

119TH CONGRESS
1ST SESSION

H. R. 2450

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefit management services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 27, 2025

Ms. McDONALD RIVET (for herself, Mr. CARTER of Georgia, Mr. MENENDEZ, and Mr. JAMES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefit management 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 “Prescription Drug
5 Transparency and Affordability Act”.

1 **SEC. 2. OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT**
2 **SERVICES.**

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

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

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

11 “(a) IN GENERAL.—For plan years beginning on or
12 after the date that is 30 months after the date of enact-
13 ment of this section (referred to in this subsection and
14 subsection (b) as the ‘effective date’), a group health plan
15 or a health insurance issuer offering group health insur-
16 ance coverage, or an entity providing pharmacy benefit
17 management services on behalf of such a plan or issuer,
18 shall not enter into a contract, including an extension or
19 renewal of a contract, entered into on or after the effective
20 date, with an applicable entity unless such applicable enti-
21 ty agrees to—

22 “(1) not limit or delay the disclosure of infor-
23 mation to the group health plan (including such a
24 plan offered through a health insurance issuer) in
25 such a manner that prevents an entity providing
26 pharmacy benefit management services on behalf of

1 a group health plan or health insurance issuer offer-
2 ing group health insurance coverage from making
3 the reports described in subsection (b); and

4 “(2) provide the entity providing pharmacy ben-
5 efit management services on behalf of a group health
6 plan or health insurance issuer relevant information
7 necessary to make the reports described in sub-
8 section (b).

9 “(b) REPORTS.—

10 “(1) IN GENERAL.—For plan years beginning
11 on or after the effective date, in the case of any con-
12 tract between a group health plan or a health insur-
13 ance issuer offering group health insurance coverage
14 offered in connection with such a plan and an entity
15 providing pharmacy benefit management services on
16 behalf of such plan or issuer, including an extension
17 or renewal of such a contract, entered into on or
18 after the effective date, the entity providing phar-
19 macy benefit management services on behalf of such
20 a group health plan or health insurance issuer, not
21 less frequently than every 6 months (or, at the re-
22 quest of a group health plan, not less frequently
23 than quarterly, and under the same conditions,
24 terms, and cost of the semiannual report under this
25 subsection), shall submit to the group health plan a

1 report in accordance with this section. Each such re-
2 port shall be made available to such group health
3 plan in plain language, in a machine-readable for-
4 mat, and as the Secretary may determine, other for-
5 mats. Each such report shall include the information
6 described in paragraph (2).

7 “(2) INFORMATION DESCRIBED.—For purposes
8 of paragraph (1), the information described in this
9 paragraph is, with respect to drugs covered by a
10 group health plan or group health insurance cov-
11 erage offered by a health insurance issuer in connec-
12 tion with a group health plan during each reporting
13 period—

14 “(A) in the case of a group health plan
15 that is offered by a specified large employer or
16 that is a specified large plan, and is not offered
17 as health insurance coverage, or in the case of
18 health insurance coverage for which the election
19 under paragraph (3) is made for the applicable
20 reporting period—

21 “(i) a list of drugs for which a claim
22 was filed and, with respect to each such
23 drug on such list—

24 “(I) the contracted compensation
25 paid by the group health plan or

1 health insurance issuer for each cov-
2 ered drug (identified by the National
3 Drug Code) to the entity providing
4 pharmacy benefit management serv-
5 ices or other applicable entity on be-
6 half of the group health plan or health
7 insurance issuer;

8 “(II) the contracted compensa-
9 tion paid to the pharmacy, by any en-
10 tity providing pharmacy benefit man-
11 agement services or other applicable
12 entity on behalf of the group health
13 plan or health insurance issuer, for
14 each covered drug (identified by the
15 National Drug Code);

16 “(III) for each such claim, the
17 difference between the amount paid
18 under subclause (I) and the amount
19 paid under subclause (II);

20 “(IV) the proprietary name, es-
21 tablished name or proper name, and
22 National Drug Code;

23 “(V) for each claim for the drug
24 (including original prescriptions and
25 refills) and for each dosage unit of the

1 drug for which a claim was filed, the
2 type of dispensing channel used to
3 furnish the drug, including retail, mail
4 order, or specialty pharmacy;

5 “(VI) with respect to each drug
6 dispensed, for each type of dispensing
7 channel (including retail, mail order,
8 or specialty pharmacy)—

9 “(aa) whether such drug is a
10 brand name drug or a generic
11 drug, and—

12 “(AA) in the case of a
13 brand name drug, the whole-
14 sale acquisition cost, listed
15 as cost per days supply and
16 cost per dosage unit, on the
17 date such drug was dis-
18 pensed; and

19 “(BB) in the case of a
20 generic drug, the average
21 wholesale price, listed as
22 cost per days supply and
23 cost per dosage unit, on the
24 date such drug was dis-
25 pensed; and

1 “(bb) the total number of—
2 “(AA) prescription
3 claims (including original
4 prescriptions and refills);

5 “(BB) participants and
6 beneficiaries for whom a
7 claim for such drug was
8 filed through the applicable
9 dispensing channel;

10 “(CC) dosage units and
11 dosage units per fill of such
12 drug; and

13 “(DD) days supply of
14 such drug per fill;

15 “(VII) the net price per course of
16 treatment or single fill, such as a 30-
17 day supply or 90-day supply to the
18 plan or coverage after rebates, fees,
19 alternative discounts, or other remun-
20 eration received from applicable enti-
21 ties;

22 “(VIII) the total amount of out-
23 of-pocket spending by participants
24 and beneficiaries on such drug, in-
25 cluding spending through copayments,

1 coinsurance, and deductibles, but not
2 including any amounts spent by par-
3 ticipants and beneficiaries on drugs
4 not covered under the plan or cov-
5 erage, or for which no claim is sub-
6 mitted under the plan or coverage;

7 “(IX) the total net spending on
8 the drug;

9 “(X) the total amount received,
10 or expected to be received, by the plan
11 or issuer from any applicable entity in
12 rebates, fees, alternative discounts, or
13 other remuneration;

14 “(XI) the total amount received,
15 or expected to be received, by the enti-
16 ty providing pharmacy benefit man-
17 agement services, from applicable en-
18 tities, in rebates, fees, alternative dis-
19 counts, or other remuneration from
20 such entities—

21 “(aa) for claims incurred
22 during the reporting period; and

23 “(bb) that is related to utili-
24 zation of such drug or spending
25 on such drug; and

1 “(XII) to the extent feasible, in-
2 formation on the total amount of re-
3 muneration for such drug, including
4 copayment assistance dollars paid, co-
5 payment cards applied, or other dis-
6 counts provided by each drug manu-
7 facturer (or entity administering co-
8 payment assistance on behalf of such
9 drug manufacturer), to the partici-
10 pants and beneficiaries enrolled in
11 such plan or coverage;

12 “(ii) a list of each therapeutic class
13 (as defined by the Secretary) for which a
14 claim was filed under the group health
15 plan or health insurance coverage during
16 the reporting period, and, with respect to
17 each such therapeutic class—

18 “(I) the total gross spending on
19 drugs in such class before rebates,
20 price concessions, alternative dis-
21 counts, or other remuneration from
22 applicable entities;

23 “(II) the net spending in such
24 class after such rebates, price conces-

1 sions, alternative discounts, or other
2 remuneration from applicable entities;

3 “(III) the total amount received,
4 or expected to be received, by the enti-
5 ty providing pharmacy benefit man-
6 agement services, from applicable en-
7 tities, in rebates, fees, alternative dis-
8 counts, or other remuneration from
9 such entities—

10 “(aa) for claims incurred
11 during the reporting period; and

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

14 “(IV) the average net spending
15 per 30-day supply and per 90-day
16 supply by the plan or by the issuer
17 with respect to such coverage and its
18 participants and beneficiaries, among
19 all drugs within the therapeutic class
20 for which a claim was filed during the
21 reporting period;

