

AMENDMENT NO. _____ Calendar No. _____

Purpose: In the nature of a substitute.

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

S. 1339

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

Referred to the Committee on _____ and
ordered to be printed

Ordered to lie on the table and to be printed

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

Viz:

1 Strike all after the enacting clause and insert the fol-
2 lowing:

3 **SECTION 1. SHORT TITLE.**

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

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

8 (a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of
9 the Public Health Service Act (42 U.S.C. 300gg et seq.)
10 is amended—

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

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

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

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

20 “(2) provide the group health plan or health in-
21 surance issuer offering group health insurance cov-
22 erage, or an entity providing pharmacy benefits
23 management services on behalf of a plan or cov-
24 erage, relevant information necessary to make the
25 reports described in subsection (b).

1 “(b) REPORTS.—

2 “(1) IN GENERAL.—For plan years beginning
3 on or after the date that is 30 months after the date
4 of enactment of the Pharmacy Benefit Manager Re-
5 form Act, not less frequently than annually, an enti-
6 ty providing pharmacy benefit management services
7 on behalf of a covered group health plan or group
8 health insurance coverage (whether such coverage is
9 covered group health insurance coverage or not)
10 shall submit to the plan sponsor of such covered
11 group health plan or issuer of such health insurance
12 coverage a report in accordance with this subsection
13 and make such report available to the plan sponsor
14 or issuer in plain language, in a machine-readable
15 format, and, as the Secretary, the Secretary of
16 Labor, and the Secretary of the Treasury may deter-
17 mine, other formats. Each such report shall include,
18 with respect to the covered group health plan or
19 health insurance coverage—

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

1 to the participants and beneficiaries in such
2 plan or coverage;

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

9 “(i) the brand name, generic or non-
10 proprietary name, and National Drug
11 Code;

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

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

1 “(iv) the wholesale acquisition cost,
2 listed as cost per days supply, cost per dos-
3 age unit;

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

8 “(I) including copayments, coin-
9 surance, and deductibles; and

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

15 “(vi) for each of the 50 prescription
16 drugs with the highest gross spending
17 under the group health plan or health in-
18 surance coverage during the reporting pe-
19 riod—

20 “(I) a list of all other drugs in
21 the same therapeutic class (as defined
22 by the Secretary, the Secretary of
23 Labor, and the Secretary of the
24 Treasury), including brand name
25 drugs and biological products and ge-

1 neric drugs or biosimilar biological
2 products that are in the same thera-
3 peutic class as such drug;

4 “(II) if applicable, the rationale
5 for preferred formulary placement of
6 such drug in that therapeutic class,
7 selected from a list of standard ra-
8 tionales established by the Secretary,
9 the Secretary of Labor, and the Sec-
10 retary of the Treasury, in consultation
11 with stakeholders; and

12 “(III) any change in formulary
13 placement compared to the prior plan
14 year;

15 “(C) a list of each therapeutic class of
16 drugs for which a claim was filed under the
17 health plan during the reporting period, and,
18 with respect to each such therapeutic class of
19 drugs, during the reporting period—

20 “(i) total gross spending by the plan
21 or coverage;

22 “(ii) the number of participants and
23 beneficiaries who filled a prescription for a
24 drug in that class;

1 “(iii) if applicable to that class, a de-
2 scription of the formulary tiers and utiliza-
3 tion management mechanisms (such as
4 prior authorization or step therapy) em-
5 ployed for drugs in that class;

6 “(iv) the total out-of-pocket spending
7 by participants and beneficiaries, including
8 participant and beneficiary spending
9 through copayments, coinsurance, and
10 deductibles; and

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

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

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

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

23 “(II) the total net spending by
24 the health plan 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 health plan and its par-
4 ticipants and beneficiaries, among all
5 drugs within the therapeutic class for
6 which a claim was filed during the re-
7 porting period;

8 “(D) total gross spending on prescription
9 drugs by the plan or coverage during the re-
10 porting period;

11 “(E) the total amount received, or ex-
12 pected to be received, by the health plan or
13 health insurance issuer, from applicable enti-
14 ties, in rebates, fees, alternative discounts, and
15 other remuneration received from any such en-
16 tities, related to utilization of drug or drug
17 spending under that health plan or health in-
18 surance coverage during the reporting period;

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

22 “(G) amounts paid directly or indirectly in
23 rebates, fees, or any other type of compensation
24 (as defined in section 408(b)(2)(B)(ii)(dd)(AA)
25 of the Employee Retirement Income Security

1 Act of 1974) to brokers, consultants, advisors,
2 or any other individual or firm for referral of
3 the group health plan's or health insurance
4 issuer's business to the pharmacy benefit man-
5 ager, consideration of the entity providing phar-
6 macy benefit management services by the group
7 health plan or health insurance issuer, or the
8 retention of the entity by the group health plan
9 or health insurance issuer;

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

23 “(ii) the percentage of total prescriptions
24 charged to the plan, issuer, or participants and
25 beneficiaries in the plan or coverage, that were

1 dispensed by mail order, specialty, or retail
2 pharmacies that are affiliated with or under
3 common ownership with the entity providing
4 pharmacy benefit management services; and

5 “(iii) a list of all drugs dispensed by such
6 affiliated pharmacy or pharmacy under common
7 ownership and charged to the plan, issuer, or
8 participants and beneficiaries of the plan, dur-
9 ing the applicable period, and, with respect to
10 each drug—

11 “(I)(aa) the amount charged, per dos-
12 age unit, per 30-day supply, and per 90-
13 day supply, with respect to participants
14 and beneficiaries in the plan or coverage,
15 to the plan or issuer; and

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

19 “(II) the median amount charged to
20 the plan or issuer, per dosage unit, per 30-
21 day supply, and per 90-day supply, includ-
22 ing amounts paid by the participants and
23 beneficiaries, when the same drug is dis-
24 pensed by other pharmacies that are not
25 affiliated with or under common ownership

1 with the entity and that are included in the
2 pharmacy network of that plan or cov-
3 erage;

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

13 “(IV) the lowest cost, per dosage unit,
14 per 30-day supply, and per 90-day supply,
15 for such drug, including amounts charged
16 to the plan and participants and bene-
17 ficiaries, that is available from any phar-
18 macy included in the network of the plan
19 or coverage;

20 “(V) the net acquisition cost per dos-
21 age unit, per 30-day supply, and per 90-
22 day supply, if the drug is subject to a max-
23 imum price discount; and

24 “(VI) other information with respect
25 to the cost of the drug, as determined by

1 the Secretary, such as average sales price,
2 wholesale acquisition cost, and national av-
3 erage drug acquisition cost per dosage unit
4 or per 30-day supply, for such drug, in-
5 cluding amounts charged to the plan or
6 issuer and participants and beneficiaries
7 among all pharmacies included in the net-
8 work of the plan or coverage;

9 “(I) a summary document for plan spon-
10 sors or issuers that includes such information
11 described in subparagraphs (A) through (H) as
12 the Secretary, the Secretary of Labor, and the
13 Secretary of the Treasury determines useful for
14 plan sponsors and health insurance issuers for
15 purposes of selecting pharmacy benefit manage-
16 ment services, such as an estimated net price to
17 plan sponsor and participant or beneficiary, a
18 cost per claim, the fee structure or reimburse-
19 ment model, and estimated cost per participant
20 or beneficiary; and

21 “(J) a summary document for participants
22 or beneficiaries, which shall be made available
23 to participants or beneficiaries upon request to
24 the plan sponsor, that contains such informa-
25 tion described in subparagraphs (D) through

1 (G) as the Secretary determines useful for par-
2 ticipants or beneficiaries in better under-
3 standing their plan or benefits, except that such
4 summary document for participants or bene-
5 ficiaries shall contain only aggregate informa-
6 tion.

7 “(2) REGULATIONS.—Not later than 2 years
8 after the date of enactment of the Pharmacy Benefit
9 Manager Reform Act, the Secretary, the Secretary
10 of Labor, and the Secretary of the Treasury shall,
11 through notice and comment rulemaking, promul-
12 gate final regulations to implement the requirements
13 of this subsection. In promulgating such regulations,
14 the Secretary, the Secretary of Labor, and the Sec-
15 retary of the Treasury shall, to the extent prac-
16 ticable, align the reporting requirements under this
17 subsection with the reporting requirements under
18 section 2799A–10.

