefit manage-*  
11           *ment services;*

12           *“(3) the term ‘covered group health plan’ means*  
13           *a group health plan maintained by a large employer;*

14           *“(4) the term ‘gross spending’, with respect to*  
15           *prescription drug benefits under a group health plan,*  
16           *means the amount spent by a group health plan on*  
17           *prescription drug benefits, calculated before the appli-*  
18           *cation of rebates, fees, alternative discounts, or other*  
19           *remuneration;*

20           *“(5) the term ‘large employer’ means, in connec-*  
21           *tion with a group health plan with respect to a cal-*  
22           *endar year and a plan year, an employer who em-*  
23           *ployed an average of at least 50 employees on busi-*  
24           *ness days during the preceding calendar year and*

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

3               “(6) the term ‘net spending’, with respect to pre-  
4       *scription drug benefits under a group health plan,*  
5       *means the amount spent by a group health plan on*  
6       *prescription drug benefits, calculated after the appli-*  
7       *cation of rebates, fees, alternative discounts, or other*  
8       *remuneration;*

9               “(7) the term ‘plan sponsor’ has the meaning  
10       *given such term in section 3(16)(B) of the Employee*  
11       *Retirement Income Security Act of 1974 (29 U.S.C.*  
12       *1002(16)(B));*

13               “(8) the term ‘remuneration’ has the meaning  
14       *given such term by the Secretary, the Secretary of*  
15       *Labor, and the Secretary of Health and Human Serv-*  
16       *ices, through rulemaking, which shall be reevaluated*  
17       *by such secretaries every 5 years; and*

18               “(9) the term ‘wholesale acquisition cost’ has the  
19       *meaning given such term in section 1847A(c)(6)(B) of*  
20       *the Social Security Act (42 U.S.C. 1395w-*  
21       *3a(c)(6)(B)).”.*

22               (2) *CLERICAL AMENDMENT.*—*The table of sec-*  
23       *tions for subchapter B of chapter 100 of the Internal*  
24       *Revenue Code of 1986 is amended by adding at the*  
25       *end the following new item:*

*“Sec. 9826. Oversight of entities that provide pharmacy benefit management services.”.*

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

4           *“(d) ENTITIES PROVIDING PHARMACY BENEFIT MAN-*  
 5           *AGEMENT SERVICES.—Beginning 2 years after the date of*  
 6           *enactment of the Pharmacy Benefit Manager Reform Act,*  
 7           *entities providing pharmacy benefit management services*  
 8           *shall report to plan sponsors of group health plans informa-*  
 9           *tion required under paragraphs (4), (5), (6), (7)(A)(iii),*  
 10          *and (7)(B) of subsection (a).”.*

11          (i) *FUNDING.—*

12               (1) *For purposes of carrying out the amendments*  
 13               *made by subsection (a) there is appropriated to the*  
 14               *Centers for Medicare & Medicaid Services, out of*  
 15               *amounts in the Treasury not otherwise appropriated,*  
 16               *\$40,000,000 for fiscal year 2023, to remain available*  
 17               *until expended.*

18               (2) *For purposes of carrying out the amendments*  
 19               *made by subsection (b), there is appropriated to the*  
 20               *Department of Labor, out of amounts in the Treasury*  
 21               *not otherwise appropriated, \$4,500,000 for fiscal year*  
 22               *2023, to remain available until expended.*

23               (e) *ASPE STUDY.—The Assistant Secretary for Plan-*  
 24               *ning and Evaluation of the Department of Health and*

1 *Human Services shall conduct or commission a study on*  
2 *how the United States health care market would be im-*  
3 *acted by potential regulatory changes disallowing manu-*  
4 *facturer rebates in the manner and to the extent allowed*  
5 *on the date of enactment of this Act, with a focus on the*  
6 *impact to stakeholders in the commercial insurance market,*  
7 *and, not later than 1 year after the date of enactment of*  
8 *this Act, submit a report to Congress on the results of such*  
9 *study. Such study and report shall consider the following:*

10           (1) *The impact of making no such regulatory*  
11 *changes, as well as potential behavioral changes by*  
12 *plan sponsors, members, and pharmaceutical manu-*  
13 *facturers, such as tighter formularies, changes to price*  
14 *concessions, or changes in utilization, if such regu-*  
15 *latory changes are made.*

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

19           (3) *The feasibility of a partial point-of-sale*  
20 *manufacturer rebate versus a full point-of-sale manu-*  
21 *facturer rebate.*

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

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



1     *drug manufacturers, distributors, wholesalers, rebate*  
2     *aggregators, pharmacy services administrative orga-*  
3     *nizations, or group purchasing organizations.*

4             (6) *Behavioral changes between entities that con-*  
5     *tract with pharmaceutical manufacturers and entities*  
6     *that participate in the pharmaceutical supply chain.*

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

13            (8) *The impact on pharmacies, including phar-*  
14    *macy rebates, pharmacy fees, and dispensing chan-*  
15    *nels.*

16            (9) *The impact of manufacturer rebates on get-*  
17    *ting insulin products to market, and the market dy-*  
18    *namics and extent to which biosimilar biological*  
19    *product development and competition could increase,*  
20    *or is increasing, the number of biological products ap-*  
21    *proved and available to patients, including by exam-*  
22    *ining barriers to—*

23                    (A) *placement of biosimilar biological prod-*  
24    *ucts on health insurance formularies;*

1           (B) market entry of insulin products in the  
2           United States, as compared to other highly devel-  
3           oped nations; and

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

6           (f) GAO STUDY.—

7           (1) IN GENERAL.—Not later than January 1,  
8           2029, the Comptroller General of the United States  
9           shall report to Congress on—

10           (A) pharmacy networks of a selection of  
11           group health plans, health insurance issuers, and  
12           entities providing pharmacy benefit management  
13           services on behalf of such group health plan or  
14           group or individual health insurance coverage,  
15           including networks that have pharmacies that  
16           are affiliated with or in common ownership with  
17           group health plans, health insurance issuers, or  
18           entities providing pharmacy benefit management  
19           services or pharmacy benefit administrative serv-  
20           ices under group health plan or group or indi-  
21           vidual health insurance coverage;

22           (B) as it relates to pharmacy networks that  
23           include pharmacies affiliated with or in common  
24           ownership with plans, issuers, or entities, as de-  
25           scribed in subparagraph (A)—

1                   (i) whether such networks are designed  
2                   to encourage participants and beneficiaries  
3                   of a plan or coverage to use such phar-  
4                   macies over other network pharmacies for  
5                   specific services or drugs, and if so, the rea-  
6                   sons the networks give for encouraging use  
7                   of such pharmacies; and

8                   (ii) whether such pharmacies are used  
9                   by participants and beneficiaries dispro-  
10                  tionately more in the aggregate or for spe-  
11                  cific drugs compared to other network phar-  
12                  macies;

13                  (C) whether group health plans and health  
14                  insurance issuers offering group health insurance  
15                  coverage have options to elect different network  
16                  pricing arrangements in the marketplace with  
17                  entities that provide pharmacy benefit manage-  
18                  ment services, and the prevalence of electing such  
19                  different network pricing arrangements among a  
20                  selection of such plans and issuers;

21                  (D) pharmacy network design parameters  
22                  that encourage participants and beneficiaries in  
23                  the plan or coverage to fill prescriptions at mail  
24                  order, specialty, or retail pharmacies that are

1 wholly or partially owned by that issuer or enti-  
2 ty; and

3 (E) for a selection of plans and issuers, the  
4 degree to which mail order, specialty, or retail  
5 pharmacies that dispense prescription drugs to  
6 participants and beneficiaries in a group health  
7 plan or group health insurance coverage that are  
8 affiliated with or in common ownership with  
9 group health plans, health insurance issuers, or  
10 entities providing pharmacy benefit management  
11 services or pharmacy benefit administrative serv-  
12 ices under a group health plan or group health  
13 insurance coverage receive reimbursement that is  
14 greater than the median price charged to the  
15 group health plan or health insurance issuer  
16 when the same drug is dispensed to participants  
17 and beneficiaries in the plan or coverage by  
18 other pharmacies included in the pharmacy net-  
19 work of that plan or issuer that are not affiliated  
20 with or in common ownership with the health  
21 insurance issuer or entity providing pharmacy  
22 benefit management services.

