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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Public Health Service Act, the Employee Retirement Income Security Act, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefits manager services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. KUSTER introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefits manager services, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmacy Benefits
5 Manager Accountability Act”.

1 **SEC. 2. OVERSIGHT OF PHARMACY BENEFITS MANAGER**
2 **SERVICES.**

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

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

7 **“SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFITS MAN-**
8 **AGER SERVICES.**

9 “(a) IN GENERAL.—For plan years beginning on or
10 after January 1, 2025, a group health plan or health in-
11 surance issuer offering group health insurance coverage
12 or an entity or subsidiary providing pharmacy benefits
13 management services on behalf of such a plan or issuer
14 shall not enter into a contract with a drug manufacturer,
15 distributor, wholesaler, subcontractor, rebate aggregator,
16 or any associated third party that limits the disclosure of
17 information to plan sponsors in such a manner that pre-
18 vents the plan or issuer, or an entity or subsidiary pro-
19 viding pharmacy benefits management services on behalf
20 of a plan or issuer, from making the reports described in
21 subsection (b).

22 “(b) REPORTS.—

23 “(1) IN GENERAL.—For plan years beginning
24 on or after January 1, 2025, not less frequently
25 than annually, a health insurance issuer offering
26 group health insurance coverage or an entity pro-

1 viding pharmacy benefits management services on
2 behalf of a group health plan or an issuer providing
3 group health insurance coverage shall submit to the
4 plan sponsor (as defined in section 3(16)(B) of the
5 Employee Retirement Income Security Act of 1974)
6 of such group health plan or health insurance cov-
7 erage a report in accordance with this subsection
8 and make such report available to the plan sponsor
9 in a machine-readable format. Each such report
10 shall include, with respect to the applicable group
11 health plan or health insurance coverage—

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

19 “(B) a list of each drug covered by such
20 plan, issuer, or entity providing pharmacy bene-
21 fits management services that was dispensed
22 during the reporting period, including, with re-
23 spect to each such drug during the reporting
24 period—

1 “(i) the brand name, chemical entity,
2 and National Drug Code;

3 “(ii) the number of participants and
4 beneficiaries for whom the drug was filled
5 during the plan year, the total number of
6 prescription fills for the drug (including
7 original prescriptions and refills), and the
8 total number of dosage units of the drug
9 dispensed across the plan year, including
10 whether the dispensing channel was by re-
11 tail, mail order, or specialty pharmacy;

12 “(iii) the wholesale acquisition cost,
13 listed as cost per days supply and cost per
14 pill, or in the case of a drug in another
15 form, per dose;

16 “(iv) the total out-of-pocket spending
17 by participants and beneficiaries on such
18 drug, including participant and beneficiary
19 spending through copayments, coinsurance,
20 and deductibles; and

21 “(v) for any drug for which gross
22 spending of the group health plan or
23 health insurance coverage exceeded
24 \$10,000 during the reporting period—

1 “(I) a list of all other drugs in
2 the same therapeutic category or
3 class, including brand name drugs
4 and biological products and generic
5 drugs or biosimilar biological products
6 that are in the same therapeutic cat-
7 egory or class as such drug; and

8 “(II) the rationale for preferred
9 formulary placement of such drug in
10 that therapeutic category or class, if
11 applicable;

12 “(C) a list of each therapeutic category or
13 class of drugs that were dispensed under the
14 health plan or health insurance coverage during
15 the reporting period, and, with respect to each
16 such therapeutic category or class of drugs,
17 during the reporting period—

18 “(i) total gross spending by the plan,
19 before manufacturer rebates, fees, or other
20 manufacturer remuneration;

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

24 “(iii) if applicable to that category or
25 class, a description of the formulary tiers

1 and utilization mechanisms (such as prior
2 authorization or step therapy) employed
3 for drugs in that category or class;