19 “(3) ADDITIONAL REPORTING.—

20 “(A) REPORTING WITH RESPECT TO
21 GROUP HEALTH PLANS OFFERED BY SMALL
22 EMPLOYERS.—For plan years beginning on or
23 after the date that is 30 months after the date
24 of enactment of the Pharmacy Benefit Manager
25 Reform Act, not less frequently than annually,

1 an entity providing pharmacy benefit manage-
2 ment services on behalf of a group health plan
3 that is not a covered group health plan shall
4 submit to the plan sponsor of such group health
5 plan a report in accordance with this para-
6 graph, and make such report available to the
7 plan sponsor in a machine-readable format, and
8 such other formats as the Secretary, the Sec-
9 retary of Health and Human Services, and the
10 Secretary of the Treasury may determine. Each
11 such report shall include, with respect to the
12 applicable group health plan—

13 “(i) the information described in sub-
14 paragraphs (D), (E), (F), and (G) of para-
15 graph (1);

16 “(ii) as applicable, information col-
17 lected from drug manufacturers by such
18 plan on the total amount of copayment as-
19 sistance dollars paid, or copayment cards
20 applied, that were funded by applicable
21 drug manufacturers with respect to the
22 participants and beneficiaries in such plan,
23 except that such information shall not
24 identify any drug manufacturer; and

1 “(iii) a summary document that in-
2 cludes such information described in
3 clauses (i) and (ii) as the Secretary deter-
4 mines useful for plan sponsors for pur-
5 poses of selecting pharmacy benefit man-
6 agement services, provided that such sum-
7 mary documents include only aggregate in-
8 formation.

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

11 “(i) IN GENERAL.—A plan sponsor of
12 group health insurance coverage offered in
13 connection with a group health plan may,
14 on an annual basis, for plan years begin-
15 ning on or after the date that is 30 months
16 after the date of enactment of the Phar-
17 macy Benefit Manager Reform Act, elect
18 to require an entity providing pharmacy
19 benefit management services on behalf of a
20 health insurance issuer offering group
21 health insurance coverage to submit to
22 such plan sponsor a report in accordance
23 with this subsection.

24 “(ii) CONTENTS OF REPORTS.—

1 (E), (F), and (G) of paragraph
2 (1); and

3 “(bb) as applicable, informa-
4 tion collected from drug manu-
5 facturers by such issuer or entity
6 on the total amount of copay-
7 ment assistance dollars paid, or
8 copayment cards applied, that
9 were funded by applicable drug
10 manufacturers with respect to
11 the participants and beneficiaries
12 in such plan, except that such in-
13 formation shall not identify any
14 drug manufacturer.

15 “(iii) REQUIRED REPORTING FOR
16 COVERED GROUP HEALTH INSURANCE COV-
17 ERAGE.—Each health insurance issuer that
18 offers covered group health insurance cov-
19 erage shall annually submit the informa-
20 tion described in paragraph (1)(I), regard-
21 less of whether the plan sponsor made the
22 election described in clause (i) for the ap-
23 plicable year.

24 “(iv) REQUIRED REPORTING FOR
25 OTHER GROUP HEALTH INSURANCE COV-

1 ERAGE.—Each health insurance issuer that
2 offers group health insurance coverage that
3 is not covered group health insurance shall
4 annually submit a summary document that
5 includes such information described in sub-
6 clauses (aa) and (bb) of clause (ii)(II) as
7 the Secretary determines useful for plan
8 sponsors for purposes of selecting phar-
9 macy benefit management services, pro-
10 vided that such summary documents in-
11 clude only aggregate information.

12 “(4) PRIVACY REQUIREMENTS.—

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

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
2 Regulations (or successor regulations).

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

5 “(i) REASONABLE RESTRICTIONS.—

6 Nothing in this section prevents a health
7 insurance issuer offering group health in-
8 surance coverage or an entity providing
9 pharmacy benefit management services on
10 behalf of a group health plan or group
11 health insurance coverage from placing
12 reasonable restrictions (as the Secretary,
13 the Secretary of Labor, and the Secretary
14 of the Treasury may determine) on the
15 public disclosure of the information con-
16 tained in a report under paragraph (1) or
17 (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 group health insur-
23 ance coverage may not restrict disclosure
24 of such reports to the Department of
25 Health and Human Services, the Depart-

1 ment of Labor, the Department of the
2 Treasury, or any other Federal agency re-
3 sponsible for enforcement activities under
4 this section for purposes of enforcement
5 under this section or other applicable law,
6 or to the Comptroller General of the
7 United States in accordance with para-
8 graph (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 dis-
14 charge, any employee, or otherwise dis-
15 criminate against any employee with re-
16 spect to the compensation, terms, condi-
17 tions, or privileges of employment of the
18 employee, because of information sub-
19 mitted under paragraph (1) or (3) attrib-
20 uted to the employee or a dependent of the
21 employee; or

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

1 erwise adversely affect the status of the
2 employee as an employee, because of infor-
3 mation submitted under paragraph (1) or
4 (3) attributed to the employee or a depend-
5 ent of the employee.

6 “(B) DISCLOSURE AND REDISCLOSURE.—
7 A plan sponsor shall not disclose the informa-
8 tion received under paragraph (1) or (3) ex-
9 cept—

10 “(i) to an occupational or other health
11 researcher if the research is conducted in
12 compliance with the regulations and pro-
13 tections provided for under part 46 of title
14 45, Code of Federal Regulations (or suc-
15 cessor regulations);

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

20 “(iii) to the Department of Health
21 and Human Services, the Department of
22 Labor, the Department of the Treasury, or
23 other Federal agency responsible for en-
24 forcement 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, to
4 abide by the same use and disclosure re-
5 strictions as the plan sponsor.

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

19 “(D) WRITTEN NOTICE.—Plan sponsors of
20 group health plans shall provide to each em-
21 ployee written notice informing the employee of
22 the requirement for health insurance issuers or
23 entities providing pharmacy benefit manage-
24 ment services to submit reports to plan spon-
25 sors under paragraphs (1) and (3), as applica-

1 ble, which may include incorporating such noti-
2 fication in plan documents provided to the em-
3 ployee, an employee handbook provided to the
4 employee, or individual notification.

5 “(E) ENFORCEMENT.—

6 “(i) IN GENERAL.—The powers, pro-
7 cedures, and remedies provided in section
8 207 of the Genetic Information Non-
9 discrimination Act to a person alleging a
10 violation of title II of such Act shall be the
11 powers, procedures, and remedies this sub-
12 paragraph provides for any person alleging
13 a violation of this paragraph.

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

1 able to aggrieved individuals with respect
2 to violations of this clause.

3 “(6) SUBMISSIONS TO GAO.—A health insur-
4 ance issuer offering group health insurance coverage
5 or an entity providing pharmacy benefit manage-
6 ment services on behalf of a group health plan shall
7 submit, upon request, to the Comptroller General of
8 the United States each of the first 2 reports sub-
9 mitted to a plan sponsor under paragraph (1) or (3)
10 with respect to such coverage or plan, and other
11 such reports as requested, in accordance with the
12 privacy requirements under paragraph (4), and such
13 other information that the Comptroller General de-
14 termines necessary to carry out the study under sec-
15 tion 2(f) of the Pharmacy Benefit Manager Reform
16 Act.

17 “(7) STANDARD FORMATS.—

18 “(A) IN GENERAL.—Not later than June
19 1, 2024, the Secretary, the Secretary of Labor,
20 and the Secretary of the Treasury shall specify,
21 through rulemaking, standard formats for enti-
22 ties providing pharmacy benefit management
23 services to submit reports required under this
24 subsection. The Secretary may provide for sepa-
25 rate standard formats for reports to plan spon-

1 sors of group health plans and reports to plan
2 sponsors of group health insurance coverage of-
3 fered in connection with a group health plan.