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

1           (A) information that would allow for iden-  
 2           tification of a specific individual, plan sponsor,  
 3           health insurance issuer, group health plan, or  
 4           entity providing pharmacy benefit management  
 5           services; or

6           (B) commercial or financial information  
 7           that is privileged or confidential.

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

13 **SEC. 3. REPORTING ON JUSTIFICATION FOR DRUG PRICE**  
 14                                   **INCREASES.**

15          Title III of the Public Health Service Act (42 U.S.C.  
 16          241 et seq.) is amended by adding at the end the following:

17 **“PART W—DRUG PRICE REPORTING; DRUG VALUE**  
 18                                   **FUND**

19 **“SEC. 3990O. REPORTING ON JUSTIFICATION FOR DRUG**  
 20                                   **PRICE INCREASES.**

21          “(a) *DEFINITIONS.*—In this section:

22                                   “(1) *MANUFACTURER.*—The term ‘manufacturer’  
 23          means the person—

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

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

3           “(B) *who is engaged in manufacturing, pre-*  
4           *paring, propagating, compounding, processing,*  
5           *packaging, repackaging, or labeling of a pre-*  
6           *scription drug.*

7           “(2) *QUALIFYING DRUG.—The term ‘qualifying*  
8           *drug’ means any drug that is approved under sub-*  
9           *section (c) or (j) of section 505 of the Federal Food,*  
10          *Drug, and Cosmetic Act or licensed under subsection*  
11          *(a) or (k) of section 351 of this Act—*

12           “(A) *that has a wholesale acquisition cost of*  
13           *\$100 or more per month supply, or per a course*  
14           *of treatment that lasts less than a month, and*  
15           *is—*

16                   “(i) *subject to section 503(b)(1) of the*  
17                   *Federal Food, Drug, and Cosmetic Act;*

18                   “(ii) *not a vaccine; and*

19                   “(iii) *not an antibiotic; and*

20           “(B) *for which, during the previous cal-*  
21           *endar year, at least 1 dollar of the total amount*  
22           *of sales was for individuals enrolled under the*  
23           *Medicare program under title XVIII of the So-*  
24           *cial Security Act (42 U.S.C. 1395 et seq.) or*  
25           *under a State Medicaid plan under title XIX of*

1           *such Act (42 U.S.C. 1396 et seq.) or under a*  
2           *waiver of such plan.*

3           “(3) *WHOLESALE ACQUISITION COST.*—*The term*  
4           *‘wholesale acquisition cost’ has the meaning given*  
5           *that term in section 1847A(c)(6)(B) of the Social Se-*  
6           *curity Act (42 U.S.C. 1395w-3a(c)(6)(B)).*

7           “(b) *REPORT.*—

8           “(1) *REPORT REQUIRED.*—*The manufacturer of*  
9           *a qualifying drug shall submit a report to the Sec-*  
10          *retary for each planned increase in price of a quali-*  
11          *fying drug that will result in an increase in the*  
12          *wholesale acquisition cost of that drug that is equal*  
13          *to—*

14                “(A) *10 percent or more over a 12-month*  
15                *period; or*

16                “(B) *25 percent or more over a 36-month*  
17                *period.*

18           “(2) *REPORT DEADLINE.*—*Each report described*  
19           *in paragraph (1) shall be submitted to the Secretary*  
20           *not later than 30 days prior to the effective date of*  
21           *such planned increase in price.*

22           “(c) *CONTENTS.*—*A report under subsection (b) shall,*  
23           *at a minimum, include—*

24                “(1) *with respect to the qualifying drug—*

1           “(A) the percentage by which the manufac-  
2           turer will raise the wholesale acquisition cost of  
3           the drug on the planned effective date of such  
4           planned increase in price;

5           “(B) a justification for, and description of,  
6           each manufacturer’s planned increase in price  
7           that will occur during the 12-month period de-  
8           scribed in subsection (b)(1)(A) or the 36-month  
9           period described in subsection (b)(1)(B), as ap-  
10          pplicable, that shall be accompanied by informa-  
11          tion to substantiate the basis for the justification  
12          and a certification that, to the manufacturer’s  
13          knowledge and belief, the justification is truthful  
14          and nonmisleading and does not describe uses of  
15          the drug beyond those listed as an indication or  
16          use in its approved labeling;

17          “(C) the identity of the initial developer of  
18          the drug, if applicable;

19          “(D) a description of the history of the  
20          manufacturer’s price increases for the drug since  
21          the approval of the application for the drug  
22          under section 505 of the Federal Food, Drug,  
23          and Cosmetic Act or the issuance of the license  
24          for the drug under section 351, or since the man-



1            *ufacturer acquired such approved application or*  
2            *license, as applicable;*

3            *“(E) the current wholesale acquisition cost*  
4            *of the drug;*

5            *“(F) the total expenditures of the manufac-*  
6            *turer for the 3 years preceding the planned in-*  
7            *crease in price on—*

8            *“(i) materials and manufacturing for*  
9            *such drug; and*

10           *“(ii) acquiring patents and licensing*  
11           *for such drug;*

12           *“(G) the percentage of total expenditures of*  
13           *the manufacturer on research and development*  
14           *for such drug that was derived from Federal*  
15           *funds;*

16           *“(H) the total expenditures of the manufac-*  
17           *turer on research and development, for the 3*  
18           *years preceding the planned increase in price for*  
19           *such drug, that is necessary to demonstrate that*  
20           *it meets applicable standards for approval under*  
21           *section 505 of the Federal Food, Drug, and Cos-*  
22           *metic Act or licensure under such section 351, as*  
23           *applicable;*

24           *“(I) the total expenditures of the manufac-*  
25           *turer on research and development for such drug*

1           *that is pursuing new or expanded indications for*  
2           *such drug through supplemental applications*  
3           *under section 505(b) of the Federal Food, Drug,*  
4           *and Cosmetic Act or section 351(a) of this Act;*

5           “(J) *the total expenditures of the manufac-*  
6           *turer on research and development for such drug*  
7           *that is carrying out postmarket requirements re-*  
8           *lated to such drug, including those under section*  
9           *505(o)(3) of the Federal Food, Drug, and Cos-*  
10          *metic Act;*

11          “(K) *the total revenue and the net profit*  
12          *generated from the qualifying drug for each cal-*  
13          *endar year since the approval of the application*  
14          *for the drug under section 505 of the Federal*  
15          *Food, Drug, and Cosmetic Act or the issuance of*  
16          *the license for the drug under section 351, or*  
17          *since the manufacturer acquired such approved*  
18          *application or license; and*

19          “(L) *the total costs associated with mar-*  
20          *keting and advertising for the qualifying drug;*

21          “(2) *with respect to the manufacturer—*

22                 “(A) *the total revenue and the net profit of*  
23                 *the manufacturer—*

24                         “(i) *for the 12-month period preceding*  
25                         *the date of the report, in the case of a report*