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

9 “(v) for each therapeutic category or
10 class under which 3 or more drugs are in-
11 cluded on the formulary of such plan or
12 coverage—

13 “(I) the amount received, or ex-
14 pected to be received, from drug man-
15 ufacturers in rebates, fees, alternative
16 discounts, or other remuneration—

17 “(aa) that has been paid, or
18 is to be paid, by drug manufac-
19 turers for claims incurred during
20 the reporting period; or

21 “(bb) that is related to utili-
22 zation of drugs, in such thera-
23 peutic category or class;

24 “(II) the total net spending, after
25 deducting rebates, price concessions,

1 alternative discounts or other remuneration from drug manufacturers, by
2 the health plan or health insurance coverage on that category or class of
3 drugs; and
4
5

6 “(III) the net price per course of treatment or single fill, such as a 30-
7 day supply or 90-day supply, incurred by the health plan or health insurance
8 coverage and its participants and beneficiaries, after manufacturer re-
9 bates, fees, and other remuneration for drugs dispensed within such thera-
10 peutic category or class during the reporting period;
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16 “(D) total gross spending on prescription drugs by the plan or coverage during the re-
17 porting period, before rebates and other manufacturer fees or remuneration;
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19

20 “(E) total amount received, or expected to be received, by the health plan or health insur-
21 ance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any
22 third party, other than the plan sponsor, re-
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1 lated to utilization of drug or drug spending
2 under that health plan or health insurance cov-
3 erage during the reporting period;

4 “(F) the total net spending on prescription
5 drugs by the health plan or health insurance
6 coverage during the reporting period; and

7 “(G) amounts paid directly or indirectly in
8 rebates, fees, or any other type of remuneration
9 to brokers, consultants, advisors, or any other
10 individual or firm who referred the group health
11 plan’s or health insurance issuer’s business to
12 the pharmacy benefits manager.

13 “(2) PRIVACY REQUIREMENTS.—Health insur-
14 ance issuers offering group health insurance cov-
15 erage and entities providing pharmacy benefits man-
16 agement services on behalf of a group health plan
17 shall provide information under paragraph (1) in a
18 manner consistent with the privacy, security, and
19 breach notification regulations promulgated under
20 section 264(c) of the Health Insurance Portability
21 and Accountability Act of 1996, and shall restrict
22 the use and disclosure of such information according
23 to such privacy regulations.

24 “(3) DISCLOSURE AND REDISCLOSURE.—

1 “(A) LIMITATION TO BUSINESS ASSOCI-
2 ATES.—A group health plan receiving a report
3 under paragraph (1) may disclose such informa-
4 tion only to business associates of such plan as
5 defined in section 160.103 of title 45, Code of
6 Federal Regulations (or successor regulations).

7 “(B) CLARIFICATION REGARDING PUBLIC
8 DISCLOSURE OF INFORMATION.—Nothing in
9 this section prevents a health insurance issuer
10 offering group health insurance coverage or an
11 entity providing pharmacy benefits management
12 services on behalf of a group health plan from
13 placing reasonable restrictions on the public dis-
14 closure of the information contained in a report
15 described in paragraph (1), except that such
16 issuer or entity may not restrict disclosure of
17 such report to the Department of Health and
18 Human Services, the Department of Labor, the
19 Department of the Treasury, the Comptroller
20 General of the United States, or applicable
21 State agencies.

22 “(C) LIMITED FORM OF REPORT.—The
23 Secretary shall define through rulemaking a
24 limited form of the report under paragraph (1)
25 required of plan sponsors who are drug manu-

1 facturers, drug wholesalers, or other direct par-
2 ticipants in the drug supply chain, in order to
3 prevent anti-competitive behavior.