4 “(B) FORM OF REPORT.—The Secretary,
5 the Secretary of Labor, and the Secretary of
6 the Treasury shall define through rulemaking a
7 form of the reports under paragraphs (1) and
8 (3) required to be submitted to plan sponsors
9 who also are drug manufacturers, drug whole-
10 salers, entities providing pharmacy benefit man-
11 agement services, or other direct participants in
12 the drug supply chain, in the case that such
13 secretaries determine that changes to the stand-
14 ard format are necessary to prevent anti-
15 competitive behavior.

16 “(c) LIMITATIONS ON SPREAD PRICING.—

17 “(1) IN GENERAL.—For plan years beginning
18 on or after the date that is 30 months after the date
19 of enactment of the Pharmacy Benefit Manager Re-
20 form Act, a group health plan or health insurance
21 issuer offering group or individual health insurance
22 coverage shall ensure that the amount required to be
23 paid by a participant, beneficiary, or enrollee for a
24 prescription drug covered under the plan or cov-
25 erage, and an entity providing pharmacy benefit

1 management services on behalf of such a plan or
2 coverage shall ensure that the total amount required
3 to be paid by the plan or issuer and participant,
4 beneficiary, or enrollee for a prescription drug cov-
5 ered under the plan or coverage, does not exceed the
6 price paid to the pharmacy, excluding penalties paid
7 by the pharmacy (as described in paragraph (2)) to
8 such plan, issuer, or entity.

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

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

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

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

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

1 “(1) IN GENERAL.—For plan years beginning
2 on or after the date that is 30 months after the date
3 of enactment of the Pharmacy Benefit Manager Re-
4 form Act, a third-party administrator of a group
5 health plan or an entity providing pharmacy benefit
6 management services on behalf of a group health
7 plan or health insurance issuer offering group health
8 insurance coverage shall—

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

16 “(B) ensure that any contract entered into,
17 by such third-party administrator or entity pro-
18 viding pharmacy benefit management services
19 on behalf of such a plan or coverage, with re-
20 bate aggregators (or other purchasing entity de-
21 signed to aggregate rebates), applicable group
22 purchasing organizations, or any subsidiary,
23 parent, affiliate, or subcontractor of the plan,
24 entity, rebate aggregator (or other purchasing
25 entity designed to aggregate rebates), or appli-

1 cable group purchasing organization remit 100
2 percent of rebates, fees, alternative discounts,
3 and other remuneration received that are re-
4 lated to utilization of drugs under such health
5 plan or health insurance coverage to the third-
6 party administrator, or entity providing phar-
7 macy benefit management services.

8 “(2) FORM AND MANNER OF REMITTANCE.—
9 With respect to such rebates, fees, alternative dis-
10 counts, and other remuneration—

11 “(A) the rebates fees, alternative dis-
12 counts, and other remuneration under para-
13 graph (1)(A) shall be—

14 “(i) remitted—

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

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

24 “(ii) fully disclosed and enumerated to
25 the group health plan or health insurance

1 issuer, as described in paragraphs (1) and
2 (3) of subsection (b); and

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

12 “(B) the rebates fees, alternative dis-
13 counts, and other remuneration under para-
14 graph (1)(B) shall be remitted in accordance
15 with such procedures as the Secretary, Sec-
16 retary of Labor, and Secretary of the Treasury
17 establish; and

18 “(C) the records of such rebates, fees, al-
19 ternative discounts, and other remuneration
20 shall be available for audit by the plan sponsor,
21 issuer, or a third party designated by a plan
22 sponsor, not less than once per plan year.

23 “(3) AUDIT OF REBATE CONTRACTS.—A third-
24 party administrator of a group health plan, a health
25 insurance issuer offering group health insurance cov-

1 erage, or an entity providing pharmacy benefit man-
2 agement services under such health plan or health
3 insurance coverage shall make rebate contracts with
4 rebate aggregators or drug manufacturers available
5 for audit by such plan sponsor or designated third
6 party, subject to reasonable restrictions (as deter-
7 mined by the Secretary, the Secretary of Labor, and
8 the Secretary of the Treasury) on confidentiality to
9 prevent re-disclosure of such contracts.

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

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

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

21 “(B) require a third-party administrator of
22 a group health plan or an entity providing
23 pharmacy benefit management services on
24 under such health plan or health insurance cov-

1 erage to remit bona fide service fees to plan
2 sponsors to the group health plan; or

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

7 “(e) ENFORCEMENT.—

8 “(1) IN GENERAL.—The Secretary shall enforce
9 this section.

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

1 “(3) FALSE INFORMATION.—A group health
2 plan, a health insurance issuer, an entity providing
3 pharmacy benefit management services, or a third-
4 party administrator that knowingly provides false in-
5 formation under this section shall be subject to a
6 civil money penalty in an amount not to exceed
7 \$100,000 for each item of false information. Such
8 civil money penalty shall be in addition to other pen-
9 alties as may be prescribed by law.

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

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

24 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed to permit a health insurance issuer,

1 group health plan, or other entity to restrict disclosure to,
2 or otherwise limit the access of, the Secretary of Health
3 and Human Services to a report described in subsection
4 (b)(1) or information related to compliance with sub-
5 sections (a), (b), (c), or (d) by such issuer, plan, or entity.

6 “(g) DEFINITIONS.—In this section—

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

8 “(A) an applicable group purchasing orga-
9 nization, drug manufacturer, distributor, whole-
10 saler, rebate aggregator (or other purchasing
11 entity designed to aggregate rebates), or associ-
12 ated third party;

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

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

22 “(2) the term ‘applicable group purchasing or-
23 ganization’ means a group purchasing organization
24 that is affiliated with or under common ownership

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

3 “(3) 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 “(4) the term ‘covered group health plan’
8 means a group health plan maintained by a large
9 employer;

10 “(5) 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 rebates, fees, alternative dis-
16 counts, or other remuneration;

17 “(6) 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 “(7) 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 rebates, fees, alternative discounts,
5 or other remuneration;

6 “(8) 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;

9 “(9) the term ‘remuneration’ has the meaning
10 given such term by the Secretary, the Secretary of
11 Labor, and the Secretary of the Treasury, through
12 rulemaking and reevaluated by such Secretaries
13 every 5 years;

14 “(10) 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 “(11) the term ‘wholesale acquisition cost’ has
22 the meaning given such term in section
23 1847A(c)(6)(B) of the Social Security Act.”;

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

25 (A) in subsection (a)—

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

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

7 (B) in subsection (b)—

8 (i) in paragraph (1), by inserting
9 “(other than section 2799A–11)” after
10 “part D”;

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

14 (iii) in paragraph (2)(C)(ii), by insert-
15 ing “(other than section 2799A–11)” after
16 “part D”; and

17 (3) in section 2799A–10 (42 U.S.C. 42 U.S.C.
18 300gg–120), by adding at the end the following:

19 “(d) ENTITIES PROVIDING PHARMACY BENEFIT
20 MANAGEMENT SERVICES.—Beginning 2 years after the
21 date of enactment of the Pharmacy Benefit Manager Re-
22 form Act, entities providing pharmacy benefit manage-
23 ment services shall report to plan sponsors of group health
24 plans or group health insurance coverage information re-

1 quired under paragraphs (4), (5), (6), (7)(A)(iii), and
2 (7)(B) of subsection (a).”.

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

5 (1) IN GENERAL.—Subtitle B of title I of the
6 Employee Retirement Income Security Act of 1974
7 (29 U.S.C. 1021 et seq.) is amended—

8 (A) in subpart B of part 7 (29 U.S.C.
9 1185 et seq.), by adding at the end the fol-
10 lowing:

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

13 “(a) IN GENERAL.—For plan years beginning on or
14 after the date that is 30 months after the date of enact-
15 ment of the Pharmacy Benefit Manager Reform Act, a
16 group health plan (or health insurance issuer offering
17 group health insurance coverage in connection with such
18 a plan) or an entity providing pharmacy benefit manage-
19 ment services on behalf of such a plan or issuer shall not
20 enter into a contract with an applicable entity unless such
21 applicable entity agrees to—

22 “(1) not limit the disclosure of information to
23 plan sponsors in such a manner that prevents the
24 plan or issuer, or an entity providing pharmacy ben-
25 efit management services on behalf of a plan or

1 issuer, from making the reports described in sub-
2 section (b); and

3 “(2) provide the group health plan or health in-
4 surance issuer offering group health insurance cov-
5 erage, or an entity providing pharmacy benefits
6 management services on behalf of a plan or cov-
7 erage, relevant information necessary to make the
8 reports described in subsection (b).