1           *based on an increase described in subsection*  
2           *(b)(1)(A);*

3           *“(ii) for the 36-month period preceding*  
4           *the date of the report, in the case of a report*  
5           *based on an increase described in subsection*  
6           *(b)(1)(B);*

7           *“(B) all stock-based performance metrics*  
8           *used by the manufacturer to determine executive*  
9           *compensation—*

10           *“(i) for the 12-month period preceding*  
11           *the date of the report, in the case of a report*  
12           *based on an increase described in subsection*  
13           *(b)(1)(A); or*

14           *“(ii) for the 36-month period preceding*  
15           *the date of the report, in the case of a report*  
16           *based on an increase described in subsection*  
17           *(b)(1)(B); and*

18           *“(C) any additional information the manu-*  
19           *facturer chooses to provide related to drug pric-*  
20           *ing decisions, such as total expenditures on—*

21           *“(i) drug research and development; or*

22           *“(ii) clinical trials on drugs, conducted*  
23           *with the intent of using the data to support*  
24           *approval of an application under section*  
25           *505(b) of the Federal Food, Drug, and Cos-*

1                    *metic Act or section 351(a), but for which*  
2                    *such application was not submitted or filed,*  
3                    *or failed to receive approval by the Food*  
4                    *and Drug Administration; and*

5                    *“(3) such other related information as the Sec-*  
6                    *retary considers appropriate, as specified through no-*  
7                    *tice and comment rulemaking.*

8                    *“(d) CIVIL MONEY PENALTY.—Any manufacturer of a*  
9                    *qualifying drug that fails to submit a report for the drug*  
10                   *as required by this section, or knowingly provides false in-*  
11                   *formation, shall be subject to a civil money penalty of*  
12                   *\$100,000 for each day on which the violation continues.*

13                   *“(e) PUBLIC POSTING.—*

14                   *“(1) IN GENERAL.—Subject to paragraph (3),*  
15                   *not later than 30 days after the submission of a re-*  
16                   *port under subsection (b), the Secretary shall post the*  
17                   *report on the public website of the Department of*  
18                   *Health and Human Services, accompanied by lan-*  
19                   *guage indicating that such public posting does not*  
20                   *represent an endorsement or validation of the report’s*  
21                   *content by the Secretary.*

22                   *“(2) FORMAT.—In developing the format of such*  
23                   *report for public posting, the Secretary shall consult*  
24                   *stakeholders, including beneficiary groups, and shall*  
25                   *seek feedback on the content and format from con-*

1 *sumer advocates and readability experts to ensure*  
2 *such public reports are user-friendly to the public and*  
3 *are written in plain language that consumers can*  
4 *readily understand.*

5 *“(3) TRADE SECRETS AND CONFIDENTIAL INFOR-*  
6 *MATION.—This section does not authorize the disclo-*  
7 *sure of confidential commercial information or trade*  
8 *secrets.”.*

9 **“SEC. 39900-1. USE OF CIVIL PENALTY AMOUNTS.**

10 *“The Secretary shall, without further appropriation,*  
11 *collect civil penalties under section 39900 and use the*  
12 *funds derived from such civil penalties, in addition to any*  
13 *other amounts available to the Secretary, to carry out ac-*  
14 *tivities described in this part and to improve consumer and*  
15 *provider information about drug value and drug price*  
16 *transparency.*

17 **“SEC. 39900-2. ANNUAL REPORT TO CONGRESS.**

18 *“(a) IN GENERAL.—Subject to subsection (b), the Sec-*  
19 *retary shall submit to Congress, and post on the public*  
20 *website of the Department of Health and Human Services*  
21 *in a way that is easy to find, use, and understand, an an-*  
22 *nual report—*

23 *“(1) summarizing the information reported pur-*  
24 *suant to section 39900; and*

1           “(2) including copies of the reports and sup-  
 2           porting detailed economic analyses submitted pursu-  
 3           ant to section 39900.

4           “(b) *TRADE SECRETS AND CONFIDENTIAL INFORMA-*  
 5           *TION.— This section does not authorize the disclosure of*  
 6           *confidential commercial information or trade secrets.”.*

7           **SEC. 4. STUDY ON FIDUCIARY DUTIES OF PHARMACY BEN-**  
 8                           **EFIT MANAGERS.**

9           (a) *IN GENERAL.—The Secretary of Labor shall con-*  
 10          *duct, and submit to Congress a report describing the results*  
 11          *of, a study on the impacts of a change in policy described*  
 12          *in subsection (b).*

13          (b) *POLICY DESCRIBED.—Under a policy referred to*  
 14          *in subsection (a)—*

15                 (1) *an entity providing pharmacy benefit man-*  
 16          *agement services would be considered a fiduciary*  
 17          *within the meaning of section 3(21) of the Employee*  
 18          *Retirement Income Security Act of 1974 (29 U.S.C.*  
 19          *1002(21)) with respect to a group health plan or*  
 20          *group health insurance coverage; and*

21                 (2) *such an entity would—*

22                         (A) *be subject to the responsibilities, obliga-*  
 23          *tions, and duties imposed on fiduciaries under*  
 24          *part 4 of subtitle B of title I of such Act (29*  
 25          *U.S.C. 1101 et seq.); and*

1           (B) make the required fiduciary disclosure  
2           under section 408(b)(2)(B)(iii) of such Act (29  
3           U.S.C. 1108(b)(2)(B)(iii)) with respect to the  
4           pharmacy benefit management services provided  
5           to the plan or coverage.

6           (c) *DEFINITION OF PHARMACY BENEFIT MANAGEMENT*  
7 *SERVICES.—In this section, the term “pharmacy benefit*  
8 *management services” means services related to—*

9           (1) negotiating prices with respect to prescrip-  
10          tion drugs on behalf of a group health plan or health  
11          insurance issuer offering group health insurance cov-  
12          erage; and

13          (2) managing the prescription drug benefits pro-  
14          vided by such plan or coverage, including designing  
15          and implementing a drug formulary, the processing  
16          and payment of claims for prescription drugs, the  
17          performance of drug utilization review, the processing  
18          of drug prior authorization requests, the adjudication  
19          of appeals or grievances related to the prescription  
20          drug benefit, contracting with network pharmacies,  
21          controlling the cost of covered prescription drugs, or  
22          the provision of related services.

1 **SEC. 5. CLARIFICATION OF REQUIREMENT TO DISCLOSE DI-**  
2 **RECT AND INDIRECT COMPENSATION FOR**  
3 **BROKERS AND CONSULTANTS TO EMPLOYER-**  
4 **SPONSORED HEALTH PLANS.**

5 (a) *IN GENERAL.*—Section 408(b)(2)(B)(i)(I)(bb) of  
6 the *Employee Retirement Income Security Act of 1974* (29  
7 *U.S.C. 1108(b)(2)(B)(i)(I)(bb)*) is amended by adding at  
8 the end the following:

9 “(CC) *Pharmacy benefit management services*  
10 *provided by pharmacy benefit managers or other serv-*  
11 *ice providers and related services provided by third-*  
12 *party administrators (or other entities providing such*  
13 *services) for which the covered service provider, an af-*  
14 *filiate, or a subcontractor reasonably expects to re-*  
15 *ceive indirect compensation or direct compensation*  
16 *described in item (dd).”.*

17 (b) *REGULATIONS.*—Not later than 18 months after the  
18 date of enactment of this Act, the Secretary of Labor shall  
19 promulgate regulations, through notice and comment rule-  
20 making, clarifying the requirements of section 408(b)(2)(B)  
21 of the *Employee Retirement Income Security Act of 1974*  
22 (29 *U.S.C. 1108(b)(2)(B)*) with respect to covered service  
23 providers providing services described in subitem (CC) of  
24 subclause (I)(bb) of such section, as amended by subsection  
25 (a). Such regulations shall apply with respect to any plan