22 “(V) the number of participants
23 and beneficiaries who filled a prescrip-
24 tion for a drug in such class, includ-

1 ing the National Drug Code for each
2 such drug;

3 “(VI) if applicable, a description
4 of the formulary tiers and utilization
5 mechanisms (such as prior authoriza-
6 tion or step therapy) employed for
7 drugs in that class; and

8 “(VII) the total out-of-pocket
9 spending under the plan or coverage
10 by participants and beneficiaries, in-
11 cluding spending through copayments,
12 coinsurance, and deductibles, but not
13 including any amounts spent by par-
14 ticipants and beneficiaries on drugs
15 not covered under the plan or cov-
16 erage or for which no claim is sub-
17 mitted under the plan or coverage;

18 “(iii) with respect to any drug for
19 which gross spending under the group
20 health plan or health insurance coverage
21 exceeded \$10,000 during the reporting pe-
22 riod or, in the case that gross spending
23 under the group health plan or coverage
24 exceeded \$10,000 during the reporting pe-
25 riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs
2 with the highest spending during the re-
3 porting period—

4 “(I) a list of all other drugs in
5 the same therapeutic class as such
6 drug;

7 “(II) if applicable, the rationale
8 for the formulary placement of such
9 drug in that therapeutic category or
10 class, selected from a list of standard
11 rationales established by the Sec-
12 retary, in consultation with stake-
13 holders; and

14 “(III) any change in formulary
15 placement compared to the prior plan
16 year; and

17 “(iv) in the case that such plan or
18 issuer (or an entity providing pharmacy
19 benefit management services on behalf of
20 such plan or issuer) has an affiliated phar-
21 macy or pharmacy under common owner-
22 ship, including mandatory mail and spe-
23 cialty home delivery programs, retail and
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-
4 efit design parameters that encourage
5 or require participants and bene-
6 ficiaries in the plan or coverage to fill
7 prescriptions at mail order, specialty,
8 or retail pharmacies;

9 “(II) the percentage of total pre-
10 scriptions dispensed by such phar-
11 macies to participants or beneficiaries
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-
14 pensed by such pharmacies to partici-
15 pants or beneficiaries enrolled in such
16 plan or coverage, and, with respect to
17 each drug dispensed—

18 “(aa) the amount charged,
19 per dosage unit, per 30-day sup-
20 ply, or per 90-day supply (as ap-
21 plicable) to the plan or issuer,
22 and to participants and bene-
23 ficiaries;

24 “(bb) the median amount
25 charged to such plan or issuer,

1 and the interquartile range of the
2 costs, per dosage unit, per 30-
3 day supply, and per 90-day sup-
4 ply, including amounts paid by
5 the participants and bene-
6 ficiaries, when the same drug is
7 dispensed by other pharmacies
8 that are not affiliated with or
9 under common ownership with
10 the entity and that are included
11 in the pharmacy network of such
12 plan or coverage;

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

23 “(dd) the net acquisition
24 cost per dosage unit, per 30-day
25 supply, and per 90-day supply, if

1 such drug is subject to a max-
2 imum price discount; and

3 “(B) with respect to any group health
4 plan, including group health insurance coverage
5 offered in connection with such a plan, regard-
6 less of whether the plan or coverage is offered
7 by a specified large employer or whether it is a
8 specified large plan—

9 “(i) a summary document for the
10 group health plan that includes such infor-
11 mation described in clauses (i) through (iv)
12 of subparagraph (A), as specified by the
13 Secretary through guidance, program in-
14 struction, or otherwise (with no require-
15 ment of notice and comment rulemaking),
16 that the Secretary determines useful to
17 group health plans for purposes of select-
18 ing pharmacy benefit management serv-
19 ices, such as an estimated net price to
20 group health plan and participant or bene-
21 ficiary, a cost per claim, the fee structure
22 or reimbursement model, and estimated
23 cost per participant or beneficiary;

24 “(ii) a summary document for plans
25 and issuers to provide to participants and

1 beneficiaries, which shall be made available
2 to participants or beneficiaries upon re-
3 quest to their group health plan (including
4 in the case of group health insurance cov-
5 erage offered in connection with such a
6 plan), that—

7 “(I) contains such information
8 described in clauses (iii), (iv), (v), and
9 (vi), as applicable, as specified by the
10 Secretary through guidance, program
11 instruction, or otherwise (with no re-
12 quirement of notice and comment
13 rulemaking) that the Secretary deter-
14 mines useful to participants or bene-
15 ficiaries in better understanding the
16 plan or coverage or benefits under
17 such plan or coverage;

18 “(II) contains only aggregate in-
19 formation; and

20 “(III) states that participants
21 and beneficiaries may request specific,
22 claims-level information required to be
23 furnished under subsection (c) from
24 the group health plan or health insur-
25 ance issuer; and

1 “(iii) with respect to drugs covered by
2 such plan or coverage during such report-
3 ing period—

4 “(I) the total net spending by the
5 plan or coverage for all such drugs;

6 “(II) the total amount received,
7 or expected to be received, by the plan
8 or issuer from any applicable entity in
9 rebates, fees, alternative discounts, or
10 other remuneration; and

11 “(III) to the extent feasible, in-
12 formation on the total amount of re-
13 muneration for such drugs, including
14 copayment assistance dollars paid, co-
15 payment cards applied, or other dis-
16 counts provided by each drug manu-
17 facturer (or entity administering co-
18 payment assistance on behalf of such
19 drug manufacturer) to participants
20 and beneficiaries;

21 “(iv) amounts paid directly or indi-
22 rectly in rebates, fees, or any other type of
23 compensation (as defined in section
24 408(b)(2)(B)(ii)(dd)(AA) of the Employee
25 Retirement Income Security Act) to bro-

1 kerage firms, brokers, consultants, advi-
2 sors, or any other individual or firm, for—

3 “(I) the referral of the group
4 health plan’s or health insurance
5 issuer’s business to an entity pro-
6 viding pharmacy benefit management
7 services, including the identity of the
8 recipient of such amounts;

9 “(II) consideration of the entity
10 providing pharmacy benefit manage-
11 ment services by the group health
12 plan or health insurance issuer; or

13 “(III) the retention of the entity
14 by the group health plan or health in-
15 surance issuer;

16 “(v) an explanation of any benefit de-
17 sign parameters that encourage or require
18 participants and beneficiaries in such plan
19 or coverage to fill prescriptions at mail
20 order, specialty, or retail pharmacies that
21 are affiliated with or under common own-
22 ership with the entity providing pharmacy
23 benefit management services under such
24 plan or coverage, including mandatory mail
25 and specialty home delivery programs, re-

1 tail and mail auto-refill programs, and
2 cost-sharing assistance incentives directly
3 or indirectly funded by such entity; and

4 “(vi) total gross spending on all drugs
5 under the plan or coverage during the re-
6 porting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE
8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
10 the case of group health insurance coverage offered
11 in connection with a group health plan that is of-
12 fered by a specified large employer or is a specified
13 large plan, such group health plan may, on an an-
14 nual basis, for plan years beginning on or after the
15 date that is 30 months after the date of enactment
16 of this section, elect to require an entity providing
17 pharmacy benefit management services on behalf of
18 the health insurance issuer to submit to such group
19 health plan a report that includes all of the informa-
20 tion described in paragraph (2)(A), in addition to
21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing
24 pharmacy benefit management services on be-
25 half of a group health plan or a health insur-

1 ance issuer offering group health insurance cov-
2 erage shall report information under paragraph
3 (1) in a manner consistent with the privacy reg-
4 ulations promulgated under section 13402(a) of
5 the Health Information Technology for Eco-
6 nomic and Clinical Health Act and consistent
7 with the privacy regulations promulgated under
8 the Health Insurance Portability and Account-
9 ability Act of 1996 in part 160 and subparts A
10 and E of part 164 of title 45, Code of Federal
11 Regulations (or successor regulations) (referred
12 to in this paragraph as the ‘HIPAA privacy
13 regulations’) and shall restrict the use and dis-
14 closure of such information according to such
15 privacy regulations and such HIPAA privacy
16 regulations.