9 “(b) REPORTS.—

10 “(1) IN GENERAL.—For plan years beginning
11 on or after the date that is 30 months after the date
12 of enactment of the Pharmacy Benefit Manager Re-
13 form Act, not less frequently than annually, an enti-
14 ty providing pharmacy benefit management services
15 on behalf of a covered group health plan or group
16 health insurance coverage (whether such coverage is
17 covered group health insurance coverage or not)
18 shall submit to the plan sponsor of such covered
19 group health plan or issuer of such health insurance
20 coverage a report in accordance with this subsection
21 and make such report available to the plan sponsor
22 or issuer in plain language, in a machine-readable
23 format, and, as the Secretary, the Secretary of
24 Labor, and the Secretary of the Treasury may deter-
25 mine, other formats. Each such report shall include,

1 with respect to the covered group health plan or
2 health insurance coverage—

3 “(A) as applicable, information collected
4 from drug manufacturers by such entity on the
5 total amount of copayment assistance dollars
6 paid, or copayment cards applied, that were
7 funded by the drug manufacturer with respect
8 to the participants and beneficiaries in such
9 plan or coverage;

10 “(B) a list of each drug covered by such
11 plan, coverage, or entity providing pharmacy
12 benefit management services for which a claim
13 was filed during the reporting period, including,
14 with respect to each such drug during the re-
15 porting period—

16 “(i) the brand name, generic or non-
17 proprietary name, and National Drug
18 Code;

19 “(ii) the number of participants and
20 beneficiaries for whom a claim for the drug
21 was filed during the reporting period, the
22 total number of prescription claims for the
23 drug (including original prescriptions and
24 refills), and the total number of dosage

1 units of the drug for which a claim was
2 filed across the reporting period;

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

7 “(iv) the wholesale acquisition cost,
8 listed as cost per days supply, cost per dos-
9 age unit;

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

14 “(I) including copayments, coin-
15 surance, and deductibles; and

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

21 “(vi) for each of the 50 prescription
22 drugs with the highest gross spending
23 under the group health plan or health in-
24 surance coverage during the reporting pe-
25 riod—

1 “(I) a list of all other drugs in
2 the same therapeutic class (as defined
3 by the Secretary, the Secretary of
4 Labor, and the Secretary of the
5 Treasury), including brand name
6 drugs and biological products and ge-
7 neric drugs or biosimilar biological
8 products that are in the same thera-
9 peutic class as such drug;

10 “(II) if applicable, the rationale
11 for preferred formulary placement of
12 such drug in that therapeutic class,
13 selected from a list of standard ra-
14 tionales established by the Secretary,
15 the Secretary of Labor, and the Sec-
16 retary of the Treasury, in consultation
17 with stakeholders; and

18 “(III) any change in formulary
19 placement compared to the prior plan
20 year;

21 “(C) a list of each therapeutic class of
22 drugs for which a claim was filed under the
23 health plan during the reporting period, and,
24 with respect to each such therapeutic class of
25 drugs, during the reporting period—

1 “(i) total gross spending by the plan
2 or coverage;

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

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

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

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

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

24 “(aa) for claims incurred
25 during the reporting period; or

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

3 “(II) the total net spending by
4 the health plan on that class of drugs;
5 and

6 “(III) the average net spending
7 per 30-day supply and per 90-day
8 supply by the health plan and its par-
9 ticipants and beneficiaries, among all
10 drugs within the therapeutic class for
11 which a claim was filed during the re-
12 porting period;

13 “(D) total gross spending on prescription
14 drugs by the plan or coverage during the re-
15 porting period;

16 “(E) the total amount received, or ex-
17 pected to be received, by the health plan or
18 health insurance issuer, from applicable enti-
19 ties, in rebates, fees, alternative discounts, and
20 other remuneration received from any such en-
21 tities, related to utilization of drug or drug
22 spending under that health plan or health in-
23 surance coverage during the reporting period;

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

4 “(G) amounts paid directly or indirectly in
5 rebates, fees, or any other type of compensation
6 (as defined in section 408(b)(2)(B)(ii)(dd)(AA)
7 of the Employee Retirement Income Security
8 Act of 1974) to brokers, consultants, advisors,
9 or any other individual or firm for referral of
10 the group health plan’s or health insurance
11 issuer’s business to the pharmacy benefit man-
12 ager, consideration of the entity providing phar-
13 macy benefit management services by the group
14 health plan or health insurance issuer, or the
15 retention of the entity by the group health plan
16 or health insurance issuer;

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

1 programs, retail and mail auto-refill programs,
2 and cost-sharing assistance incentives funded
3 by an entity providing pharmacy benefit man-
4 agement services;

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

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

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

23 “(bb) the amount charged, per dosage
24 unit, per 30-day supply, and per 90-day
25 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
7 affiliated with or under common ownership
8 with the entity and that are included in the
9 pharmacy network of that plan or cov-
10 erage;

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

20 “(IV) the lowest cost, per dosage unit,
21 per 30-day supply, and per 90-day supply,
22 for such drug, including amounts charged
23 to the plan and participants and bene-
24 ficiaries, that is available from any phar-

1 macy included in the network of the plan
2 or coverage;

3 “(V) the net acquisition cost per dos-
4 age unit, per 30-day supply, and per 90-
5 day supply, if the drug is subject to a max-
6 imum price discount; and

7 “(VI) other information with respect
8 to the cost of the drug, as determined by
9 the Secretary, 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, in-
13 cluding amounts charged to the plan or
14 issuer and participants and beneficiaries
15 among all pharmacies included in the net-
16 work of the plan or coverage;

17 “(I) a summary document for plan spon-
18 sors or issuers that includes such information
19 described in subparagraphs (A) through (H) as
20 the Secretary, the Secretary of Labor, and the
21 Secretary of the Treasury determines useful for
22 plan sponsors and health insurance issuers for
23 purposes of selecting pharmacy benefit manage-
24 ment services, such as an estimated net price to
25 plan sponsor and participant or beneficiary, a

1 cost per claim, the fee structure or reimburse-
2 ment model, and estimated cost per participant
3 or beneficiary; and

4 “(J) a summary document for participants
5 or beneficiaries, which shall be made available
6 to participants or beneficiaries upon request to
7 the plan sponsor, that contains such informa-
8 tion described in subparagraphs (D) through
9 (G) as the Secretary determines useful for par-
10 ticipants or beneficiaries in better under-
11 standing their plan or benefits, except that such
12 summary document for participants or bene-
13 ficiaries shall contain only aggregate informa-
14 tion.

15 “(2) REGULATIONS.—Not later than 2 years
16 after the date of enactment of the Pharmacy Benefit
17 Manager Reform Act, the Secretary, the Secretary
18 of Health and Human Services, and the Secretary of
19 the Treasury shall, through notice and comment
20 rulemaking, promulgate final regulations final regu-
21 lations to implement the requirements of this sub-
22 section. In promulgating such regulations, the Sec-
23 retary, the Secretary of Labor, and the Secretary of
24 the Treasury shall, to the extent practicable, align

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

3 “(3) ADDITIONAL REPORTING.—

4 “(A) REPORTING WITH RESPECT TO
5 GROUP HEALTH PLANS OFFERED BY SMALL
6 EMPLOYERS.—For plan years beginning on or
7 after the date that is 30 months after the date
8 of enactment of the Pharmacy Benefit Manager
9 Reform Act, not less frequently than annually,
10 an entity providing pharmacy benefit manage-
11 ment services on behalf of a group health plan
12 that is not a covered group health plan shall
13 submit to the plan sponsor of such group health
14 plan a report in accordance with this para-
15 graph, and make such report available to the
16 plan sponsor in a machine-readable format, and
17 such other formats as the Secretary, the Sec-
18 retary of Health and Human Services, and the
19 Secretary of the Treasury may determine. Each
20 such report shall include, with respect to the
21 applicable group health 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
7 participants and beneficiaries in such plan,
8 except that such information shall not
9 identify any drug manufacturer; and

10 “(iii) a summary document that in-
11 cludes such information described in
12 clauses (i) and (ii) as the Secretary deter-
13 mines useful for plan sponsors for pur-
14 poses of selecting pharmacy benefit man-
15 agement services, provided that such sum-
16 mary documents include only aggregate in-
17 formation.