4 “(4) REPORT TO GAO.—A health insurance
5 issuer offering group health insurance coverage or
6 an entity providing pharmacy benefits management
7 services on behalf of a group health plan shall sub-
8 mit to the Comptroller General of the United States
9 each of the first 4 reports submitted to a plan spon-
10 sor under paragraph (1) with respect to such cov-
11 erage or plan, and other such reports as requested,
12 in accordance with the privacy requirements under
13 paragraph (2), the disclosure and redisclosure stand-
14 ards under paragraph (3), the standards specified
15 pursuant to paragraph (5), and such other informa-
16 tion that the Comptroller General determines nec-
17 essary to carry out the study under section 2(d) of
18 the Pharmacy Benefits Manager Accountability Act.

19 “(5) STANDARD FORMAT.—Not later than June
20 1, 2023, the Secretary shall specify through rule-
21 making standards for health insurance issuers and
22 entities required to submit reports under paragraph
23 (4) to submit such reports in a standard format.

24 “(c) ENFORCEMENT.—

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

4 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
5 TION.—A health insurance issuer or an entity pro-
6 viding pharmacy benefits management services that
7 violates subsection (a) or fails to provide information
8 required under subsection (b) shall be subject to a
9 civil monetary penalty in the amount of \$10,000 for
10 each day during which such violation continues or
11 such information is not disclosed or reported.

12 “(3) FALSE INFORMATION.—A health insurance
13 issuer or entity providing pharmacy benefits man-
14 agement services that knowingly provides false infor-
15 mation under this section shall be subject to a civil
16 money penalty in an amount not to exceed \$100,000
17 for each item of false information. Such civil money
18 penalty shall be in addition to other penalties as
19 may be prescribed by law.

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

1 or proceeding under section 1128A of the Social Se-
2 curity Act.

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

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

16 “(e) DEFINITION.—In this section, the term ‘whole-
17 sale acquisition cost’ has the meaning given such term in
18 section 1847A(c)(6)(B) of the Social Security Act.”; and

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

20 (A) in subsection (a)—

21 (i) in paragraph (1), by inserting
22 “(other than subsections (a) and (b) of
23 section 2799A-11)” after “part D”; and

1 (ii) in paragraph (2), by inserting
2 “(other than subsections (a) and (b) of
3 section 2799A–11)” after “part D”; and
4 (B) in subsection (b)—

5 (i) in paragraph (1), by inserting
6 “(other than subsections (a) and (b) of
7 section 2799A–11)” after “part D”;

8 (ii) in paragraph (2)(A), by inserting
9 “(other than subsections (a) and (b) of
10 section 2799A–11)” after “part D”; and

11 (iii) in paragraph (2)(C)(ii), by insert-
12 ing “(other than subsections (a) and (b) of
13 section 2799A–11)” after “part D”.

14 (b) ERISA.—

15 (1) IN GENERAL.—Subtitle B of title I of the
16 Employee Retirement Income Security Act of 1974
17 (29 U.S.C. 1021 et seq.) is amended—

18 (A) in subpart B of part 7 (29 U.S.C.
19 1185 et seq.), by adding at the end the fol-
20 lowing:

21 **“SEC. 726. OVERSIGHT OF PHARMACY BENEFITS MANAGER**
22 **SERVICES.**

23 “(a) IN GENERAL.—For plan years beginning on or
24 after January 1, 2025, a group health plan (or health in-
25 surance issuer offering group health insurance coverage

1 in connection with such a plan) or an entity or subsidiary
2 providing pharmacy benefits management services on be-
3 half of such a plan or issuer shall not enter into a contract
4 with a drug manufacturer, distributor, wholesaler, subcon-
5 tractor, rebate aggregator, or any associated third party
6 that limits the disclosure of information to plan sponsors
7 in such a manner that prevents the plan or issuer, or an
8 entity or subsidiary providing pharmacy benefits manage-
9 ment services on behalf of a plan or issuer, from making
10 the reports described in subsection (b).