17 “(B) ADDITIONAL REQUIREMENTS.—

18 “(i) IN GENERAL.—An entity pro-
19 viding pharmacy benefit management serv-
20 ices on behalf of a group health plan or
21 health insurance issuer offering group
22 health insurance coverage that submits a
23 report under paragraph (1) shall ensure
24 that such report contains only summary
25 health information, as defined in section

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

3 “(ii) RESTRICTIONS.—In carrying out
4 this subsection, a group health plan shall
5 comply with section 164.504(f) of title 45,
6 Code of Federal Regulations (or a suc-
7 cessor regulation), and a plan sponsor shall
8 act in accordance with the terms of the
9 agreement described in such section.

10 “(C) RULE OF CONSTRUCTION.—

11 “(i) Nothing in this section shall be
12 construed to modify the requirements for
13 the creation, receipt, maintenance, or
14 transmission of protected health informa-
15 tion under the HIPAA privacy regulations.

16 “(ii) Nothing in this section shall be
17 construed to affect the application of any
18 Federal or State privacy or civil rights law,
19 including the HIPAA privacy regulations,
20 the Genetic Information Nondiscrimination
21 Act of 2008 (Public Law 110–233) (in-
22 cluding the amendments made by such
23 Act), the Americans with Disabilities Act
24 of 1990 (42 U.S.C. 12101 et seq), section
25 504 of the Rehabilitation Act of 1973 (29

1 U.S.C. 794), section 1557 of the Patient
2 Protection and Affordable Care Act (42
3 U.S.C. 18116), title VI of the Civil Rights
4 Act of 1964 (42 U.S.C. 2000d), and title
5 VII of the Civil Rights Act of 1964 (42
6 U.S.C. 2000e).

7 “(D) WRITTEN NOTICE.—Each plan year,
8 group health plans, including with respect to
9 group health insurance coverage offered in con-
10 nection with a group health plan, shall provide
11 to each participant or beneficiary written notice
12 informing the participant or beneficiary of the
13 requirement for entities providing pharmacy
14 benefit management services on behalf of the
15 group health plan or health insurance issuer of-
16 fering group health insurance coverage to sub-
17 mit reports to group health plans under para-
18 graph (1), as applicable, which may include in-
19 corporating such notification in plan documents
20 provided to the participant or beneficiary, or
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to the entity from which the report

1 was received or to that entity's business associ-
2 ates as defined in section 160.103 of title 45,
3 Code of Federal Regulations (or successor regu-
4 lations) or as permitted by the HIPAA privacy
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC
7 DISCLOSURE OF INFORMATION.—Nothing in
8 this section shall prevent an entity providing
9 pharmacy benefit management services on be-
10 half of a group health plan or health insurance
11 issuer offering group health insurance coverage,
12 from placing reasonable restrictions on the pub-
13 lic disclosure of the information contained in a
14 report described in paragraph (1), except that
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report
17 to the Department of Health and Human
18 Services, the Department of Labor, or the
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-
21 poses of subsection (c), or any other public
22 disclosure requirement under this section.

23 “(G) LIMITED FORM OF REPORT.—The
24 Secretary shall define through rulemaking a
25 limited form of the report under paragraph (1)

1 required with respect to any group health plan
2 established by a plan sponsor that is, or is af-
3 filiated with, a drug manufacturer, drug whole-
4 saler, or other direct participant in the drug
5 supply chain, in order to prevent anti-competi-
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18
9 months after the date of enactment of this sec-
10 tion, the Secretary shall specify through rule-
11 making a standard format for entities providing
12 pharmacy benefit management services on be-
13 half of group health plans and health insurance
14 issuers offering group health insurance cov-
15 erage, to submit reports required under para-
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not
18 later than 18 months after the date of enact-
19 ment of this section, the Secretary shall,
20 through rulemaking, promulgate any other final
21 regulations necessary to implement the require-
22 ments of this section. In promulgating such
23 regulations, the Secretary shall, to the extent
24 practicable, align the reporting requirements

1 under this section with the reporting require-
2 ments under section 2799A–10.

3 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
5 including with respect to group health insurance coverage
6 offered in connection with a group health plan, upon re-
7 quest of a participant or beneficiary, shall provide to such
8 participant or beneficiary—

9 “(1) the summary document described in sub-
10 section (b)(2)(B)(ii); and

11 “(2) the information described in subsection
12 (b)(2)(A)(i)(III) with respect to a claim made by or
13 on behalf of such participant or beneficiary.

14 “(d) ENFORCEMENT.—

15 “(1) IN GENERAL.—The Secretary shall enforce
16 this section. The enforcement authority under this
17 subsection shall apply only with respect to group
18 health plans (including group health insurance cov-
19 erage offered in connection with such a plan) to
20 which the requirements of subparts I and II of part
21 A and part D apply in accordance with section 2722,
22 and with respect to entities providing pharmacy ben-
23 efit management services on behalf of such plans
24 and applicable entities providing services on behalf
25 of such plans.

1 “(2) FAILURE TO PROVIDE INFORMATION.—A
2 group health plan, a health insurance issuer offering
3 group health insurance coverage, an entity providing
4 pharmacy benefit management services on behalf of
5 such a plan or issuer, or an applicable entity pro-
6 viding services on behalf of such a plan or issuer
7 that violates subsection (a); an entity providing
8 pharmacy benefit management services on behalf of
9 such a plan or issuer that fails to provide the infor-
10 mation required under subsection (b); or a group
11 health plan that fails to provide the information re-
12 quired under subsection (c), shall be subject to a
13 civil monetary penalty in the amount of \$10,000 for
14 each day during which such violation continues or
15 such information is not disclosed or reported.

16 “(3) FALSE INFORMATION.—A health insurance
17 issuer, an entity providing pharmacy benefit man-
18 agement services, or a third party administrator pro-
19 viding services on behalf of such issuer offered by a
20 health insurance issuer that knowingly provides false
21 information under this section shall be subject to a
22 civil monetary penalty in an amount not to exceed
23 \$100,000 for each item of false information. Such
24 civil monetary penalty shall be in addition to other
25 penalties as may be prescribed by law.

1 “(4) PROCEDURE.—The provisions of section
2 1128A of the Social Security Act, other than sub-
3 sections (a) and (b) and the first sentence of sub-
4 section (c)(1) of such section shall apply to civil
5 monetary penalties under this subsection in the
6 same manner as such provisions apply to a penalty
7 or proceeding under such section.

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

14 “(e) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to permit a health insurance issuer,
16 group health plan, entity providing pharmacy benefit man-
17 agement services on behalf of a group health plan or
18 health insurance issuer, or other entity to restrict disclo-
19 sure to, or otherwise limit the access of, the Secretary to
20 a report described in subsection (b)(1) or information re-
21 lated to compliance with subsections (a), (b), (c), or (d)
22 by such issuer, plan, or entity.

23 “(f) DEFINITIONS.—In this section:

24 “(1) APPLICABLE ENTITY.—The term ‘applica-
25 ble entity’ means—

1 “(A) an applicable group purchasing orga-
2 nization, drug manufacturer, distributor, whole-
3 saler, rebate aggregator (or other purchasing
4 entity designed to aggregate rebates), or associ-
5 ated third party;

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

12 “(C) such other entity as the Secretary
13 may specify through rulemaking.

14 “(2) APPLICABLE GROUP PURCHASING ORGANI-
15 ZATION.—The term ‘applicable group purchasing or-
16 ganization’ means a group purchasing organization
17 that is affiliated with or under common ownership
18 with an entity providing pharmacy benefit manage-
19 ment services.