1 *year that begins on or after the date that is 6 months after*  
 2 *such regulations are promulgated.*

3 (c) *SENSE OF CONGRESS.—It is the sense of Congress*  
 4 *that the amendment made by subsection (a) clarifies the*  
 5 *existing requirement of covered service providers with re-*  
 6 *spect to services described in section*  
 7 *408(b)(2)(B)(ii)(I)(bb)(BB) of the Employee Retirement In-*  
 8 *come Security Act of 1974 (29 U.S.C.*  
 9 *1108(b)(2)(B)(ii)(I)(bb)(BB)) that were in effect since the*  
 10 *application date described in section 202(e) of the No Sur-*  
 11 *prises Act (Public Law 116–260; 29 U.S.C. 1108 note), and*  
 12 *does not impose any additional requirement under section*  
 13 *408(b)(2)(B) of such Act.*

14 **SEC. 6. STUDY ON NALOXONE ACCESS.**

15 (a) *IN GENERAL.—The Comptroller General of the*  
 16 *United States shall conduct a study on actions that may*  
 17 *be taken to ensure appropriate access and affordability of*  
 18 *naloxone for individuals seeking to purchase naloxone. Such*  
 19 *study shall address what is known about—*

20 (1) *coverage of naloxone (in any available form),*  
 21 *including whether naloxone can be covered as an over-*  
 22 *the-counter drug under a group health plan or group*  
 23 *or individual health insurance coverage (as such*  
 24 *terms are defined in section 2791 of the Public Health*  
 25 *Service Act (42 U.S.C. 300gg–91));*

1           (2) *the out-of-pocket cost to consumers pur-*  
 2 *chasing naloxone—*

3                 (A) *with a prescription, with and without*  
 4 *coverage under any such plan or coverage; and*

5                 (B) *over the counter, with and without cov-*  
 6 *erage under any such plan or coverage; and*

7           (3) *other factors impacting coverage, including*  
 8 *barriers in covering naloxone as an over-the-counter*  
 9 *drug, the relative net costs of naloxone when pur-*  
 10 *chased over the counter without insurance coverage*  
 11 *compared to when purchased with a prescription and*  
 12 *covered under a group health plan or health insur-*  
 13 *ance coverage, and the availability of naloxone pur-*  
 14 *chased and distributed through public health entities.*

15           (b) *REPORT.—Not later than 2 years after the date*  
 16 *of the enactment of this Act, the Comptroller General of the*  
 17 *United States shall submit to Congress a report that con-*  
 18 *tains the findings of the study conducted under subsection*  
 19 *(a).*

20 **SEC. 7. PROHIBITION ON BLOCKING CONSUMER DECISION-**  
 21 **SUPPORT TOOLS.**

22           (a) *PHSA.—Part D of title XXVII of the Public*  
 23 *Health Service Act (42 U.S.C. 300gg–111 et seq.), as*  
 24 *amended by section 2, is further amended by adding at the*  
 25 *end the following:*

1 **“SEC. 2799A-12. PROHIBITION ON BLOCKING CONSUMER**  
2 **DECISION-SUPPORT TOOLS.**

3       “(a) *IN GENERAL.*—A group health plan or a health  
4 insurance issuer offering group or individual health insur-  
5 ance coverage shall not enter into a contract with an entity  
6 that provides pharmacy benefit management services with  
7 respect to such plan or coverage if such contract includes  
8 any terms, conditions, or costs that would prevent or re-  
9 strict a covered third party from accessing or using infor-  
10 mation, for purposes of the consumer decision-support tool,  
11 relevant to the operability, implementation, and utilization  
12 of the consumer-decision support tool regarding prescrip-  
13 tion drug benefits under the plan or coverage that are ad-  
14 ministered by the entity providing pharmacy benefit man-  
15 agement services in contract with the plan or issuer.

16       “(b) *DEFINITIONS.*—In this section:

17               “(1) *CONSUMER DECISION-SUPPORT TOOL.*—The  
18 term ‘consumer decision-support tool’ means a tool  
19 designed to inform enrollees in a group health plan  
20 or health insurance coverage about all costs to the en-  
21 rollee for prescription drugs covered by the plan or  
22 coverage, including out-of-pocket, copayment, and co-  
23 insurance responsibility, as well as means for reduc-  
24 ing the cost to the enrollee, such as manufacturer co-  
25 payment assistance, purchasing at the cash price, and  
26 purchasing through mail order pharmacy benefits.

1           “(2) *COVERED THIRD PARTY.*—*The term ‘covered*  
2 *third party’ means a third party that is in contract,*  
3 *as a business associate (as defined in section 160.103*  
4 *of title 45, Code of Federal Regulations (or successor*  
5 *regulations)), with a group health plan or a health*  
6 *insurance issuer offering group or individual health*  
7 *insurance coverage to provide a consumer decision-*  
8 *support tool.*

9           “(c) *RULES OF CONSTRUCTION REGARDING PRI-*  
10 *VACY.*—

11           “(1) *Nothing in this section shall be construed to*  
12 *alter existing obligations of a covered entity or busi-*  
13 *ness associate under the privacy, security, and breach*  
14 *notification regulations in parts 160 and 164 of title*  
15 *45, Code of Federal Regulations (or successor regula-*  
16 *tions).*

17           “(2) *Nothing in this section shall be construed to*  
18 *require a group health plan, a health insurance issuer*  
19 *offering group or individual health insurance cov-*  
20 *erage, or an entity providing pharmacy benefit man-*  
21 *agement services to share protected health informa-*  
22 *tion, as defined in section 160.103 of title 45, Code*  
23 *of Federal Regulations (or successor regulations), with*  
24 *a covered third party.”.*

25           “(b) *ERISA.*—

1           (1) *IN GENERAL.*—Subpart B of part 7 of sub-  
2       title B of title I of the Employee Retirement Income  
3       Security Act of 1974 (29 U.S.C. 1185 et seq.), as  
4       amended by section 2, is further amended by adding  
5       at the end the following:

6       **“SEC. 727. PROHIBITION ON BLOCKING CONSUMER DECI-**  
7                                       **SION-SUPPORT TOOLS.**

8       “(a) *IN GENERAL.*—A group health plan or a health  
9       insurance issuer offering group health insurance coverage  
10      shall not enter into a contract with an entity that provides  
11      pharmacy benefit management services with respect to such  
12      plan or coverage if such contract includes any terms, condi-  
13      tions, or costs that would prevent or restrict a covered third  
14      party from accessing or using information, for purposes of  
15      the consumer decision-support tool, relevant to the oper-  
16      ability, implementation, and utilization of the consumer-  
17      decision support tool regarding prescription drug benefits  
18      under the plan or coverage that are administered by the  
19      entity providing pharmacy benefit management services in  
20      contract with the plan or issuer.