11 “(b) REPORTS.—

12 “(1) IN GENERAL.—For plan years beginning
13 on or after January 1, 2025, not less frequently
14 than annually, a health insurance issuer offering
15 group health insurance coverage or an entity pro-
16 viding pharmacy benefits management services on
17 behalf of a group health plan or an issuer providing
18 group health insurance coverage shall submit to the
19 plan sponsor (as defined in section 3(16)(B)) of
20 such group health plan or group health insurance
21 coverage a report in accordance with this subsection
22 and make such report available to the plan sponsor
23 in a machine-readable format. Each such report
24 shall include, with respect to the applicable group
25 health plan or health insurance coverage—

1 “(A) as applicable, information collected
2 from drug manufacturers by such issuer or en-
3 tity on the total amount of copayment assist-
4 ance dollars paid, or copayment cards applied,
5 that were funded by the drug manufacturer
6 with respect to the participants and bene-
7 ficiaries in such plan or coverage;

8 “(B) a list of each drug covered by such
9 plan, issuer, or entity providing pharmacy bene-
10 fits management services that was dispensed
11 during the reporting period, including, with re-
12 spect to each such drug during the reporting
13 period—

14 “(i) the brand name, chemical entity,
15 and National Drug Code;

16 “(ii) the number of participants and
17 beneficiaries for whom the drug was filled
18 during the plan year, the total number of
19 prescription fills for the drug (including
20 original prescriptions and refills), and the
21 total number of dosage units of the drug
22 dispensed across the plan year, including
23 whether the dispensing channel was by re-
24 tail, mail order, or specialty pharmacy;

1 “(iii) the wholesale acquisition cost,
2 listed as cost per days supply and cost per
3 pill, or in the case of a drug in another
4 form, per dose;

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

10 “(v) for any drug for which gross
11 spending of the group health plan or
12 health insurance coverage exceeded
13 \$10,000 during the reporting period—

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

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

1 “(C) a list of each therapeutic category or
2 class of drugs that were dispensed under the
3 health plan or health insurance coverage during
4 the reporting period, and, with respect to each
5 such therapeutic category or class of drugs,
6 during the reporting period—

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

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

13 “(iii) if applicable to that category or
14 class, a description of the formulary tiers
15 and utilization mechanisms (such as prior
16 authorization or step therapy) employed
17 for drugs in that category or class;

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

23 “(v) for each therapeutic category or
24 class under which 3 or more drugs are in-

1 cluded on the formulary of such plan or
2 coverage—

3 “(I) the amount received, or ex-
4 pected to be received, from drug man-
5 ufacturers in rebates, fees, alternative
6 discounts, or other remuneration—

7 “(aa) that has been paid, or
8 is to be paid, by drug manufac-
9 turers for claims incurred during
10 the reporting period; or

11 “(bb) that is related to utili-
12 zation of drugs, in such thera-
13 peutic category or class;

14 “(II) the total net spending, after
15 deducting rebates, price concessions,
16 alternative discounts or other remu-
17 neration from drug manufacturers, by
18 the health plan or health insurance
19 coverage on that category or class of
20 drugs; and

21 “(III) the net price per course of
22 treatment or single fill, such as a 30-
23 day supply or 90-day supply, incurred
24 by the health plan or health insurance
25 coverage and its participants and

1 beneficiaries, after manufacturer re-
2 bates, fees, and other remuneration
3 for drugs dispensed within such thera-
4 peutic category or class during the re-
5 porting period;

6 “(D) total gross spending on prescription
7 drugs by the plan or coverage during the re-
8 porting period, before rebates and other manu-
9 facturer fees or remuneration;

10 “(E) total amount received, or expected to
11 be received, by the health plan or health insur-
12 ance coverage in drug manufacturer rebates,
13 fees, alternative discounts, and all other remu-
14 neration received from the manufacturer or any
15 third party, other than the plan sponsor, re-
16 lated to utilization of drug or drug spending
17 under that health plan or health insurance cov-
18 erage 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; and

22 “(G) amounts paid directly or indirectly in
23 rebates, fees, or any other type of remuneration
24 to brokers, consultants, advisors, or any other
25 individual or firm who referred the group health

1 plan’s or health insurance issuer’s business to
2 the pharmacy benefits manager.