20 “(3) CONTRACTED COMPENSATION.—The term
21 ‘contracted compensation’ means the sum of any in-
22 gredient cost and dispensing fee for a drug (inclusive
23 of the out-of-pocket costs to the participant or bene-
24 ficiary), or another analogous compensation struc-

1 ture that the Secretary may specify through regula-
2 tions.

3 “(4) GROSS SPENDING.—The term ‘gross
4 spending’, with respect to prescription drug benefits
5 under a group health plan or health insurance cov-
6 erage, means the amount spent by a group health
7 plan or health insurance issuer on prescription drug
8 benefits, calculated before the application of rebates,
9 fees, alternative discounts, or other remuneration.

10 “(5) NET SPENDING.—The term ‘net spending’,
11 with respect to prescription drug benefits under a
12 group health plan or health insurance coverage,
13 means the amount spent by a group health plan or
14 health insurance issuer on prescription drug bene-
15 fits, calculated after the application of rebates, fees,
16 alternative discounts, or other remuneration.

17 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
18 has the meaning given such term in section 3(16)(B)
19 of the Employee Retirement Income Security Act of
20 1974.

21 “(7) REMUNERATION.—The term ‘remunera-
22 tion’ has the meaning given such term by the Sec-
23 retary through rulemaking, which shall be reeval-
24 ated by the Secretary every 5 years.

1 “(8) SPECIFIED LARGE EMPLOYER.—The term
2 ‘specified large employer’ means, in connection with
3 a group health plan (including group health insur-
4 ance coverage offered in connection with such a
5 plan) established or maintained by a single em-
6 ployer, with respect to a calendar year or a plan
7 year, as applicable, an employer who employed an
8 average of at least 100 employees on business days
9 during the preceding calendar year or plan year and
10 who employs at least 1 employee on the first day of
11 the calendar year or plan year.

12 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
13 ified large plan’ means a group health plan (includ-
14 ing group health insurance coverage offered in con-
15 nection with such a plan) established or maintained
16 by a plan sponsor described in clause (ii) or (iii) of
17 section 3(16)(B) of the Employee Retirement In-
18 come Security Act of 1974 that had an average of
19 at least 100 participants on business days during
20 the preceding calendar year or plan year, as applica-
21 ble.

22 “(10) WHOLESALE ACQUISITION COST.—The
23 term ‘wholesale acquisition cost’ has the meaning
24 given such term in section 1847A(c)(6)(B) of the
25 Social Security Act.”; and

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

2 (A) in subsection (a)—

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

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

9 (B) in subsection (b)—

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

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

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

19 (b) EMPLOYEE RETIREMENT INCOME SECURITY ACT
 20 OF 1974.—

21 (1) IN GENERAL.—Subtitle B of title I of the
 22 Employee Retirement Income Security Act of 1974
 23 (29 U.S.C. 1021 et seq.) is amended—

1 (A) in subpart B of part 7 (29 U.S.C.
2 1185 et seq.), by adding at the end the fol-
3 lowing:

4 **“SEC. 726. 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 this section (referred to in this subsection and
9 subsection (b) as the ‘effective date’), a group health plan
10 or a health insurance issuer offering group health insur-
11 ance coverage, or an entity providing pharmacy benefit
12 management services on behalf of such a plan or issuer,
13 shall not enter into a contract, including an extension or
14 renewal of a contract, entered into on or after the effective
15 date, with an applicable entity unless such applicable enti-
16 ty agrees to—

17 “(1) not limit or delay the disclosure of infor-
18 mation to the group health plan (including such a
19 plan offered through a health insurance issuer) in
20 such a manner that prevents an entity providing
21 pharmacy benefit management services on behalf of
22 a group health plan or health insurance issuer offer-
23 ing group health insurance coverage from making
24 the reports described in subsection (b); and

1 “(2) provide the entity providing pharmacy ben-
2 efit management services on behalf of a group health
3 plan or health insurance issuer relevant information
4 necessary to make the reports described in sub-
5 section (b).

6 “(b) REPORTS.—

7 “(1) IN GENERAL.—For plan years beginning
8 on or after the effective date, in the case of any con-
9 tract between a group health plan or a health insur-
10 ance issuer offering group health insurance coverage
11 offered in connection with such a plan and an entity
12 providing pharmacy benefit management services on
13 behalf of such plan or issuer, including an extension
14 or renewal of such a contract, entered into on or
15 after the effective date, the entity providing phar-
16 macy benefit management services on behalf of such
17 a group health plan or health insurance issuer, not
18 less frequently than every 6 months (or, at the re-
19 quest of a group health plan, not less frequently
20 than quarterly, and under the same conditions,
21 terms, and cost of the semiannual report under this
22 subsection), shall submit to the group health plan a
23 report in accordance with this section. Each such re-
24 port shall be made available to such group health
25 plan in plain language, in a machine-readable for-

1 mat, and as the Secretary may determine, other for-
2 mats. Each such report shall include the information
3 described in paragraph (2).

4 “(2) INFORMATION DESCRIBED.—For purposes
5 of paragraph (1), the information described in this
6 paragraph is, with respect to drugs covered by a
7 group health plan or group health insurance cov-
8 erage offered by a health insurance issuer in connec-
9 tion with a group health plan during each reporting
10 period—

11 “(A) in the case of a group health plan
12 that is offered by a specified large employer or
13 that is a specified large plan, and is not offered
14 as health insurance coverage, or in the case of
15 health insurance coverage for which the election
16 under paragraph (3) is made for the applicable
17 reporting period—

18 “(i) a list of drugs for which a claim
19 was filed and, with respect to each such
20 drug on such list—

21 “(I) the contracted compensation
22 paid by the group health plan or
23 health insurance issuer for each cov-
24 ered drug (identified by the National
25 Drug Code) to the entity providing

1 pharmacy benefit management serv-
2 ices or other applicable entity on be-
3 half of the group health plan or health
4 insurance issuer;

5 “(II) the contracted compensa-
6 tion paid to the pharmacy, by any en-
7 tity providing pharmacy benefit man-
8 agement services or other applicable
9 entity on behalf of the group health
10 plan or health insurance issuer, for
11 each covered drug (identified by the
12 National Drug Code);

13 “(III) for each such claim, the
14 difference between the amount paid
15 under subclause (I) and the amount
16 paid under subclause (II);

17 “(IV) the proprietary name, es-
18 tablished name or proper name, and
19 National Drug Code;

20 “(V) for each claim for the drug
21 (including original prescriptions and
22 refills) and for each dosage unit of the
23 drug for which a claim was filed, the
24 type of dispensing channel used to

1 furnish the drug, including retail, mail
2 order, or specialty pharmacy;

3 “(VI) with respect to each drug
4 dispensed, for each type of dispensing
5 channel (including retail, mail order,
6 or specialty pharmacy)—

7 “(aa) whether such drug is a
8 brand name drug or a generic
9 drug, and—

10 “(AA) in the case of a
11 brand name drug, the whole-
12 sale acquisition cost, listed
13 as cost per days supply and
14 cost per dosage unit, on the
15 date such drug was dis-
16 pensed; and

17 “(BB) in the case of a
18 generic drug, the average
19 wholesale price, listed as
20 cost per days supply and
21 cost per dosage unit, on the
22 date such drug was dis-
23 pensed; and

24 “(bb) the total number of—

1 “(AA) prescription
2 claims (including original
3 prescriptions and refills);

4 “(BB) participants and
5 beneficiaries for whom a
6 claim for such drug was
7 filed through the applicable
8 dispensing channel;

9 “(CC) dosage units and
10 dosage units per fill of such
11 drug; and

12 “(DD) days supply of
13 such drug per fill;

14 “(VII) the net price per course of
15 treatment or single fill, such as a 30-
16 day supply or 90-day supply to the
17 plan or coverage after rebates, fees,
18 alternative discounts, or other remun-
19 eration received from applicable enti-
20 ties;

21 “(VIII) the total amount of out-
22 of-pocket spending by participants
23 and beneficiaries on such drug, in-
24 cluding spending through copayments,
25 coinsurance, and deductibles, but not