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

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

1 macy Benefit Manager Reform Act, elect
2 to require an entity providing pharmacy
3 benefit management services on behalf of a
4 health insurance issuer offering group
5 health insurance coverage to submit to
6 such plan sponsor a report in accordance
7 with this subsection.

8 “(ii) CONTENTS OF REPORTS.—

9 “(I) COVERED GROUP HEALTH
10 INSURANCE COVERAGE.—In the case
11 of an entity providing pharmacy ben-
12 efit management services on behalf of
13 an issuer that offers covered group
14 health insurance coverage, a report
15 provided pursuant to clause (i) shall
16 include, with respect to the applicable
17 covered group health insurance cov-
18 erage, the information required under
19 paragraph (1) for covered group
20 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
2 group health insurance, a report pro-
3 vided pursuant to clause (i) shall in-
4 clude, with respect to the applicable
5 group 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 manu-
12 facturers by such issuer or entity
13 on the total amount of copay-
14 ment assistance dollars paid, or
15 copayment cards applied, that
16 were funded by applicable drug
17 manufacturers with respect to
18 the participants and beneficiaries
19 in such plan, except that such in-
20 formation shall not identify any
21 drug manufacturer.

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

1 erage shall annually submit the informa-
2 tion described in paragraph (1)(I), regard-
3 less of whether the plan sponsor made the
4 election described in clause (i) for the ap-
5 plicable 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 sub-
13 clauses (aa) and (bb) of clause (ii)(II) as
14 the Secretary determines useful for plan
15 sponsors for purposes of selecting phar-
16 macy benefit management services, pro-
17 vided that such summary documents in-
18 clude only aggregate information.

19 “(4) PRIVACY REQUIREMENTS.—

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

1 regulations in parts 160 and 164 of title 45,
2 Code of Federal Regulations (or successor regu-
3 lations).

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

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

11 “(i) REASONABLE RESTRICTIONS.—
12 Nothing in this section prevents a health
13 insurance issuer offering group health in-
14 surance coverage or an entity providing
15 pharmacy benefit management services on
16 behalf of a group health plan or group
17 health insurance coverage from placing
18 reasonable restrictions (as the Secretary,
19 the Secretary of Health and Human Serv-
20 ices, and the Secretary of the Treasury
21 may determine) on the public disclosure of
22 the information contained in a report
23 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 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 “(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 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 (3) 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 (3) 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 (3) 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 suc-
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) WRITTEN NOTICE.—Plan sponsors of
2 group health plans shall provide to each em-
3 ployee written notice informing the employee of
4 the requirement for health insurance issuers or
5 entities providing pharmacy benefit manage-
6 ment services to submit reports to plan spon-
7 sors under paragraphs (1) and (3), as applica-
8 ble, which may include incorporating such noti-
9 fication in plan documents provided to the em-
10 ployee, an employee handbook provided to the
11 employee, or individual notification.

12 “(E) ENFORCEMENT.—

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

22 “(ii) PROHIBITION AGAINST RETALIA-
23 TION.—No person shall discriminate
24 against any individual because such indi-
25 vidual has opposed any act or practice

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

10 “(6) SUBMISSIONS TO GAO.—A health insur-
11 ance issuer offering group health insurance coverage
12 or an entity providing pharmacy benefit manage-
13 ment services on behalf of a group health plan shall
14 submit, upon request, to the Comptroller General of
15 the United States each of the first 2 reports sub-
16 mitted to a plan sponsor under paragraph (1) or (3)
17 with respect to such coverage or plan, and other
18 such reports as requested, in accordance with the
19 privacy requirements under paragraph (4), and such
20 other information that the Comptroller General de-
21 termines necessary to carry out the study under sec-
22 tion 2(f) of the Pharmacy Benefit Manager Reform
23 Act.

24 “(7) STANDARD FORMATS.—

1 “(A) IN GENERAL.—Not later than June
2 1, 2024, the Secretary, the Secretary of Health
3 and Human Services, and the Secretary of the
4 Treasury shall specify, through rulemaking,
5 standard formats for entities providing phar-
6 macy benefit management services to submit re-
7 ports required under this subsection. The Sec-
8 retary may provide for separate standard for-
9 mats for reports to plan sponsors of group
10 health plans and reports to plan sponsors of
11 group health insurance coverage offered in con-
12 nection with a group health plan.

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

25 “(c) LIMITATIONS ON SPREAD PRICING.—

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

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

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

23 “(B) A penalty paid if the original claim
24 payment made by the plan, issuer, or entity to
25 the pharmacy was inconsistent with the reim-

1 bursement terms in any contract between the
2 pharmacy and the plan, issuer, or entity.

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

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

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

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

23 “(B) ensure that any contract entered into,
24 by such third-party administrator or entity pro-
25 viding pharmacy benefit management services

1 on behalf of such a plan or coverage, with re-
2 bate aggregators (or other purchasing entity de-
3 signed to aggregate rebates), applicable group
4 purchasing organizations, or any subsidiary,
5 parent, affiliate, or subcontractor of the plan,
6 entity, rebate aggregator (or other purchasing
7 entity designed to aggregate rebates), or appli-
8 cable group purchasing organization remit 100
9 percent of rebates, fees, alternative discounts,
10 and other remuneration received that are re-
11 lated to utilization of drugs under such health
12 plan or health insurance coverage to the third-
13 party administrator, or entity providing phar-
14 macy benefit management services.

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

16 With respect to such rebates, fees, alternative dis-
17 counts, and other remuneration—

18 “(A) the rebates fees, alternative dis-
19 counts, and other remuneration under para-
20 graph (1)(A) shall be—

21 “(i) remitted—

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

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

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

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

19 “(B) the rebates fees, alternative dis-
20 counts, and other remuneration under para-
21 graph (1)(B) shall be remitted in accordance
22 with such procedures as the Secretary, Sec-
23 retary of Labor, and Secretary of the Treasury
24 establish; and

1 “(C) the records of such rebates, fees, al-
2 ternative discounts, and other remuneration
3 shall be available for audit by the plan sponsor,
4 issuer, or a third party designated by a plan
5 sponsor, not less than once per plan year.

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

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

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

24 “(A) prohibit payments to entities offering
25 pharmacy benefit management services for bona

1 fide services using a fee structure not described
2 in this subsection, provided that such fees are
3 transparent to group health plans and health
4 insurance issuers;

5 “(B) require a third-party administrator of
6 a group health plan or an entity providing
7 pharmacy benefit management services on
8 under such health plan or health insurance cov-
9 erage to remit bona fide service fees to plan
10 sponsors to the group health plan; or

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

15 “(e) ENFORCEMENT.—

16 “(1) IN GENERAL.—The Secretary shall enforce
17 this section.

18 “(2) VIOLATIONS.—A group health plan, a
19 health insurance issuer, or an entity providing phar-
20 macy benefit management services that violates sub-
21 section (a); an entity providing pharmacy benefit
22 management services that fails to provide informa-
23 tion required under subsection (b); a group health
24 plan, health insurance issuer, or entity providing
25 pharmacy benefit management services that violates

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

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

17 “(4) PROCEDURE.—The Secretary shall impose
18 civil monetary penalties under this subsection in the
19 same manner and according to the same procedures
20 as the Secretary imposes civil monetary penalties as
21 described in section 502(c)(10).

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

1 has made a good-faith effort to comply with this sec-
2 tion.

3 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed to permit a health insurance issuer,
5 group health plan, or other entity to restrict disclosure to,
6 or otherwise limit the access of, the Secretary of Labor
7 to a report described in subsection (b)(1) or information
8 related to compliance with subsections (a), (b), (c), or (d)
9 by such issuer, plan, or entity.