21      “(b) *DEFINITIONS.*—In this section:

22           “(1) *CONSUMER DECISION-SUPPORT TOOL.*—The  
23      term ‘consumer decision-support tool’ means a tool  
24      designed to inform participants and beneficiaries in  
25      a group health plan or health insurance coverage

1     *about all costs to the participant or beneficiary for*  
2     *prescription drugs covered by the plan or coverage,*  
3     *including out-of-pocket, copayment, and coinsurance*  
4     *responsibility, as well as means for reducing the cost*  
5     *to the participant or beneficiary, such as manufac-*  
6     *turer copayment assistance, purchasing at the cash*  
7     *price, and purchasing through mail order pharmacy*  
8     *benefits.*

9             “(2) *COVERED THIRD PARTY.*—*The term ‘covered*  
10     *third party’ means a third party that is in contract,*  
11     *as a business associate (as defined in section 160.103*  
12     *of title 45, Code of Federal Regulations (or successor*  
13     *regulations)), with a group health plan or a health*  
14     *insurance issuer offering group health insurance cov-*  
15     *erage to provide a consumer decision-support tool.*

16             “(c) *RULES OF CONSTRUCTION.*—

17             “(1) *Nothing in this section shall be construed to*  
18     *alter existing obligations of a covered entity or busi-*  
19     *ness associate under the privacy, security, and breach*  
20     *notification regulations in parts 160 and 164 of title*  
21     *45, Code of Federal Regulations (or successor regula-*  
22     *tions).*

23             “(2) *Nothing in this section shall be construed to*  
24     *require a group health plan, a health insurance issuer*  
25     *offering group health insurance coverage, or an entity*

1       *providing pharmacy benefit management services to*  
 2       *share protected health information, as defined in sec-*  
 3       *tion 160.103 of title 45, Code of Federal Regulations*  
 4       *(or successor regulations), with a covered third*  
 5       *party.”.*

6               (2) *CLERICAL AMENDMENT.—The table of con-*  
 7       *tents in section 1 of the Employee Retirement Income*  
 8       *Security Act of 1974 (29 U.S.C. 1001 et seq.), as*  
 9       *amended by section 2, is further amended by insert-*  
 10       *ing after the item relating to section 726 the fol-*  
 11       *lowing:*

“*Sec. 727. Prohibition on blocking consumer decision-support tools.*”.

12              (c) *INTERNAL REVENUE CODE.—*

13                   (1) *IN GENERAL.—Subchapter B of chapter 100*  
 14       *of the Internal Revenue Code of 1986, as amended by*  
 15       *section 2, is further amended by adding at the end the*  
 16       *following new section:*

17       **“SEC. 9827. PROHIBITION ON BLOCKING CONSUMER DECI-**  
 18       **SION-SUPPORT TOOLS.**

19           “(a) *IN GENERAL.—A group health plan offering*  
 20       *group health insurance coverage shall not enter into a con-*  
 21       *tract with an entity that provides pharmacy benefit man-*  
 22       *agement services with respect to such plan if such contract*  
 23       *includes any terms, conditions, or costs that would prevent*  
 24       *or restrict a covered third party from accessing or using*  
 25       *information, for purposes of the consumer decision-support*

1 *tool, relevant to the operability, implementation, and utili-*  
2 *zation of the consumer-decision support tool regarding pre-*  
3 *scription drug benefits under the plan that are adminis-*  
4 *tered by the entity providing pharmacy benefit manage-*  
5 *ment services in contract with the plan.*

6 “(b) *DEFINITIONS.—In this section:*

7 “(1) *CONSUMER DECISION-SUPPORT TOOL.—The*  
8 *term ‘consumer decision-support tool’ means a tool*  
9 *designed to inform participants and beneficiaries in*  
10 *a group health plan about all costs to the participant*  
11 *or beneficiary for prescription drugs covered by the*  
12 *plan, including out-of-pocket, copayment, and coin-*  
13 *insurance responsibility, as well as means for reducing*  
14 *the cost to the participant or beneficiary, such as*  
15 *manufacturer copayment assistance, purchasing at*  
16 *the cash price, and purchasing through mail order*  
17 *pharmacy benefits.*

18 “(2) *COVERED THIRD PARTY.—The term ‘covered*  
19 *third party’ means a third party that is in contract,*  
20 *as a business associate (as defined in section 160.103*  
21 *of title 45, Code of Federal Regulations (or successor*  
22 *regulations)), with a group health plan or a health*  
23 *insurance issuer offering group health insurance cov-*  
24 *erage to provide a consumer decision-support tool.*

25 “(c) *RULES OF CONSTRUCTION.—*



1           “(1) *Nothing in this section shall be construed to*  
 2           *alter existing obligations of a covered entity or busi-*  
 3           *ness associate under the privacy, security, and breach*  
 4           *notification regulations in parts 160 and 164 of title*  
 5           *45, Code of Federal Regulations (or successor regula-*  
 6           *tions).*”

7           “(2) *Nothing in this section shall be construed to*  
 8           *require a group health plan or an entity providing*  
 9           *pharmacy benefit management services to share pro-*  
 10          *tected health information, as defined in section*  
 11          *160.103 of title 45, Code of Federal Regulations (or*  
 12          *successor regulations), with a covered third party.*”

13           (2) *CLERICAL AMENDMENT.—The table of sec-*  
 14          *tions for subchapter B of chapter 100 of such Code,*  
 15          *as amended by section 2, is further amended by add-*  
 16          *ing at the end the following new item:*

“*Sec. 9827. Prohibition on blocking consumer decision-support tools.*”

17          (d) *APPLICATION.—The amendments made by sub-*  
 18          *sections (a), (b), and (c) shall apply with respect to plan*  
 19          *years beginning on or after the date that is 2 years after*  
 20          *the date of enactment of this Act.*

21          (e) *REGULATIONS.—The Secretary of Health and*  
 22          *Human Services, the Secretary of Labor, and the Secretary*  
 23          *of the Treasury shall jointly promulgate regulations to*  
 24          *carry out the amendments made by subsections (a), (b), and*

1 (c), and shall issue draft regulations not later than 1 year  
 2 after the date of enactment of this Act.

3 **SEC. 8. REQUIREMENT TO PROVIDE HEALTH CLAIMS, NET-**  
 4 **WORK, AND COST INFORMATION.**

5 (a) *IN GENERAL.*—Part A of title XXVII of the Public  
 6 Health Service Act (42 U.S.C. 300gg et seq.) is amended  
 7 by inserting after section 2715A the following:

8 **“SEC. 2715B. REQUIREMENT TO PROVIDE HEALTH CLAIMS,**  
 9 **NETWORK, AND COST INFORMATION.**

10 “(a) *IN GENERAL.*—A group health plan or a health  
 11 insurance issuer offering group or individual health insur-  
 12 ance coverage shall make available for access, exchange, and  
 13 use without special effort, through application program-  
 14 ming interfaces (or successor technology or standards), con-  
 15 sistent with standards and implementation specifications  
 16 adopted under section 3004, the information described in  
 17 subsection (b), in the manner described in subsection (b),  
 18 as applicable, and otherwise consistent with this section.