3 “(2) PRIVACY REQUIREMENTS.—Health insur-
4 ance issuers offering group health insurance cov-
5 erage and entities providing pharmacy benefits man-
6 agement services on behalf of a group health plan
7 shall provide information under paragraph (1) in a
8 manner consistent with the privacy, security, and
9 breach notification regulations promulgated under
10 section 264(c) of the Health Insurance Portability
11 and Accountability Act of 1996, and shall restrict
12 the use and disclosure of such information according
13 to such privacy regulations.

14 “(3) DISCLOSURE AND REDISCLOSURE.—

15 “(A) LIMITATION TO BUSINESS ASSOCI-
16 ATES.—A group health plan receiving a report
17 under paragraph (1) may disclose such informa-
18 tion only to business associates of such plan as
19 defined in section 160.103 of title 45, Code of
20 Federal Regulations (or successor regulations).

21 “(B) CLARIFICATION REGARDING PUBLIC
22 DISCLOSURE OF INFORMATION.—Nothing in
23 this section prevents a health insurance issuer
24 offering group health insurance coverage or an
25 entity providing pharmacy benefits management

1 services on behalf of a group health plan from
2 placing reasonable restrictions on the public dis-
3 closure of the information contained in a report
4 described in paragraph (1), except that such
5 issuer or entity may not restrict disclosure of
6 such report to the Department of Health and
7 Human Services, the Department of Labor, the
8 Department of the Treasury, the Comptroller
9 General of the United States, or applicable
10 State agencies.

11 “(C) LIMITED FORM OF REPORT.—The
12 Secretary shall define through rulemaking a
13 limited form of the report under paragraph (1)
14 required of plan sponsors who are drug manu-
15 facturers, drug wholesalers, or other direct par-
16 ticipants in the drug supply chain, in order to
17 prevent anti-competitive behavior.

18 “(4) REPORT TO GAO.—A health insurance
19 issuer offering group health insurance coverage or
20 an entity providing pharmacy benefits management
21 services on behalf of a group health plan shall sub-
22 mit to the Comptroller General of the United States
23 each of the first 4 reports submitted to a plan spon-
24 sor under paragraph (1) with respect to such cov-
25 erage or plan, and other such reports as requested,

1 in accordance with the privacy requirements under
2 paragraph (2), the disclosure and redisclosure stand-
3 ards under paragraph (3), the standards specified
4 pursuant to paragraph (5), and such other informa-
5 tion that the Comptroller General determines nec-
6 essary to carry out the study under section 2(d) of
7 the Pharmacy Benefits Manager Accountability Act.

8 “(5) STANDARD FORMAT.—Not later than June
9 1, 2023, the Secretary shall specify through rule-
10 making standards for health insurance issuers and
11 entities required to submit reports under paragraph
12 (4) to submit such reports in a standard format.

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

20 “(d) DEFINITION.—In this section, the term ‘whole-
21 sale acquisition cost’ has the meaning given such term in
22 section 1847A(c)(6)(B) of the Social Security Act.”; and

23 (B) in section 502 (29 U.S.C. 1132)—

24 (i) in subsection (a)—

1 (I) in paragraph (6), by striking
2 “or (9)” and inserting “(9), or (13)”;

3 (II) in paragraph (10), by strik-
4 ing at the end “or”;

5 (III) in paragraph (11), at the
6 end by striking the period and insert-
7 ing “; or”; and

8 (IV) by adding at the end the fol-
9 lowing new paragraph:

10 “(12) by the Secretary, in consultation with the
11 Secretary of Health and Human Services, and the
12 Secretary of the Treasury, to enforce section 726.”;