10 “(g) DEFINITIONS.—In this section—

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

12 “(A) an applicable group purchasing orga-
13 nization, drug manufacturer, distributor, whole-
14 saler, rebate aggregator (or other purchasing
15 entity designed to aggregate rebates), or associ-
16 ated 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 the Treasury may specify
2 through rulemaking;

3 “(2) the term ‘applicable group purchasing or-
4 ganization’ means a group purchasing organization
5 that is affiliated with or under common ownership
6 with an entity providing pharmacy benefit manage-
7 ment services;

8 “(3) the term ‘covered group health insurance
9 coverage’ means health insurance coverage offered in
10 connection with a group health plan maintained by
11 a large employer;

12 “(4) the term ‘covered group health plan’
13 means a group health plan maintained by a large
14 employer;

15 “(5) the term ‘gross 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 be-
20 fore the application of rebates, fees, alternative dis-
21 counts, or other remuneration;

22 “(6) the term ‘large 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 50 employees on busi-

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

4 “(7) the term ‘net spending’, with respect to
5 prescription drug benefits under a group health plan
6 or health insurance coverage, means the amount
7 spent by a group health plan or health insurance
8 issuer on prescription drug benefits, calculated after
9 the application of rebates, fees, alternative discounts,
10 or other remuneration;

11 “(8) the term ‘plan sponsor’ has the meaning
12 given such term in section 3(16)(B);

13 “(9) the term ‘remuneration’ has the meaning
14 given such term by the Secretary, the Secretary of
15 Health and Human Services, and the Secretary of
16 the Treasury, through rulemaking and reevaluated
17 by such Secretaries every 5 years;

18 “(10) the term ‘small employer’ means, in con-
19 nection with a group health plan with respect to a
20 calendar year and a plan year, an employer who em-
21 ployed an average of at least 1 but not more than
22 49 employees on business days during the preceding
23 calendar year and who employs at least 1 employee
24 on the first day of the plan year; and

1 (1) IN GENERAL.—Subchapter B of chapter
2 100 of the Internal Revenue Code of 1986 is amend-
3 ed by 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 enact-
8 ment of the Pharmacy Benefit Manager Reform Act, a
9 group health plan or an entity providing pharmacy benefit
10 management services on behalf of such a plan shall not
11 enter into a contract with an applicable entity unless such
12 applicable 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
17 the reports described in subsection (b); and

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

22 “(b) REPORTS.—

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

1 form Act, not less frequently than annually, an enti-
2 ty providing pharmacy benefit management services
3 on behalf of a covered group health plan shall sub-
4 mit to the plan sponsor of such covered group health
5 plan a report in accordance with this subsection and
6 make such report available to the plan sponsor in
7 plain language, in a machine-readable format, and,
8 as the Secretary, the Secretary of Labor, and the
9 Secretary of Health and Human Services may deter-
10 mine, other formats. Each such report shall include,
11 with respect 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 the drug manufacturer with respect
17 to the participants and beneficiaries in such
18 plan;

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

1 “(i) the brand name, generic or non-
2 proprietary name, and National Drug
3 Code;

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

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

16 “(iv) the wholesale acquisition cost,
17 listed as cost per days supply and cost per
18 dosage unit;

19 “(v) the total out-of-pocket spending
20 by participants and beneficiaries on such
21 drug after application of any benefits
22 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
4 or for which no claim is submitted to
5 the plan; and

6 “(vi) for each of the 50 prescription
7 drugs with the highest gross spending
8 under the group health plan during the re-
9 porting period—

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

20 “(II) if applicable, the rationale
21 for preferred formulary placement of
22 such drug in that therapeutic class,
23 selected from a list of standard ra-
24 tionales established by the Secretary,
25 the Secretary of Labor, and the Sec-

1 retary of Health and Human Services,
2 in consultation with stakeholders; and

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

6 “(C) a list of each therapeutic class of
7 drugs for which a claim was filed under the
8 health plan during the reporting period, and,
9 with respect to each such therapeutic class of
10 drugs, during the reporting period—

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

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 applicable entities, in rebates,
7 fees, alternative discounts, or other
8 remuneration—

9 “(aa) for claims incurred
10 during the reporting period; or

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

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

16 “(III) the average net spending
17 per 30-day supply and per 90-day
18 supply by the health plan and its par-
19 ticipants and beneficiaries, among all
20 drugs within the therapeutic class for
21 which a claim was filed during the re-
22 porting period;

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

1 “(E) the total amount received, or ex-
2 pected to be received, by the health plan, from
3 applicable entities, in rebates, fees, alternative
4 discounts, and other remuneration received
5 from any such entities, related to utilization of
6 drug or drug spending under that health plan
7 during the reporting period;

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

11 “(G) amounts paid directly or indirectly in
12 rebates, fees, or any other type of compensation
13 (as defined in section 408(b)(2)(B)(ii)(dd)(AA)
14 of the Employee Retirement Income Security
15 Act of 1974 (29 U.S.C.
16 1108(b)(2)(B)(ii)(dd)(A))) to brokers, consult-
17 ants, advisors, or any other individual or firm
18 for referral of the group health plan’s business
19 to the pharmacy benefit manager, consideration
20 of the entity providing pharmacy benefit man-
21 agement services by the group health plan, or
22 the retention of the entity by the group health
23 plan;

24 “(H)(i) an explanation of any benefit de-
25 sign parameters that encourage or require par-

1 participants and beneficiaries in the plan to fill
2 prescriptions at mail order, specialty, or retail
3 pharmacies that are affiliated with or under
4 common ownership with the entity providing
5 pharmacy benefit management services under
6 such plan, including mandatory mail and spe-
7 cialty home delivery programs, retail and mail
8 auto-refill programs, and cost-sharing assist-
9 ance incentives funded by an entity providing
10 pharmacy benefit management services;

11 “(ii) the percentage of total prescriptions
12 charged to the plan or participants and bene-
13 ficiaries in the plan, that were dispensed by
14 mail order, specialty, or retail pharmacies that
15 are affiliated with or under common ownership
16 with the entity providing pharmacy benefit
17 management services; and

18 “(iii) a list of all drugs dispensed by such
19 affiliated pharmacy or pharmacy under common
20 ownership and charged to the plan, or partici-
21 pants and beneficiaries of the plan, during the
22 applicable period, and, with respect to each
23 drug—

24 “(I)(aa) the amount charged, per dos-
25 age unit, per 30-day supply, and per 90-

1 day supply, with respect to participants
2 and beneficiaries in the plan, to the plan;
3 and

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

7 “(II) the median amount charged to
8 the plan, per dosage unit, per 30-day sup-
9 ply, and per 90-day supply, including
10 amounts paid by the participants and
11 beneficiaries, when the same drug is dis-
12 pensed by other pharmacies that are not
13 affiliated with or under common ownership
14 with the entity and that are included in the
15 pharmacy network of that plan;

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

1 “(IV) the lowest cost, per dosage unit,
2 per 30-day supply, and per 90-day supply,
3 for such drug, including amounts charged
4 to the plan and participants and bene-
5 ficiaries, that is available from any phar-
6 macy included in the network of the plan
7 ;

8 “(V) the net acquisition cost per dos-
9 age unit, per 30-day supply, and per 90-
10 day supply, if the drug is subject to a max-
11 imum price discount; and

12 “(VI) other information with respect
13 to the cost of the drug, as determined by
14 the Secretary, such as average sales price,
15 wholesale acquisition cost, and national av-
16 erage drug acquisition cost per dosage unit
17 or per 30-day supply, for such drug, in-
18 cluding amounts charged to the plan and
19 participants and beneficiaries among all
20 pharmacies included in the network of the
21 plan;

22 “(I) a summary document for plan spon-
23 sors that includes such information described in
24 subparagraphs (A) through (H) as the Sec-
25 retary, the Secretary of Labor, and the Sec-

1 retary of the Treasury determines useful for
2 plan sponsors for purposes of selecting phar-
3 macy benefit management services, such as an
4 estimated net price to plan sponsor and partici-
5 pant or beneficiary, a cost per claim, the fee
6 structure or reimbursement model, and esti-
7 mated cost per participant or beneficiary; and

8 “(J) a summary document for participants
9 or beneficiaries, which shall be made available
10 to participants or beneficiaries upon request to
11 the plan sponsor, that contains such informa-
12 tion described in subparagraphs (D) through
13 (G) as the Secretary determines useful for par-
14 ticipants or beneficiaries in better under-
15 standing their plan or benefits, except that such
16 summary document for participants or bene-
17 ficiaries shall contain only aggregate informa-
18 tion.