1 including any amounts spent by par-
2 ticipants and beneficiaries on drugs
3 not covered under the plan or cov-
4 erage, or for which no claim is sub-
5 mitted under the plan or coverage;

6 “(IX) the total net spending on
7 the drug;

8 “(X) the total amount received,
9 or expected to be received, by the plan
10 or issuer from any applicable entity in
11 rebates, fees, alternative discounts, or
12 other remuneration;

13 “(XI) the total amount received,
14 or expected to be received, by the enti-
15 ty providing pharmacy benefit man-
16 agement services, from applicable en-
17 tities, in rebates, fees, alternative dis-
18 counts, or other remuneration from
19 such entities—

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

22 “(bb) that is related to utili-
23 zation of such drug or spending
24 on such drug; and

1 “(XII) to the extent feasible, in-
2 formation on the total amount of re-
3 muneration for such drug, including
4 copayment assistance dollars paid, co-
5 payment cards applied, or other dis-
6 counts provided by each drug manu-
7 facturer (or entity administering co-
8 payment assistance on behalf of such
9 drug manufacturer), to the partici-
10 pants and beneficiaries enrolled in
11 such plan or coverage;

12 “(ii) a list of each therapeutic class
13 (as defined by the Secretary) for which a
14 claim was filed under the group health
15 plan or health insurance coverage during
16 the reporting period, and, with respect to
17 each such therapeutic class—

18 “(I) the total gross spending on
19 drugs in such class before rebates,
20 price concessions, alternative dis-
21 counts, or other remuneration from
22 applicable entities;

23 “(II) the net spending in such
24 class after such rebates, price conces-

1 sions, alternative discounts, or other
2 remuneration from applicable entities;

3 “(III) the total amount received,
4 or expected to be received, by the enti-
5 ty providing pharmacy benefit man-
6 agement services, from applicable en-
7 tities, in rebates, fees, alternative dis-
8 counts, or other remuneration from
9 such entities—

10 “(aa) for claims incurred
11 during the reporting period; and

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

14 “(IV) the average net spending
15 per 30-day supply and per 90-day
16 supply by the plan or by the issuer
17 with respect to such coverage and its
18 participants and beneficiaries, among
19 all drugs within the therapeutic class
20 for which a claim was filed during the
21 reporting period;

22 “(V) the number of participants
23 and beneficiaries who filled a prescrip-
24 tion for a drug in such class, includ-

1 ing the National Drug Code for each
2 such drug;

3 “(VI) if applicable, a description
4 of the formulary tiers and utilization
5 mechanisms (such as prior authoriza-
6 tion or step therapy) employed for
7 drugs in that class; and

8 “(VII) the total out-of-pocket
9 spending under the plan or coverage
10 by participants and beneficiaries, in-
11 cluding spending through copayments,
12 coinsurance, and deductibles, but not
13 including any amounts spent by par-
14 ticipants and beneficiaries on drugs
15 not covered under the plan or cov-
16 erage or for which no claim is sub-
17 mitted under the plan or coverage;

18 “(iii) with respect to any drug for
19 which gross spending under the group
20 health plan or health insurance coverage
21 exceeded \$10,000 during the reporting pe-
22 riod or, in the case that gross spending
23 under the group health plan or coverage
24 exceeded \$10,000 during the reporting pe-
25 riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs
2 with the highest spending during the re-
3 porting period—

4 “(I) a list of all other drugs in
5 the same therapeutic class as such
6 drug;

7 “(II) if applicable, the rationale
8 for the formulary placement of such
9 drug in that therapeutic category or
10 class, selected from a list of standard
11 rationales established by the Sec-
12 retary, in consultation with stake-
13 holders; and

14 “(III) any change in formulary
15 placement compared to the prior plan
16 year; and

17 “(iv) in the case that such plan or
18 issuer (or an entity providing pharmacy
19 benefit management services on behalf of
20 such plan or issuer) has an affiliated phar-
21 macy or pharmacy under common owner-
22 ship, including mandatory mail and spe-
23 cialty home delivery programs, retail and
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-
4 efit design parameters that encourage
5 or require participants and bene-
6 ficiaries in the plan or coverage to fill
7 prescriptions at mail order, specialty,
8 or retail pharmacies;

9 “(II) the percentage of total pre-
10 scriptions dispensed by such phar-
11 macies to participants or beneficiaries
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-
14 pensed by such pharmacies to partici-
15 pants or beneficiaries enrolled in such
16 plan or coverage, and, with respect to
17 each drug dispensed—

18 “(aa) the amount charged,
19 per dosage unit, per 30-day sup-
20 ply, or per 90-day supply (as ap-
21 plicable) to the plan or issuer,
22 and to participants and bene-
23 ficiaries;

24 “(bb) the median amount
25 charged to such plan or issuer,

1 and the interquartile range of the
2 costs, per dosage unit, per 30-
3 day supply, and per 90-day sup-
4 ply, including amounts paid by
5 the participants and bene-
6 ficiaries, when the same drug is
7 dispensed by other pharmacies
8 that are not affiliated with or
9 under common ownership with
10 the entity and that are included
11 in the pharmacy network of such
12 plan or coverage;

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

23 “(dd) the net acquisition
24 cost per dosage unit, per 30-day
25 supply, and per 90-day supply, if

1 such drug is subject to a max-
2 imum price discount; and

3 “(B) with respect to any group health
4 plan, including group health insurance coverage
5 offered in connection with such a plan, regard-
6 less of whether the plan or coverage is offered
7 by a specified large employer or whether it is a
8 specified large plan—

9 “(i) a summary document for the
10 group health plan that includes such infor-
11 mation described in clauses (i) through (iv)
12 of subparagraph (A), as specified by the
13 Secretary through guidance, program in-
14 struction, or otherwise (with no require-
15 ment of notice and comment rulemaking),
16 that the Secretary determines useful to
17 group health plans for purposes of select-
18 ing pharmacy benefit management serv-
19 ices, such as an estimated net price to
20 group health plan and participant or bene-
21 ficiary, a cost per claim, the fee structure
22 or reimbursement model, and estimated
23 cost per participant or beneficiary;

24 “(ii) a summary document for plans
25 and issuers to provide to participants and

1 beneficiaries, which shall be made available
2 to participants or beneficiaries upon re-
3 quest to their group health plan (including
4 in the case of group health insurance cov-
5 erage offered in connection with such a
6 plan), that—

7 “(I) contains such information
8 described in clauses (iii), (iv), (v), and
9 (vi), as applicable, as specified by the
10 Secretary through guidance, program
11 instruction, or otherwise (with no re-
12 quirement of notice and comment
13 rulemaking) that the Secretary deter-
14 mines useful to participants or bene-
15 ficiaries in better understanding the
16 plan or coverage or benefits under
17 such plan or coverage;

18 “(II) contains only aggregate in-
19 formation; and

20 “(III) states that participants
21 and beneficiaries may request specific,
22 claims-level information required to be
23 furnished under subsection (c) from
24 the group health plan or health insur-
25 ance issuer;

1 “(iii) with respect to drugs covered by
2 such plan or coverage during such report-
3 ing period—

4 “(I) the total net spending by the
5 plan or coverage for all such drugs;

6 “(II) the total amount received,
7 or expected to be received, by the plan
8 or issuer from any applicable entity in
9 rebates, fees, alternative discounts, or
10 other remuneration; and

11 “(III) to the extent feasible, in-
12 formation on the total amount of re-
13 muneration for such drugs, including
14 copayment assistance dollars paid, co-
15 payment cards applied, or other dis-
16 counts provided by each drug manu-
17 facturer (or entity administering co-
18 payment assistance on behalf of such
19 drug manufacturer) to participants
20 and beneficiaries;

21 “(iv) amounts paid directly or indi-
22 rectly in rebates, fees, or any other type of
23 compensation (as defined in section
24 408(b)(2)(B)(ii)(dd)(AA)) to brokerage