13 (ii) in subsection (b)(3), by inserting
14 “and subsections (a)(12) and (c)(13)” be-
15 fore “, the Secretary is not”; and

16 (iii) in subsection (c), by adding at
17 the end the following new paragraph:

18 “(13) SECRETARIAL ENFORCEMENT AUTHORITY
19 RELATING TO OVERSIGHT OF PHARMACY BENEFITS
20 MANAGER SERVICES.—

21 “(A) FAILURE TO PROVIDE TIMELY INFOR-
22 MATION.—The Secretary, in consultation with
23 the Secretary of Health and Human Services
24 and the Secretary of the Treasury, may impose
25 a penalty against any health insurance issuer or

1 entity providing pharmacy benefits management
2 services that violates section 726(a) or fails to
3 provide information required under section
4 726(b) in the amount of \$10,000 for each day
5 during which such violation continues or such
6 information is not disclosed or reported.

7 “(B) FALSE INFORMATION.—The Sec-
8 retary, in consultation with the Secretary of
9 Health and Human Services and the Secretary
10 of the Treasury, may impose a penalty against
11 a health insurance issuer or entity providing
12 pharmacy benefits management services that
13 knowingly provides false information under sec-
14 tion 726 in an amount not to exceed \$100,000
15 for each item of false information. Such penalty
16 shall be in addition to other penalties as may
17 be prescribed by law.

18 “(C) WAIVERS.—The Secretary may waive
19 penalties under subparagraph (A), or extend
20 the period of time for compliance with a re-
21 quirement of section 726, for an entity in viola-
22 tion of such section that has made a good-faith
23 effort to comply with such section.”.

24 (2) CLERICAL AMENDMENT.—The table of con-
25 tents in section 1 of the Employee Retirement In-

1 plan shall submit to the plan sponsor (as defined in
2 section 3(16)(B) of the Employee Retirement In-
3 come Security Act of 1974) of such group health
4 plan a report in accordance with this subsection and
5 make such report available to the plan sponsor in a
6 machine-readable format. Each such report shall in-
7 clude, with respect to the applicable group health
8 plan—

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

16 “(B) a list of each drug covered by such
17 plan or entity providing pharmacy benefits
18 management services that was dispensed during
19 the reporting period, including, with respect to
20 each such drug during the reporting period—

21 “(i) the brand name, chemical entity,
22 and National Drug Code;

23 “(ii) the number of participants and
24 beneficiaries for whom the drug was filled
25 during the plan year, the total number of

1 prescription fills for the drug (including
2 original prescriptions and refills), and the
3 total number of dosage units of the drug
4 dispensed across the plan year, including
5 whether the dispensing channel was by re-
6 tail, mail order, or specialty pharmacy;

7 “(iii) the wholesale acquisition cost,
8 listed as cost per days supply and cost per
9 pill, or in the case of a drug in another
10 form, per dose;

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

16 “(v) for any drug for which gross
17 spending of the group health plan exceeded
18 \$10,000 during the reporting period—

19 “(I) a list of all other drugs in
20 the same therapeutic category or
21 class, including brand name drugs
22 and biological products and generic
23 drugs or biosimilar biological products
24 that are in the same therapeutic cat-
25 egory or class as such drug; and

1 “(II) the rationale for preferred
2 formulary placement of such drug in
3 that therapeutic category or class, if
4 applicable;

5 “(C) a list of each therapeutic category or
6 class of drugs that were dispensed under the
7 health plan during the reporting period, and,
8 with respect to each such therapeutic category
9 or class of drugs, during the reporting period—

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

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

16 “(iii) if applicable to that category or
17 class, a description of the formulary tiers
18 and utilization mechanisms (such as prior
19 authorization or step therapy) employed
20 for drugs in that category or class;

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

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

4 “(I) the amount received, or ex-
5 pected to be received, from drug man-
6 ufacturers in rebates, fees, alternative
7 discounts, or other remuneration—