19 “(b) *ELECTRONIC INFORMATION.*—The following elec-  
 20 tronic information is required to be made available, as the  
 21 Secretary may specify:

22 “(1) Historical claims, provider encounter, and  
 23 payment data for each enrollee, which—

24 “(A) may include adjudicated medical and  
 25 prescription drug claims and equivalent encoun-

1           *ters, including all data elements contained in*  
2           *such transactions—*

3                     *“(i) that were adjudicated by the group*  
4                     *health plan or health insurance issuer dur-*  
5                     *ing the previous 5 years or the enrollee’s en-*  
6                     *tire period of enrollment in the applicable*  
7                     *plan or coverage if such period is less than*  
8                     *the previous 5 years;*

9                     *“(ii) that involve benefits managed by*  
10                    *any third party, such as a pharmacy bene-*  
11                    *fits manager or radiology benefits manager*  
12                    *that manages benefits or adjudicates claims*  
13                    *on behalf of the plan or coverage; and*

14                    *“(iii) from any other group health*  
15                    *plan or health insurance coverage offered by*  
16                    *the same insurance issuer, in which the*  
17                    *same enrollee was enrolled during the pre-*  
18                    *vious 5 years; and*

19                    *“(B) shall be available to an enrollee or*  
20                    *former enrollee, the enrollee’s providers, and any*  
21                    *third-party applications or services authorized*  
22                    *by the enrollee—*

23                    *“(i) through the application program-*  
24                    *ming interfaces (or successor technology or*  
25                    *standards) consistent with standards and*

1           *specifications adopted under section 3004,*  
2           *in a single, longitudinal format that is easy*  
3           *to understand, secure, and that may update*  
4           *automatically;*

5           “(ii) *as soon as practicable, and in no*  
6           *case later than the period of time deter-*  
7           *mined by the Secretary, after the claim is*  
8           *adjudicated or the data is received by the*  
9           *group health plan or health insurance*  
10          *issuer; and*

11          “(iii) *for a period of 5 years after the*  
12          *end date of the enrollee’s enrollment in the*  
13          *plan or in any coverage offered by the*  
14          *health insurance issuer.*

15          “(2) *Identifying directory information for all in-*  
16          *network providers, including facilities and practi-*  
17          *tioners, that participate in the plan or coverage,*  
18          *which shall—*

19                 “(A) *include—*

20                         “(i) *the national provider identifier for*  
21                         *in-network facilities and practitioners; and*

22                         “(ii) *the name, address, phone number,*  
23                         *and specialty for each such facility and*  
24                         *practitioner, within a timeframe deter-*  
25                         *mined by the Secretary, from when the plan*

1            *or coverage receives provider directory in-*  
2            *formation or updates from that facility or*  
3            *practitioner;*

4            *“(B) be capable of returning the informa-*  
5            *tion necessary to establish a list of participating*  
6            *in-network facilities and practitioners, in a*  
7            *given specialty or at a particular facility type,*  
8            *within a specified geographic radius; and*

9            *“(C) be capable of returning the network*  
10           *status, when presented with identifiers for a*  
11           *given enrollee and facility or practitioner.*

12           *“(3) Estimated enrollee out-of-pocket costs, in-*  
13           *cluding costs expected to be incurred through a de-*  
14           *ductible, co-payment, coinsurance, or other form of*  
15           *cost-sharing, for—*

16           *“(A) a designated set of common services or*  
17           *episodes of care, to be established by the Sec-*  
18           *retary through rulemaking, including, at a min-*  
19           *imum—*

20           *“(i) in the case of services provided by*  
21           *a hospital, the 100 most common diagnosis-*  
22           *related groups, as used in the Medicare In-*  
23           *patient Prospective Patient System (or suc-*  
24           *cessor episode-based reimbursement method-*  
25           *ology) at that hospital, based on claims*

1           *data adjudicated by the group health plan*  
2           *or health insurance issuer;*

3           “(ii) *in the case of services provided in*  
4           *an out-patient setting, including radiology,*  
5           *lab tests, and out-patient surgical proce-*  
6           *dures, any service rendered by the facility*  
7           *or practitioner, and reimbursed by the*  
8           *group health plan or health insurance*  
9           *issuer; and*

10          “(iii) *in the case of post-acute care, in-*  
11          *cluding home health providers, skilled nurs-*  
12          *ing facilities, inpatient rehabilitation facili-*  
13          *ties, and long-term care hospitals, the pa-*  
14          *tient out-of-pocket costs for an episode of*  
15          *care, as the Secretary may determine, which*  
16          *permits users to reasonably compare costs*  
17          *across different facility and service types;*  
18          *and*

19          “(B) *all prescription drugs currently in-*  
20          *cluded on any tier of the formulary of the plan*  
21          *or coverage.*

22          “(c) *AVAILABILITY AND ACCESS.—Subject to all appli-*  
23          *cable Federal and State privacy, security, and breach noti-*  
24          *fication laws, and within a timeframe determined by the*  
25          *Secretary, the application programming interfaces (or suc-*

1 *cessor technology or standards), including all data required*  
2 *to be made available through such interfaces, shall—*

3 *“(1) be made available by the applicable group*  
4 *health plan or health insurance issuer, at no charge,*  
5 *to—*

6 *“(A) enrollees and prospective enrollees in*  
7 *the group health plan or health insurance cov-*  
8 *erage;*

9 *“(B) third parties authorized by the en-*  
10 *rollee;*

11 *“(C) facilities and practitioners who are*  
12 *under contract with the plan or coverage; and*

13 *“(D) business associates of such facilities*  
14 *and practitioners, as defined in section 160.103*  
15 *of title 45, Code of Federal Regulations (or any*  
16 *successor regulations);*

17 *“(2) be available to enrollees in the group health*  
18 *plan or health insurance coverage, and to third-party*  
19 *applications or services facilitating such access by en-*  
20 *rollees, during the enrollment process and for a min-*  
21 *imum of 5 years after the end date of the enrollee’s*  
22 *enrollment in the plan or in any coverage offered by*  
23 *the health insurance issuer;*

1           “(3) permit persistent access by third-party ap-  
2           plications or services authorized by the enrollee, for a  
3           reasonable period of time;

4           “(4) employ the applicable content, vocabulary,  
5           and technical standards, as determined by the Sec-  
6           retary pursuant to title XXX; and

7           “(5) employ security and authentication stand-  
8           ards, as the Secretary determines appropriate.

9           “(d) DENIAL OR DISCONTINUANCE OF ACCESS.—A  
10          group health plan or health insurance issuer offering group  
11          or individual health insurance coverage may deny access  
12          or discontinue access of the application programming inter-  
13          faces (or successor technology or standards) to third-party  
14          applications or services on the basis of reasonable privacy  
15          or security concerns, as determined by the Secretary, in-  
16          cluding at the request of the enrollee.

17          “(e) NOTIFICATION.—When obtaining enrollee author-  
18          ization to share information with a third party under this  
19          section, a group health plan or a health insurance issuer  
20          offering group or individual health insurance coverage shall  
21          include a notification for the enrollee that information  
22          shared with a third party that is not a covered entity or  
23          business associate is not subject to the privacy, security, or  
24          breach notification rules under parts 160 and 164 of title  
25          45, Code of Federal Regulations (or successor regulations).



1           “(f) *RULE OF CONSTRUCTION REGARDING PRIVACY.*—  
 2 *Nothing in this section shall be construed to alter existing*  
 3 *obligations of a covered entity or business associate under*  
 4 *the privacy, security, and breach notification rules promul-*  
 5 *gated under section 264(c) of the Health Insurance Port-*  
 6 *ability and Accountability Act or section 13402 of the*  
 7 *HITECH Act, or to alter the Secretary’s existing authority*  
 8 *to modify such rules, under part 2 of title 42, Code of Fed-*  
 9 *eral Regulations (or successor regulations), under section*  
 10 *444 of the General Education Provisions Act (20 U.S.C.*  
 11 *1232g) (commonly referred to as the ‘Family Educational*  
 12 *Rights and Privacy Act of 1974’), under the amendments*  
 13 *made by the Genetic Information Nondiscrimination Act,*  
 14 *or under State privacy law.”.*

15           (b) *EFFECTIVE DATE.*—Section 2715B of the Public  
 16 *Health Service Act, as added by subsection (a), shall take*  
 17 *effect 18 months after the date of enactment of this Act.*

18 **SEC. 9. REQUIRED EXCEPTIONS PROCESS FOR MEDICATION**

19                                   **STEP THERAPY PROTOCOLS.**

20           (a) *SHORT TITLE.*—*This section may be cited as the*  
 21 *“Safe Step Act”.*