1 firms, brokers, consultants, advisors, or
2 any other individual or firm, for—

3 “(I) the referral of the group
4 health plan’s or health insurance
5 issuer’s business to an entity pro-
6 viding pharmacy benefit management
7 services, including the identity of the
8 recipient of such amounts;

9 “(II) consideration of the entity
10 providing pharmacy benefit manage-
11 ment services by the group health
12 plan or health insurance issuer; or

13 “(III) the retention of the entity
14 by the group health plan or health in-
15 surance issuer;

16 “(v) an explanation of any benefit de-
17 sign parameters that encourage or require
18 participants and beneficiaries in such plan
19 or coverage to fill prescriptions at mail
20 order, specialty, or retail pharmacies that
21 are affiliated with or under common own-
22 ership with the entity providing pharmacy
23 benefit management services under such
24 plan or coverage, including mandatory mail
25 and specialty home delivery programs, re-

1 tail and mail auto-refill programs, and
2 cost-sharing assistance incentives directly
3 or indirectly funded by such entity; and

4 “(vi) total gross spending on all drugs
5 under the plan or coverage during the re-
6 porting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE
8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-
9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In
10 the case of group health insurance coverage offered
11 in connection with a group health plan that is of-
12 fered by a specified large employer or is a specified
13 large plan, such group health plan may, on an an-
14 nual basis, for plan years beginning on or after the
15 date that is 30 months after the date of enactment
16 of this section, elect to require an entity providing
17 pharmacy benefit management services on behalf of
18 the health insurance issuer to submit to such group
19 health plan a report that includes all of the informa-
20 tion described in paragraph (2)(A), in addition to
21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing
24 pharmacy benefit management services on be-
25 half of a group health plan or a health insur-

1 ance issuer offering group health insurance cov-
2 erage shall report information under paragraph
3 (1) in a manner consistent with the privacy reg-
4 ulations promulgated under section 13402(a) of
5 the Health Information Technology for Eco-
6 nomic and Clinical Health Act (42 U.S.C.
7 17932(a)) and consistent with the privacy regu-
8 lations promulgated under the Health Insur-
9 ance Portability and Accountability Act of 1996
10 in part 160 and subparts A and E of part 164
11 of title 45, Code of Federal Regulations (or suc-
12 cessor regulations) (referred to in this para-
13 graph as the ‘HIPAA privacy regulations’) and
14 shall restrict the use and disclosure of such in-
15 formation according to such privacy regulations
16 and such HIPAA privacy regulations.

17 “(B) ADDITIONAL REQUIREMENTS.—

18 “(i) IN GENERAL.—An entity pro-
19 viding pharmacy benefit management serv-
20 ices on behalf of a group health plan or
21 health insurance issuer offering group
22 health insurance coverage that submits a
23 report under paragraph (1) shall ensure
24 that such report contains only summary
25 health information, as defined in section

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

3 “(ii) RESTRICTIONS.—In carrying out
4 this subsection, a group health plan shall
5 comply with section 164.504(f) of title 45,
6 Code of Federal Regulations (or a suc-
7 cessor regulation), and a plan sponsor shall
8 act in accordance with the terms of the
9 agreement described in such section.

10 “(C) RULE OF CONSTRUCTION.—

11 “(i) Nothing in this section shall be
12 construed to modify the requirements for
13 the creation, receipt, maintenance, or
14 transmission of protected health informa-
15 tion under the HIPAA privacy regulations.

16 “(ii) Nothing in this section shall be
17 construed to affect the application of any
18 Federal or State privacy or civil rights law,
19 including the HIPAA privacy regulations,
20 the Genetic Information Nondiscrimination
21 Act of 2008 (Public Law 110–233) (in-
22 cluding the amendments made by such
23 Act), the Americans with Disabilities Act
24 of 1990 (42 U.S.C. 12101 et seq), section
25 504 of the Rehabilitation Act of 1973 (29

1 U.S.C. 794), section 1557 of the Patient
2 Protection and Affordable Care Act (42
3 U.S.C. 18116), title VI of the Civil Rights
4 Act of 1964 (42 U.S.C. 2000d), and title
5 VII of the Civil Rights Act of 1964 (42
6 U.S.C. 2000e).

7 “(D) WRITTEN NOTICE.—Each plan year,
8 group health plans, including with respect to
9 group health insurance coverage offered in con-
10 nection with a group health plan, shall provide
11 to each participant or beneficiary written notice
12 informing the participant or beneficiary of the
13 requirement for entities providing pharmacy
14 benefit management services on behalf of the
15 group health plan or health insurance issuer of-
16 fering group health insurance coverage to sub-
17 mit reports to group health plans under para-
18 graph (1), as applicable, which may include in-
19 corporating such notification in plan documents
20 provided to the participant or beneficiary, or
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-
23 ATES.—A group health plan receiving a report
24 under paragraph (1) may disclose such informa-
25 tion only to the entity from which the report

1 was received or to that entity's business associ-
2 ates as defined in section 160.103 of title 45,
3 Code of Federal Regulations (or successor regu-
4 lations) or as permitted by the HIPAA privacy
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC
7 DISCLOSURE OF INFORMATION.—Nothing in
8 this section shall prevent an entity providing
9 pharmacy benefit management services on be-
10 half of a group health plan or health insurance
11 issuer offering group health insurance coverage,
12 from placing reasonable restrictions on the pub-
13 lic disclosure of the information contained in a
14 report described in paragraph (1), except that
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report
17 to the Department of Health and Human
18 Services, the Department of Labor, or the
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-
21 poses of subsection (c), or any other public
22 disclosure requirement under this section.

23 “(G) LIMITED FORM OF REPORT.—The
24 Secretary shall define through rulemaking a
25 limited form of the report under paragraph (1)

1 required with respect to any group health plan
2 established by a plan sponsor that is, or is af-
3 filiated with, a drug manufacturer, drug whole-
4 saler, or other direct participant in the drug
5 supply chain, in order to prevent anti-competi-
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18
9 months after the date of enactment of this sec-
10 tion, the Secretary shall specify through rule-
11 making a standard format for entities providing
12 pharmacy benefit management services on be-
13 half of group health plans and health insurance
14 issuers offering group health insurance cov-
15 erage, to submit reports required under para-
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not
18 later than 18 months after the date of enact-
19 ment of this section, the Secretary shall,
20 through rulemaking, promulgate any other final
21 regulations necessary to implement the require-
22 ments of this section. In promulgating such
23 regulations, the Secretary shall, to the extent
24 practicable, align the reporting requirements

1 under this section with the reporting require-
2 ments under section 725.

3 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
5 including with respect to group health insurance coverage
6 offered in connection with a group health plan, upon re-
7 quest of a participant or beneficiary, shall provide to such
8 participant or beneficiary—

9 “(1) the summary document described in sub-
10 section (b)(2)(B)(ii); and

11 “(2) the information described in subsection
12 (b)(2)(A)(i)(III) with respect to a claim made by or
13 on behalf of such participant or beneficiary.

14 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
15 tion shall be construed to permit a health insurance issuer,
16 group health plan, entity providing pharmacy benefit man-
17 agement services on behalf of a group health plan or
18 health insurance issuer, or other entity to restrict disclo-
19 sure to, or otherwise limit the access of, the Secretary to
20 a report described in subsection (b)(1) or information re-
21 lated to compliance with subsections (a), (b), or (c) of this
22 section or section 502(c)(13) by such issuer, plan, or enti-
23 ty.

24 “(e) DEFINITIONS.—In this section:

1 “(1) APPLICABLE ENTITY.—The term ‘applica-
2 ble entity’ means—

3 “(A) an applicable group purchasing orga-
4 nization, drug manufacturer, distributor, whole-
5 saler, rebate aggregator (or other purchasing
6 entity designed to aggregate rebates), or associ-
7 ated third party;

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

14 “(C) such other entity as the Secretary
15 may specify through rulemaking.