8 “(aa) that has been paid, or
9 is to be paid, by drug manufac-
10 turers for claims incurred during
11 the reporting period; or

12 “(bb) that is related to utili-
13 zation of drugs, in such thera-
14 peutic category or class;

15 “(II) the total net spending, after
16 deducting rebates, price concessions,
17 alternative discounts or other remu-
18 neration from drug manufacturers, by
19 the health plan on that category or
20 class of drugs; and

21 “(III) the net price per course of
22 treatment or single fill, such as a 30-
23 day supply or 90-day supply, incurred
24 by the health plan and its participants
25 and beneficiaries, after manufacturer

1 rebates, fees, and other remuneration
2 for drugs dispensed within such thera-
3 peutic category or class during the re-
4 porting period;

5 “(D) total gross spending on prescription
6 drugs by the plan during the reporting period,
7 before rebates and other manufacturer fees or
8 remuneration;

9 “(E) total amount received, or expected to
10 be received, by the health plan in drug manu-
11 facturer rebates, fees, alternative discounts, and
12 all other remuneration received from the manu-
13 facturer or any third party, other than the plan
14 sponsor, related to utilization of drug or drug
15 spending under that health plan during the re-
16 porting period;

17 “(F) the total net spending on prescription
18 drugs by the health plan during the reporting
19 period; and

20 “(G) amounts paid directly or indirectly in
21 rebates, fees, or any other type of remuneration
22 to brokers, consultants, advisors, or any other
23 individual or firm who referred the group health
24 plan’s business to the pharmacy benefits man-
25 ager.

1 “(2) PRIVACY REQUIREMENTS.—Entities pro-
2 viding pharmacy benefits management services on
3 behalf of a group health plan shall provide informa-
4 tion under paragraph (1) in a manner consistent
5 with the privacy, security, and breach notification
6 regulations promulgated under section 264(c) of the
7 Health Insurance Portability and Accountability Act
8 of 1996, and shall restrict the use and disclosure of
9 such information according to such privacy regula-
10 tions.

11 “(3) DISCLOSURE AND REDISCLOSURE.—

12 “(A) LIMITATION TO BUSINESS ASSOCI-
13 ATES.—A group health plan receiving a report
14 under paragraph (1) may disclose such informa-
15 tion only to business associates of such plan as
16 defined in section 160.103 of title 45, Code of
17 Federal Regulations (or successor regulations).

18 “(B) CLARIFICATION REGARDING PUBLIC
19 DISCLOSURE OF INFORMATION.—Nothing in
20 this section prevents an entity providing phar-
21 macy benefits management services on behalf of
22 a group health plan from placing reasonable re-
23 strictions on the public disclosure of the infor-
24 mation contained in a report described in para-
25 graph (1), except that such entity may not re-

1 strict disclosure of such report to the Depart-
2 ment of Health and Human Services, the De-
3 partment of Labor, the Department of the
4 Treasury, the Comptroller General of the
5 United States, or applicable State agencies.

6 “(C) LIMITED FORM OF REPORT.—The
7 Secretary shall define through rulemaking a
8 limited form of the report under paragraph (1)
9 required of plan sponsors who are drug manu-
10 facturers, drug wholesalers, or other direct par-
11 ticipants in the drug supply chain, in order to
12 prevent anti-competitive behavior.

13 “(4) REPORT TO GAO.—An entity providing
14 pharmacy benefits management services on behalf of
15 a group health plan shall submit to the Comptroller
16 General of the United States each of the first 4 re-
17 ports submitted to a plan sponsor under paragraph
18 (1) with respect to such plan, and other such reports
19 as requested, in accordance with the privacy require-
20 ments under paragraph (2), the disclosure and re-
21 disclosure standards under paragraph (3), the stand-
22 ards specified pursuant to paragraph (5), and such
23 other information that the Comptroller General de-
24 termines necessary to carry out the study under sec-

1 tion 2(d) of the Pharmacy Benefits Manager Ac-
2 countability Act.