19 “(2) REGULATIONS.—Not later than 2 years
20 after the date of enactment of the Pharmacy Benefit
21 Manager Reform Act, the Secretary, the Secretary
22 of Labor, and the Secretary of Health and Human
23 Services shall, through notice and comment rule-
24 making, promulgate final regulations final regula-
25 tions to implement the requirements of this sub-

1 section. In promulgating such regulations, the Sec-
2 retary, the Secretary of Labor, and the Secretary of
3 the Treasury shall, to the extent practicable, align
4 the reporting requirements under this subsection
5 with the reporting requirements under section 9825.

6 “(3) ADDITIONAL REPORTING.—For plan years
7 beginning on or after the date that is 30 months
8 after the date of enactment of the Pharmacy Benefit
9 Manager Reform Act, not less frequently than annu-
10 ally, an entity providing pharmacy benefit manage-
11 ment services on behalf of a group health plan that
12 is not a covered group health plan shall submit to
13 the plan sponsor of such group health plan a report
14 in accordance with this paragraph, and make such
15 report available to the plan sponsor in a machine-
16 readable format, and such other formats as the Sec-
17 retary, the Secretary of Health and Human Services,
18 and the Secretary of the Treasury may determine.
19 Each such report shall include, with respect to the
20 applicable group health plan—

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

23 “(B) as applicable, information collected
24 from drug manufacturers by such plan on the
25 total amount of copayment assistance dollars

1 paid, or copayment cards applied, that were
2 funded by applicable drug manufacturers with
3 respect to the participants and beneficiaries in
4 such plan, except that such information shall
5 not identify any drug manufacturer; and

6 “(C) a summary document that includes
7 such information described in subparagraphs
8 (A) and (B) as the Secretary determines useful
9 for plan sponsors for purposes of selecting
10 pharmacy benefit management services, pro-
11 vided that such summary documents include
12 only aggregate information.

13 “(4) PRIVACY REQUIREMENTS.—

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

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

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

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

5 “(i) REASONABLE RESTRICTIONS.—

6 Nothing in this section prevents an entity
7 providing pharmacy benefit management
8 services on behalf of a group health plan
9 from placing reasonable restrictions (as the
10 Secretary, the Secretary of Labor, and the
11 Secretary of Health and Human Services
12 may determine) on the public disclosure of
13 the information contained in a report
14 under paragraph (1) or (3).

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

1 plicable law, or to the Comptroller General
2 of the United States in accordance with
3 paragraph (6).

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

6 “(A) PROHIBITION.—A plan sponsor may
7 not—

8 “(i) fail or refuse to hire, or dis-
9 charge, any employee, or otherwise dis-
10 criminate against any employee with re-
11 spect to the compensation, terms, condi-
12 tions, or privileges of employment of the
13 employee, because of information sub-
14 mitted under paragraph (1) or (3) attrib-
15 uted to the employee or a dependent of the
16 employee; or

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

1 “(B) DISCLOSURE AND REDISCLOSURE.—

2 A plan sponsor shall not disclose the informa-
3 tion received under paragraph (1) or (3) ex-
4 cept—

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

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

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

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

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

16 “(D) WRITTEN NOTICE.—Plan sponsors of
17 group health plans shall provide to each em-
18 ployee written notice informing the employee of
19 the requirement for entities providing pharmacy
20 benefit management services to submit reports
21 to plan sponsors under paragraphs (1) and (3),
22 as applicable, which may include incorporating
23 such notification in plan documents provided to
24 the employee, an employee handbook provided
25 to the employee, or individual notification.

1 “(E) 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 reme-
20 dies 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 “(6) SUBMISSIONS TO GAO.—An entity pro-
25 viding pharmacy benefit management services on be-

1 half of a group health plan shall submit, upon re-
2 quest, to the Comptroller General of the United
3 States each of the first 2 reports submitted to a
4 plan sponsor under paragraph (1) or (3) with re-
5 spect to such plan, and other such reports as re-
6 quested, in accordance with the privacy requirements
7 under paragraph (4), and such other information
8 that the Comptroller General determines necessary
9 to carry out the study under section 2(f) of the
10 Pharmacy Benefit Manager Reform Act.

11 “(7) STANDARD FORMATS.—

12 “(A) IN GENERAL.—Not later than June
13 1, 2024, the Secretary, the Secretary of Health
14 and Human Services, and the Secretary of
15 Labor shall specify, through rulemaking, stand-
16 ard formats for entities providing pharmacy
17 benefit management services to submit reports
18 required under this subsection.

19 “(B) FORM.—The Secretary, the Secretary
20 of Health and Human Services, and the Sec-
21 retary of Labor shall define through rulemaking
22 a form of the reports under paragraphs (1) and
23 (3) required to be submitted to plan sponsors
24 who also are drug manufacturers, drug whole-
25 salers, entities providing pharmacy benefit man-

1 agement services, or other direct participants in
2 the drug supply chain, in the case that such
3 secretaries determine that changes to the stand-
4 ard format are necessary to prevent anti-
5 competitive behavior.

6 “(c) LIMITATIONS ON SPREAD PRICING.—

7 “(1) IN GENERAL.—For plan years beginning
8 on or after the date that is 30 months after the date
9 of enactment of the Pharmacy Benefit Manager Re-
10 form Act, a group health plan shall ensure that the
11 amount required to be paid by a participant or bene-
12 ficiary for a prescription drug covered under the
13 plan, and an entity providing pharmacy benefit man-
14 agement services on behalf of such a plan shall en-
15 sure that the total amount required to be paid by
16 the plan or issuer and participant or beneficiary for
17 a prescription drug covered under the plan, does not
18 exceed the price paid to the pharmacy, excluding
19 penalties paid by the pharmacy (as described in
20 paragraph (2)) to such plan or entity.

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

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

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

21 “(A) the rebates fees, alternative dis-
22 counts, and other remuneration under para-
23 graph (1)(A) shall be—

24 “(i) remitted—

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

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

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

13 “(iii) returned to the entity providing
14 pharmacy benefit management services on
15 behalf of the group health plan if an audit
16 by a plan sponsor, or a third party des-
17 ignated by a plan sponsor, indicates that
18 the amounts received are incorrect after
19 such amounts have been paid to the group
20 health plan;

21 “(B) the rebates fees, alternative dis-
22 counts, and other remuneration under para-
23 graph (1)(B) shall be remitted in accordance
24 with such procedures as the Secretary, Sec-

1 retary of Health and Human Services, and Sec-
2 retary of Labor establish; and

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

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

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

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

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

6 “(B) require a third-party administrator of
7 a group health plan or an entity providing
8 pharmacy benefit management services on
9 under such health plan to remit bona fide serv-
10 ice fees to plan sponsors to the group health
11 plan; or

12 “(C) limit the ability of a group health
13 plan to pass through rebates, fees, alternative
14 discounts, and other remuneration to the partic-
15 ipant or beneficiary.

16 “(e) ENFORCEMENT.—

17 “(1) IN GENERAL.—The Secretary shall enforce
18 this section.

19 “(2) VIOLATIONS.—A group health plan or an
20 entity providing pharmacy benefit management serv-
21 ices that violates subsection (a); an entity providing
22 pharmacy benefit management services that fails to
23 provide information required under subsection (b); a
24 group health plan or entity providing pharmacy ben-
25 efit management services that violates subsection

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

8 “(3) FALSE INFORMATION.—A group health
9 plan, an entity providing pharmacy benefit manage-
10 ment services, or a third-party administrator that
11 knowingly provides false information under this sec-
12 tion shall be subject to a civil money penalty in an
13 amount not to exceed \$100,000 for each item of
14 false information. Such civil money penalty shall be
15 in addition to other penalties as may be prescribed
16 by law.