22           (b) *REQUIRED EXCEPTIONS PROCESS FOR MEDICA-*  
 23 *TION STEP THERAPY PROTOCOLS.*—*The Employee Retire-*  
 24 *ment Income Security Act of 1974 is amended by inserting*

1 *after section 713 of such Act (29 U.S.C. 1185b) the following*  
 2 *new section:*

3 **“SEC. 713A. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**  
 4 **TION STEP THERAPY PROTOCOLS.**

5 *“(a) IN GENERAL.—In the case of a group health plan*  
 6 *or health insurance issuer offering coverage offered in con-*  
 7 *nection with such a plan that provides coverage of a pre-*  
 8 *scription drug pursuant to a medication step therapy pro-*  
 9 *ocol, the plan or issuer shall—*

10 *“(1) implement a clear, prompt, and transparent*  
 11 *process for a participant or beneficiary (or the pre-*  
 12 *scribing health care provider (referred to in this sec-*  
 13 *tion as the ‘prescriber’) on behalf of the participant*  
 14 *or beneficiary) to request an exception to such medi-*  
 15 *cation step therapy protocol, pursuant to subsection*  
 16 *(b); and*

17 *“(2) where the participant or beneficiary or pre-*  
 18 *scriber’s request for an exception to the medication*  
 19 *step therapy protocols satisfies the criteria and re-*  
 20 *quirements of subsection (b), cover the requested drug*  
 21 *in accordance with the terms established by the plan*  
 22 *or coverage for patient cost-sharing rates or amounts*  
 23 *at the beginning of the plan year.*

24 *“(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—*  
 25 *The circumstances requiring an exception to a medication*

1 *step therapy protocol, pursuant to a request under sub-*  
2 *section (a), are any of the following:*

3           “(1) *Any treatments otherwise required under*  
4 *the protocol, or treatments in the same pharma-*  
5 *cological class or having the same mechanism of ac-*  
6 *tion, including treatments provided prior to the effec-*  
7 *tive date of the participant’s or beneficiary’s coverage*  
8 *under the plan or coverage, have been ineffective in*  
9 *the treatment of the disease or condition of the partic-*  
10 *ipant or beneficiary, when prescribed consistent with*  
11 *clinical indications, clinical guidelines, or other peer-*  
12 *reviewed evidence, based on the prescribing health*  
13 *care professional’s judgement or relevant information*  
14 *provided by the participant or beneficiary (including*  
15 *the medical records of the participant or beneficiary).*

16           “(2) *Delay of effective treatment would lead to*  
17 *severe or irreversible consequences, or worsen disease*  
18 *progression or a comorbidity and the treatment other-*  
19 *wise required under the protocol is reasonably ex-*  
20 *pected by the prescriber to be ineffective based upon*  
21 *the documented physical or mental characteristics of*  
22 *the participant or beneficiary and the known charac-*  
23 *teristics of such treatment.*

24           “(3) *Any treatments otherwise required under*  
25 *the protocol are contraindicated for the participant or*

1       *beneficiary or have caused, or are likely to cause,*  
2       *based on clinical, peer-reviewed evidence, an adverse*  
3       *reaction or other physical or mental harm to the par-*  
4       *ticipant or beneficiary.*

5               “(4) *Any treatment otherwise required under the*  
6       *protocol has prevented, will prevent, or is likely to*  
7       *prevent a participant or beneficiary from achieving*  
8       *or maintaining reasonable and safe functional ability*  
9       *in performing occupational responsibilities or activi-*  
10       *ties of daily living (as defined in section 441.505 of*  
11       *title 42, Code of Federal Regulations (or successor reg-*  
12       *ulations)).*

13               “(5) *The participant or beneficiary is stable for*  
14       *his or her disease or condition on the prescription*  
15       *drug or drugs selected by the prescriber and has pre-*  
16       *viously received approval for coverage of the relevant*  
17       *drug or drugs for the disease or condition by any*  
18       *public or private health plan.*

19               “(6) *Other circumstances, as determined by the*  
20       *Secretary.*

21       “(c) *REQUIREMENT OF A CLEAR PROCESS.—*

22               “(1) *IN GENERAL.—The process required by sub-*  
23       *section (a) shall—*

24                       “(A) *provide the prescriber or participant*  
25       *or beneficiary an opportunity to present such*

1        *prescriber’s clinical rationale and relevant med-*  
2        *ical information for the group health plan or*  
3        *health insurance issuer to evaluate such request*  
4        *for exception;*

5                *“(B) develop and use a standard form and*  
6        *instructions for the request of an exception under*  
7        *subsection (b), available in paper and electronic*  
8        *forms, and allow for submission of such form by*  
9        *paper and electronic means;*

10               *“(C) provide both paper and electronic*  
11        *means for the submission of requests for addi-*  
12        *tional information;*

13               *“(D) clearly set forth all required informa-*  
14        *tion and the specific criteria that will be used to*  
15        *determine whether an exception is warranted,*  
16        *which may require disclosure of—*

17                        *“(i) the medical history or other health*  
18        *records of the participant or beneficiary*  
19        *demonstrating that the participant or bene-*  
20        *ficiary seeking an exception—*

21                                *“(I) has tried other drugs in-*  
22        *cluded in the drug therapy class with-*  
23        *out success; or*

24                                *“(II) has taken the requested drug*  
25        *for a clinically appropriate amount of*

1                    *time to establish stability, in relation*  
2                    *to the condition being treated and pre-*  
3                    *scription guidelines given by the pre-*  
4                    *scribing physician; or*

5                    *“(ii) other clinical information that*  
6                    *may be relevant to conducting the exception*  
7                    *review;*

8                    *“(E) not require the submission of any in-*  
9                    *formation or supporting documentation beyond*  
10                   *what is strictly necessary (as determined by the*  
11                   *Secretary) to determine whether a circumstance*  
12                   *listed in subsection (b) exists;*

13                   *“(F) clearly outline conditions under which*  
14                   *an exception request warrants expedited resolu-*  
15                   *tion from the group health plan or health insur-*  
16                   *ance issuer, pursuant to subsection (d)(2); and*

17                   *“(G) allow a representative of a participant*  
18                   *or beneficiary, which may include a designated*  
19                   *third-party advocate, to act on behalf of the par-*  
20                   *ticipant or beneficiary.*

21                   *“(2) AVAILABILITY OF PROCESS INFORMATION.—*  
22                   *The group health plan or health insurance issuer shall*  
23                   *make information regarding the process required*  
24                   *under subsection (a) readily available in the relevant*  
25                   *plan materials, including the summary of benefits*

1       *and, if available, on the website of the group health*  
2       *plan or health insurance issuer. Such information*  
3       *shall include—*

4               “(A) *the requirements for requesting an ex-*  
5               *ception to a medication step therapy protocol*  
6               *pursuant to this section; and*

7               “(B) *any forms, supporting information,*  
8               *and contact information, as appropriate.*

9       “(d) *TIMING FOR DETERMINATION OF EXCEPTION.—*  
10       *The process required under subsection (a)(1) shall provide*  
11       *for the disposition of requests received under such para-*  
12       *graph in accordance with the following:*

13               “(1) *Subject to paragraph (2), not later than 72*  
14               *hours after receiving an initial exception request, the*  
15               *plan or issuer shall respond to the participant or ben-*  
16               *eficiary and, if applicable, the requesting prescriber*  
17               *with either a determination of exception eligibility or*  
18               *a request for additional required information strictly*  
19               *necessary to make a determination of whether the con-*  
20               *ditions specified in subsection (b) are met. The plan*  
21               *or issuer shall respond to the participant or bene-*  
22               *ficiary and, if applicable, the requesting prescriber,*  
23               *with a determination of exception eligibility no later*  
24               *than 72 hours after receipt of the additional required*  
25               *information.*