3 “(5) STANDARD FORMAT.—Not later than June
4 1, 2023, the Secretary shall specify through rule-
5 making standards for entities required to submit re-
6 ports under paragraph (4) to submit such reports in
7 a standard format.

8 “(c) ENFORCEMENT.—

9 “(1) IN GENERAL.—The Secretary, in consulta-
10 tion with the Secretary of Labor and the Secretary
11 of Health and Human Services, shall enforce this
12 section.

13 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
14 TION.—An entity providing pharmacy benefits man-
15 agement services that violates subsection (a) or fails
16 to provide information required under subsection (b)
17 shall be subject to a civil monetary penalty in the
18 amount of \$10,000 for each day during which such
19 violation continues or such information is not dis-
20 closed or reported.

21 “(3) FALSE INFORMATION.—An entity pro-
22 viding pharmacy benefits management services that
23 knowingly provides false information under this sec-
24 tion shall be subject to a civil money penalty in an
25 amount not to exceed \$100,000 for each item of

1 false information. Such civil money penalty shall be
2 in addition to other penalties as may be prescribed
3 by law.

4 “(4) PROCEDURE.—The provisions of section
5 1128A of the Social Security Act, other than sub-
6 section (a) and (b) and the first sentence of sub-
7 section (c)(1) of such section shall apply to civil
8 monetary penalties under this subsection in the
9 same manner as such provisions apply to a penalty
10 or proceeding under section 1128A of the Social Se-
11 curity Act.

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

18 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
19 tion shall be construed to permit a group health plan or
20 other entity to restrict disclosure to, or otherwise limit the
21 access of, the Department of the Treasury to a report de-
22 scribed in subsection (b)(1) or information related to com-
23 pliance with subsection (a) by such plan or entity.

1 “(e) DEFINITION.—In this section, the term ‘whole-
2 sale acquisition cost’ has the meaning given such term in
3 section 1847A(c)(6)(B) of the Social Security Act.”.

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

“Sec. 9826. Oversight of pharmacy benefits manager services.”.

8 (d) GAO STUDY.—

9 (1) IN GENERAL.—Not later than 3 years after
10 the date of enactment of this Act, the Comptroller
11 General of the United States shall submit to Con-
12 gress a report on—

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

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

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

11 (ii) whether such pharmacies are used
12 by enrollees disproportionately more in the
13 aggregate or for specific services or drugs
14 compared to other network pharmacies;

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

23 (D) pharmacy network design parameters
24 that encourage enrollees in the plan or coverage
25 to fill prescriptions at mail order, specialty, or

1 retail pharmacies that are wholly or partially-
2 owned by that issuer or entity; and

3 (E) the degree to which mail order, spe-
4 cialty, or retail pharmacies that dispense pre-
5 scription drugs to an enrollee in a group health
6 plan or health insurance coverage that are
7 under common ownership (in whole or part)
8 with group health plans, health insurance
9 issuers, or entities providing pharmacy benefits
10 management services or pharmacy benefits ad-
11 ministrative services under group health plan or
12 group or individual health insurance coverage
13 receive reimbursement that is greater than the
14 median price charged to the group health plan
15 or health insurance issuer when the same drug
16 is dispensed to enrollees in the plan or coverage
17 by other pharmacies included in the pharmacy
18 network of that plan, issuer, or entity that are
19 not wholly or partially owned by the health in-
20 surance issuer or entity providing pharmacy
21 benefits management services.

22 (2) REQUIREMENT.—The Comptroller General
23 of the United States shall ensure that the report
24 under paragraph (1) does not contain information
25 that would allow a reader to identify a specific plan

1 or entity providing pharmacy benefits management
2 services or otherwise contain commercial or financial
3 information that is privileged or confidential.

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