16 “(2) APPLICABLE GROUP PURCHASING ORGANI-
17 ZATION.—The term ‘applicable group purchasing or-
18 ganization’ means a group purchasing organization
19 that is affiliated with or under common ownership
20 with an entity providing pharmacy benefit manage-
21 ment services.

22 “(3) CONTRACTED COMPENSATION.—The term
23 ‘contracted compensation’ means the sum of any in-
24 gredient cost and dispensing fee for a drug (inclusive
25 of the out-of-pocket costs to the participant or bene-

1 ficiary), or another analogous compensation struc-
2 ture that the Secretary may specify through regula-
3 tions.

4 “(4) GROSS SPENDING.—The term ‘gross
5 spending’, with respect to prescription drug benefits
6 under a group health plan or health insurance cov-
7 erage, means the amount spent by a group health
8 plan or health insurance issuer on prescription drug
9 benefits, calculated before the application of rebates,
10 fees, alternative discounts, or other remuneration.

11 “(5) NET SPENDING.—The term ‘net spending’,
12 with respect to prescription drug benefits under a
13 group health plan or health insurance coverage,
14 means the amount spent by a group health plan or
15 health insurance issuer on prescription drug bene-
16 fits, calculated after the application of rebates, fees,
17 alternative discounts, or other remuneration.

18 “(6) PLAN SPONSOR.—The term ‘plan sponsor’
19 has the meaning given such term in section
20 3(16)(B).

21 “(7) REMUNERATION.—The term ‘remunera-
22 tion’ has the meaning given such term by the Sec-
23 retary through rulemaking, which shall be reeval-
24 ated by the Secretary every 5 years.

1 “(8) SPECIFIED LARGE EMPLOYER.—The term
2 ‘specified large employer’ means, in connection with
3 a group health plan (including group health insur-
4 ance coverage offered in connection with such a
5 plan) established or maintained by a single em-
6 ployer, with respect to a calendar year or a plan
7 year, as applicable, an employer who employed an
8 average of at least 100 employees on business days
9 during the preceding calendar year or plan year and
10 who employs at least 1 employee on the first day of
11 the calendar year or plan year.

12 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
13 ified large plan’ means a group health plan (includ-
14 ing group health insurance coverage offered in con-
15 nection with such a plan) established or maintained
16 by a plan sponsor described in clause (ii) or (iii) of
17 section 3(16)(B) that had an average of at least 100
18 participants on business days during the preceding
19 calendar year or plan year, as applicable.

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

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

1 (i) in subsection (a)(6), by striking
2 “or (9)” and inserting “(9), or (13)”;

3 (ii) in subsection (b)(3), by striking
4 “under subsection (c)(9)” and inserting
5 “under paragraphs (9) and (13) of sub-
6 section (c)”;

7 (iii) in subsection (c), by adding at
8 the end the following:

9 “(13) SECRETARIAL ENFORCEMENT AUTHORITY
10 RELATING TO OVERSIGHT OF PHARMACY BENEFIT
11 MANAGEMENT SERVICES.—

12 “(A) FAILURE TO PROVIDE INFORMA-
13 TION.—The Secretary may impose a penalty
14 against a plan administrator of a group health
15 plan, a health insurance issuer offering group
16 health insurance coverage, or an entity pro-
17 viding pharmacy benefit management services
18 on behalf of such a plan or issuer, or an appli-
19 cable entity (as defined in section 726(f)) that
20 violates section 726(a); an entity providing
21 pharmacy benefit management services on be-
22 half of such a plan or issuer that fails to pro-
23 vide the information required under section
24 726(b); or any person who causes a group
25 health plan to fail to provide the information

1 required under section 726(c), in the amount of
2 \$10,000 for each day during which such viola-
3 tion continues or such information is not dis-
4 closed or reported.

5 “(B) FALSE INFORMATION.—The Sec-
6 retary may impose a penalty against a plan ad-
7 ministrator of a group health plan, a health in-
8 surance issuer offering group health insurance
9 coverage, an entity providing pharmacy benefit
10 management services, or an applicable entity
11 (as defined in section 726(f)) that knowingly
12 provides false information under section 726, in
13 an amount not to exceed \$100,000 for each
14 item of false information. Such penalty shall be
15 in addition to other penalties as may be pre-
16 scribed by law.

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

1 (C) in section 732(a) (29 U.S.C.
 2 1191a(a)), by striking “section 711” and in-
 3 serting “sections 711 and 726”.

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

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

9 (c) INTERNAL REVENUE CODE OF 1986.—

10 (1) IN GENERAL.—Chapter 100 of the Internal
 11 Revenue Code of 1986 is amended—

12 (A) by adding at the end of subchapter B
 13 the following:

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

16 “(a) IN GENERAL.—For plan years beginning on or
 17 after the date that is 30 months after the date of enact-
 18 ment of this section (referred to in this subsection and
 19 subsection (b) as the ‘effective date’), a group health plan,
 20 or an entity providing pharmacy benefit management serv-
 21 ices on behalf of such a plan, shall not enter into a con-
 22 tract, including an extension or renewal of a contract, en-
 23 tered into on or after the effective date, with an applicable
 24 entity unless such applicable entity agrees to—

1 “(1) not limit or delay the disclosure of infor-
2 mation to the group health plan in such a manner
3 that prevents an entity providing pharmacy benefit
4 management services on behalf of a group health
5 plan from making the reports described in sub-
6 section (b); and

7 “(2) provide the entity providing pharmacy ben-
8 efit management services on behalf of a group health
9 plan relevant information necessary to make the re-
10 ports described in subsection (b).

11 “(b) REPORTS.—

12 “(1) IN GENERAL.—For plan years beginning
13 on or after the effective date, in the case of any con-
14 tract between a group health plan and an entity pro-
15 viding pharmacy benefit management services on be-
16 half of such plan, including an extension or renewal
17 of such a contract, entered into on or after the effec-
18 tive date, the entity providing pharmacy benefit
19 management services on behalf of such a group
20 health plan, not less frequently than every 6 months
21 (or, at the request of a group health plan, not less
22 frequently than quarterly, and under the same con-
23 ditions, terms, and cost of the semiannual report
24 under this subsection), shall submit to the group
25 health plan a report in accordance with this section.

1 Each such report shall be made available to such
2 group health plan in plain language, in a machine-
3 readable format, and as the Secretary may deter-
4 mine, other formats. Each such report shall include
5 the information described in paragraph (2).

6 “(2) INFORMATION DESCRIBED.—For purposes
7 of paragraph (1), the information described in this
8 paragraph is, with respect to drugs covered by a
9 group health plan during each reporting period—

10 “(A) in the case of a group health plan
11 that is offered by a specified large employer or
12 that is a specified large plan, and is not offered
13 as health insurance coverage, or in the case of
14 health insurance coverage for which the election
15 under paragraph (3) is made for the applicable
16 reporting period—

17 “(i) a list of drugs for which a claim
18 was filed and, with respect to each such
19 drug on such list—

20 “(I) the contracted compensation
21 paid by the group health plan for each
22 covered drug (identified by the Na-
23 tional Drug Code) to the entity pro-
24 viding pharmacy benefit management

1 services or other applicable entity on
2 behalf of the group health plan;

3 “(II) the contracted compensa-
4 tion paid to the pharmacy, by any en-
5 tity providing pharmacy benefit man-
6 agement services or other applicable
7 entity on behalf of the group health
8 plan, for each covered drug (identified
9 by the National Drug Code);

10 “(III) for each such claim, the
11 difference between the amount paid
12 under subclause (I) and the amount
13 paid under subclause (II);

14 “(IV) the proprietary name, es-
15 tablished name or proper name, and
16 National Drug Code;

17 “(V) for each claim for the drug
18 (including original prescriptions and
19 refills) and for each dosage unit of the
20 drug for which a claim was filed, the
21 type of dispensing channel used to
22 furnish the drug, including retail, mail
23 order, or specialty pharmacy;