1           “(2) *In the case of a request under circumstances*  
2           *in which the applicable medication step therapy pro-*  
3           *TOCOL may seriously jeopardize the life or health of the*  
4           *participant or beneficiary, may jeopardize the ability*  
5           *of the participant or beneficiary to regain maximum*  
6           *function, or may subject the participant or bene-*  
7           *ficiary to severe pain that cannot be adequately man-*  
8           *aged without the treatment that is the subject of the*  
9           *request, the plan or issuer shall conduct a review of*  
10           *the request and respond to the participant or bene-*  
11           *ficiary and, if applicable, the requesting prescriber,*  
12           *with either a determination of exception eligibility or*  
13           *a request for additional required information strictly*  
14           *necessary to make a determination of whether the con-*  
15           *ditions specified in subsection (b) are met, in accord-*  
16           *ance with the following:*

17                   “(A) *If the plan or issuer can make a deter-*  
18                   *mination of exception eligibility without addi-*  
19                   *tional information, such determination shall be*  
20                   *made on an expedited basis, and no later than*  
21                   *24 hours after receipt of such request.*

22                   “(B) *If the plan or issuer requires addi-*  
23                   *tional information before making a determina-*  
24                   *tion of exception eligibility, the plan or issuer*  
25                   *shall respond to the participant or beneficiary*



1           *and, if applicable, the requesting prescriber, with*  
2           *a request for such information within 24 hours*  
3           *of the request for a determination, and shall re-*  
4           *spond with a determination of exception eligi-*  
5           *bility as quickly as the condition or disease re-*  
6           *quires, and no later than 24 hours after receipt*  
7           *of the additional required information.*

8           “(e) *DURATION OF A GRANT.—If an exception to a*  
9           *medication step therapy protocol is granted under this sec-*  
10          *tion to a participant or beneficiary, coverage for the re-*  
11          *quested drug shall remain in effect with respect to such par-*  
12          *ticipant or beneficiary for not less than one year.*

13          “(f) *MEDICATION STEP THERAPY PROTOCOL.—In this*  
14          *section, the term ‘medication step therapy protocol’ means*  
15          *a drug therapy utilization management protocol or pro-*  
16          *gram under which a group health plan or health insurance*  
17          *issuer offering group health insurance coverage of prescrip-*  
18          *tion drugs requires a participant or beneficiary to try an*  
19          *alternative preferred prescription drug or drugs before the*  
20          *plan or health insurance issuer approves coverage for the*  
21          *non-preferred drug therapy prescribed.*

22          “(g) *CLARIFICATION.—This section shall apply with*  
23          *respect to any group health plan or health insurance cov-*  
24          *erage offered in connection with such a plan that provides*  
25          *coverage of a prescription drug pursuant to a policy that*

1 *meets the definition of the term ‘medication step therapy*  
 2 *protocol’ in subsection (f), regardless of whether such policy*  
 3 *is described by such group health plan or health insurance*  
 4 *coverage as a step therapy protocol.*

5       “(h) *REPORTING.*—

6               “(1) *REPORTING TO THE SECRETARY.*—*Not later*  
 7 *than 3 years after the date of enactment of the Safe*  
 8 *Step Act and not later than October 1 of each year*  
 9 *thereafter, each group health plan and health insur-*  
 10 *ance issuer offering group health insurance coverage*  
 11 *shall report to the Secretary, in such manner as the*  
 12 *Secretary shall require, the following:*

13               “(A) *The number of step therapy exception*  
 14 *requests received for each exception circumstance*  
 15 *described in paragraphs (1) through (6) of sub-*  
 16 *section (b), and the numbers of such requests for*  
 17 *each such circumstance that were—*

18                       “(i) *approved;*

19                       “(ii) *deemed approved under sub-*  
 20 *section (d)(3) due to the failure of the plan*  
 21 *or issuer to timely respond;*

22                       “(iii) *denied, and the reasons for the*  
 23 *denials;*

24                       “(iv) *initially denied and appealed;*

25                       *and*

1                   “(v) *initially denied and then subse-*  
2                   *quently reversed by internal appeals or ex-*  
3                   *ternal reviews.*

4                   “(B) *The number of times a plan or issuer*  
5                   *requested additional information in response to*  
6                   *a step therapy exception request, by exception*  
7                   *circumstance described in paragraphs (1)*  
8                   *through (6) of subsection (b).*

9                   “(C) *The number of exception requests sub-*  
10                   *mitted by participants or beneficiaries, and the*  
11                   *number of exception requests submitted by pre-*  
12                   *scribers, by medical specialty.*

13                   “(D) *The medical conditions for which par-*  
14                   *ticipants and beneficiaries were granted excep-*  
15                   *tions due to the likelihood that switching from a*  
16                   *prescription drug will likely cause an adverse re-*  
17                   *action by, or physical or mental harm to, the*  
18                   *participant or beneficiary, as described in sub-*  
19                   *section (b)(3).*

20                   “(E) *The entities responsible for providing*  
21                   *pharmacy benefit management services for the*  
22                   *group health plan or health insurance coverage.*

23                   “(2) *INFORMATION.—A group health plan or*  
24                   *health insurance issuer offering group health insur-*  
25                   *ance coverage shall not enter into a contract with a*

1 *third-party administrator or an entity providing*  
2 *pharmacy benefit management services on behalf of*  
3 *the plan or coverage that prevents the plan or issuer*  
4 *from obtaining from the third-party administrator or*  
5 *the entity providing pharmacy benefit management*  
6 *services any information needed for the plan or issuer*  
7 *to comply with the reporting requirements under*  
8 *paragraph (1).*

9 “(3) *REPORTS TO CONGRESS.*—Not later than 3  
10 *years after the date of enactment of the Safe Step Act,*  
11 *and not later than October 1 of each year thereafter,*  
12 *the Secretary shall submit to Congress, and make*  
13 *publicly available, a report that contains a summary*  
14 *and analysis of the information reported under para-*  
15 *graph (1), including an analysis of, with respect to*  
16 *requests for exceptions under this section, approvals,*  
17 *and denials, including the reasons for denials; ap-*  
18 *peals and external reviews; and trends, if any, in ex-*  
19 *ception requests by medical specialty or medical con-*  
20 *dition.”.*

21 (c) *CLERICAL AMENDMENT.*—The table of contents in  
22 *section 1 of the Employee Retirement Income Security Act*  
23 *of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting*  
24 *after the item relating to section 713 the following new*  
25 *items:*

“Sec. 713A. *Required exceptions process for medication step therapy protocols.*”.

1       (d) *EFFECTIVE DATE.*—

2           (1) *IN GENERAL.*—*The amendment made by sub-*  
3 *section (b) applies with respect to plan years begin-*  
4 *ning with the first plan year that begins at least 6*  
5 *months after the date of the enactment of this Act.*

6           (2) *REGULATIONS.*—*Not later than 6 months*  
7 *after the date of the enactment of this Act, the Sec-*  
8 *retary of Labor shall issue final regulations, through*  
9 *notice and comment rulemaking, to implement the*  
10 *provisions of section 713A of the Employee Retire-*  
11 *ment Income Security Act of 1974, as added by sub-*  
12 *section (b).*

**Calendar No. 113**

118<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session  
**S. 1339**

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**A BILL**

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

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JUNE 22, 2023

Reported with an amendment