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

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

7 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion shall be construed to permit a group health plan or
9 other entity to restrict disclosure to, or otherwise limit the
10 access of, the Department of Labor to a report described
11 in subsection (b)(1) or information related to compliance
12 with subsections (a), (b), (c), or (d) by such plan or entity.

13 “(g) DEFINITIONS.—In this section—

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

15 “(A) an applicable group purchasing orga-
16 nization, drug manufacturer, distributor, whole-
17 saler, rebate aggregator (or other purchasing
18 entity designed to aggregate rebates), or associ-
19 ated third party;

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

1 “(C) such other entity as the Secretary,
2 the Secretary of Health and Human Services,
3 and the Secretary of Labor may specify through
4 rulemaking;

5 “(2) the term ‘applicable group purchasing or-
6 ganization’ means a group purchasing organization
7 that is affiliated with or under common ownership
8 with an entity providing pharmacy benefit manage-
9 ment services;

10 “(3) the term ‘covered group health plan’
11 means a group health plan maintained by a large
12 employer;

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

20 “(5) the term ‘large employer’ means, in con-
21 nection with a group health plan with respect to a
22 calendar 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
4 prescription drug benefits under a group health plan
5 or health insurance coverage, means the amount
6 spent by a group health plan or health insurance
7 issuer on prescription drug benefits, calculated after
8 the application of rebates, fees, alternative discounts,
9 or other remuneration;

10 “(7) the term ‘plan sponsor’ has the meaning
11 given such term in section 3(16)(B) of the Employee
12 Retirement Income Security Act of 1974 (29 U.S.C.
13 1002(16)(B));

14 “(8) the term ‘remuneration’ has the meaning
15 given such term by the Secretary, the Secretary of
16 Labor, and the Secretary of Health and Human
17 Services, through rulemaking and reevaluated by
18 such Secretaries every 5 years;

19 “(9) the term ‘small employer’ means, in con-
20 nection with a group health plan with respect to a
21 calendar year and a plan year, an employer who em-
22 ployed an average of at least 1 but not more than
23 49 employees on business days during the preceding
24 calendar year and who employs at least 1 employee
25 on the first day of the plan year; 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
4 U.S.C. 1395w–3a(c)(6)(B)).”.

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

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

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

12 “(d) ENTITIES PROVIDING PHARMACY BENEFIT
13 MANAGEMENT SERVICES.—Beginning 2 years after the
14 date of enactment of the Pharmacy Benefit Manager Re-
15 form Act, entities providing pharmacy benefit manage-
16 ment services shall report to plan sponsors of group health
17 plans information required under paragraphs (4), (5), (6),
18 (7)(A)(iii), and (7)(B) of subsection (a).”.

19 (d) FUNDING.—

20 (1) For purposes of carrying out the amend-
21 ments made by subsection (a) there are appropriated
22 to the Centers for Medicare & Medicaid Services, out
23 of amounts in the Treasury not otherwise appro-

1 appropriated, \$40,000,000 for fiscal year 2023, to remain
2 available until expended.

3 (2) For purposes of carrying out the amend-
4 ments made by subsection (b), there are appro-
5 priated to the Department of Labor, out of amounts
6 in the Treasury not otherwise appropriated,
7 \$4,500,000 for fiscal year 2023, to remain available
8 until expended.

9 (e) ASPE STUDY.—The Assistant Secretary for
10 Planning and Evaluation of the Department of Health and
11 Human Services shall conduct or commission a study on
12 how the United States health care market would be im-
13 pacted by potential regulatory changes disallowing manu-
14 facturer rebates in the manner and to the extent allowed
15 on the date of enactment of this Act, with a focus on the
16 impact to stakeholders in the commercial insurance mar-
17 ket, and, not later than 1 year after the date of enactment
18 of this Act, submit a report to Congress on the results
19 of such study. Such study and report shall consider the
20 following:

21 (1) The impact of making no such regulatory
22 changes, as well as potential behavioral changes by
23 plan sponsors, members, and pharmaceutical manu-
24 facturers, such as tighter formularies, changes to

1 price concessions, changes in utilization, if such reg-
2 ulatory changes are made.

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

6 (3) The feasibility of a partial point-of-sale
7 manufacturer rebate versus a full point-of-sale man-
8 ufacturer rebate.

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

11 (5) Possible behavioral changes by other third
12 parties in the pharmaceutical supply chain including
13 drug manufacturers, distributors, wholesalers, rebate
14 aggregators, pharmacy services administrative orga-
15 nizations, or group purchasing organizations.

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

19 (7) Alternative price negotiation mechanisms,
20 including the impact of the Act of June 19, 1936
21 (commonly known as the “Robinson–Patman Act”;
22 49 Stat. 1526, chapter 592; 15 U.S.C. 13a et seq.),
23 and the amendments made by that Act, on drug
24 pricing negotiations.

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

4 (9) The impact of manufacturer rebates on get-
5 ting insulin products to market, and the market dy-
6 namics and extent biosimilar biological product de-
7 velopment and competition could increase, or is in-
8 creasing, the number of biological products approved
9 and available to patients, including by examining
10 barriers to—

11 (A) placement of biosimilar biological prod-
12 ucts on health insurance formularies;

13 (B) market entry of insulin product in the
14 United States, as compared to other highly de-
15 veloped nations; and

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

18 (f) GAO STUDY.—

19 (1) IN GENERAL.—Not later than January 1,
20 2029, the Comptroller General of the United States
21 shall report to Congress on—

22 (A) pharmacy networks of a selection of
23 group health plans, health insurance issuers,
24 and entities providing pharmacy benefit man-
25 agement services under such group health plan

1 or group or individual health insurance cov-
2 erage, including networks that have pharmacies
3 that are affiliated with or in common ownership
4 with group health plans, health insurance
5 issuers, or entities providing pharmacy benefit
6 management services or pharmacy benefit ad-
7 ministrative services under group health plan or
8 group or individual health insurance coverage;

9 (B) as it relates to pharmacy networks
10 that include pharmacies affiliated with or in
11 common ownership with plans, issuers, or enti-
12 ties, as described in subparagraph (A)—

13 (i) whether such networks are de-
14 signed to encourage participants and bene-
15 ficiaries of a plan or coverage to use such
16 pharmacies over other network pharmacies
17 for specific services or drugs, and if so, the
18 reasons the networks give for encouraging
19 use of such pharmacies; and

20 (ii) whether such pharmacies are used
21 by participants and beneficiaries dispropor-
22 tionately more in the aggregate or for spe-
23 cific drugs compared to other network
24 pharmacies;

1 (C) whether group health plans and health
2 insurance issuers offering group health insur-
3 ance coverage have options to elect different
4 network pricing arrangements in the market-
5 place with entities that provide pharmacy ben-
6 efit management services, and the prevalence of
7 electing such different network pricing arrange-
8 ments among a selection of such plans and
9 issuers;

10 (D) pharmacy network design parameters
11 that encourage participants and beneficiaries in
12 the plan or coverage to fill prescriptions at mail
13 order, specialty, or retail pharmacies that are
14 wholly or partially-owned by that issuer or enti-
15 ty; and

16 (E) for a selection of plans and issuers, the
17 degree to which mail order, specialty, or retail
18 pharmacies that dispense prescription drugs to
19 participants and beneficiaries in a group health
20 plan or health insurance coverage that are af-
21 filiated with or in common ownership with
22 group health plans, health insurance issuers, or
23 entities providing pharmacy benefit manage-
24 ment services or pharmacy benefit administra-
25 tive services under group health plan or group

1 health insurance coverage receive reimburse-
2 ment that is greater than the median price
3 charged to the group health plan or health in-
4 surance issuer when the same drug is dispensed
5 to participants and beneficiaries in the plan or
6 coverage by other pharmacies included in the
7 pharmacy network of that plan or issuer that
8 are not affiliated with or in common ownership
9 with the health insurance issuer or entity pro-
10 viding pharmacy benefit management services.

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

14 (A) information that would allow for iden-
15 tification of a specific individual, plan sponsor,
16 health insurance issuer, plan, or entity pro-
17 viding pharmacy benefit management services;
18 or

19 (B) commercial or financial information
20 that is privileged or confidential.

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