24 “(VI) with respect to each drug
25 dispensed, for each type of dispensing

1 channel (including retail, mail order,
2 or specialty pharmacy)—

3 “(aa) whether such drug is a
4 brand name drug or a generic
5 drug, and—

6 “(AA) in the case of a
7 brand name drug, the whole-
8 sale acquisition cost, listed
9 as cost per days supply and
10 cost per dosage unit, on the
11 date such drug was dis-
12 pensed; and

13 “(BB) in the case of a
14 generic drug, the average
15 wholesale price, listed as
16 cost per days supply and
17 cost per dosage unit, on the
18 date such drug was dis-
19 pensed; and

20 “(bb) the total number of—

21 “(AA) prescription
22 claims (including original
23 prescriptions and refills);

24 “(BB) participants and
25 beneficiaries for whom a

1 claim for such drug was
2 filed through the applicable
3 dispensing channel;

4 “(CC) dosage units and
5 dosage units per fill of such
6 drug; and

7 “(DD) days supply of
8 such drug per fill;

9 “(VII) the net price per course of
10 treatment or single fill, such as a 30-
11 day supply or 90-day supply to the
12 plan after rebates, fees, alternative
13 discounts, or other remuneration re-
14 ceived from applicable entities;

15 “(VIII) the total amount of out-
16 of-pocket spending by participants
17 and beneficiaries on such drug, in-
18 cluding spending through copayments,
19 coinsurance, and deductibles, but not
20 including any amounts spent by par-
21 ticipants and beneficiaries on drugs
22 not covered under the plan, or for
23 which no claim is submitted under the
24 plan;

1 “(IX) the total net spending on
2 the drug;

3 “(X) the total amount received,
4 or expected to be received, by the plan
5 from any applicable entity in rebates,
6 fees, alternative discounts, or other
7 remuneration;

8 “(XI) the total amount received,
9 or expected to be received, by the enti-
10 ty providing pharmacy benefit man-
11 agement services, from applicable en-
12 tities, in rebates, fees, alternative dis-
13 counts, or other remuneration from
14 such entities—

15 “(aa) for claims incurred
16 during the reporting period; and

17 “(bb) that is related to utili-
18 zation of such drug or spending
19 on such drug; and

20 “(XII) to the extent feasible, in-
21 formation on the total amount of re-
22 muneration for such drug, including
23 copayment assistance dollars paid, co-
24 payment cards applied, or other dis-
25 counts provided by each drug manu-

1 facturer (or entity administering co-
2 payment assistance on behalf of such
3 drug manufacturer), to the partici-
4 pants and beneficiaries enrolled in
5 such plan;

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

11 “(I) the total gross spending on
12 drugs in such class before rebates,
13 price concessions, alternative dis-
14 counts, or other remuneration from
15 applicable entities;

16 “(II) the net spending in such
17 class after such rebates, price conces-
18 sions, alternative discounts, or other
19 remuneration from applicable entities;

20 “(III) the total amount received,
21 or expected to be received, by the enti-
22 ty providing pharmacy benefit man-
23 agement services, from applicable en-
24 tities, in rebates, fees, alternative dis-

1 counts, or other remuneration from
2 such entities—

3 “(aa) for claims incurred
4 during the reporting period; and

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

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

14 “(V) the number of participants
15 and beneficiaries who filled a prescrip-
16 tion for a drug in such class, includ-
17 ing the National Drug Code for each
18 such drug;

19 “(VI) if applicable, a description
20 of the formulary tiers and utilization
21 mechanisms (such as prior authoriza-
22 tion or step therapy) employed for
23 drugs in that class; and

24 “(VII) the total out-of-pocket
25 spending under the plan by partici-

1 pants and beneficiaries, including
2 spending through copayments, coin-
3 surance, and deductibles, but not in-
4 cluding any amounts spent by partici-
5 pants and beneficiaries on drugs not
6 covered under the plan or for which
7 no claim is submitted under the plan;

8 “(iii) with respect to any drug for
9 which gross spending under the group
10 health plan exceeded \$10,000 during the
11 reporting period or, in the case that gross
12 spending under the group health plan ex-
13 ceeded \$10,000 during the reporting pe-
14 riod with respect to fewer than 50 drugs,
15 with respect to the 50 prescription drugs
16 with the highest spending during the re-
17 porting period—

18 “(I) a list of all other drugs in
19 the same therapeutic class as such
20 drug;

21 “(II) if applicable, the rationale
22 for the formulary placement of such
23 drug in that therapeutic category or
24 class, selected from a list of standard
25 rationales established by the Sec-

1 retary, in consultation with stake-
2 holders; and

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

6 “(iv) in the case that such plan (or an
7 entity providing pharmacy benefit manage-
8 ment services on behalf of such plan) has
9 an affiliated pharmacy or pharmacy under
10 common ownership, including mandatory
11 mail and specialty home delivery programs,
12 retail and mail auto-refill programs, and
13 cost sharing assistance incentives funded
14 by an entity providing pharmacy benefit
15 services—

16 “(I) an explanation of any ben-
17 efit design parameters that encourage
18 or require participants and bene-
19 ficiaries in the plan to fill prescrip-
20 tions at mail order, specialty, or retail
21 pharmacies;

22 “(II) the percentage of total pre-
23 scriptions dispensed by such phar-
24 macies to participants or beneficiaries
25 in such plan; and

1 “(III) a list of all drugs dis-
2 pensed by such pharmacies to partici-
3 pants or beneficiaries enrolled in such
4 plan, and, with respect to each drug
5 dispensed—

6 “(aa) the amount charged,
7 per dosage unit, per 30-day sup-
8 ply, or per 90-day supply (as ap-
9 plicable) to the plan, and to par-
10 ticipants and beneficiaries;

11 “(bb) the median amount
12 charged to such plan, and the
13 interquartile range of the costs,
14 per dosage unit, per 30-day sup-
15 ply, and per 90-day supply, in-
16 cluding amounts paid by the par-
17 ticipants and beneficiaries, when
18 the same drug is dispensed by
19 other pharmacies that are not af-
20 filiated with or under common
21 ownership with the entity and
22 that are included in the phar-
23 macy network of such plan;

24 “(cc) the lowest cost per
25 dosage unit, per 30-day supply

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

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

13 “(B) with respect to any group health
14 plan, regardless of whether the plan is offered
15 by a specified large employer or whether it is a
16 specified large plan—

17 “(i) a summary document for the
18 group health plan that includes such infor-
19 mation described in clauses (i) through (iv)
20 of subparagraph (A), as specified by the
21 Secretary through guidance, program in-
22 struction, or otherwise (with no require-
23 ment of notice and comment rulemaking),
24 that the Secretary determines useful to
25 group health plans for purposes of select-

1 ing pharmacy benefit management serv-
2 ices, such as an estimated net price to
3 group health plan and participant or bene-
4 ficiary, a cost per claim, the fee structure
5 or reimbursement model, and estimated
6 cost per participant or beneficiary;

7 “(ii) a summary document for plans
8 to provide to participants and beneficiaries,
9 which shall be made available to partici-
10 pants or beneficiaries upon request to their
11 group health plan, that—

12 “(I) contains such information
13 described in clauses (iii), (iv), (v), and
14 (vi), as applicable, as specified by the
15 Secretary through guidance, program
16 instruction, or otherwise (with no re-
17 quirement of notice and comment
18 rulemaking) that the Secretary deter-
19 mines useful to participants or bene-
20 ficiaries in better understanding the
21 plan or benefits under such plan;

22 “(II) contains only aggregate in-
23 formation; and

24 “(III) states that participants
25 and beneficiaries may request specific,

1 claims-level information required to be
2 furnished under subsection (c) from
3 the group health plan; and

4 “(iii) with respect to drugs covered by
5 such plan during such reporting period—

6 “(I) the total net spending by the
7 plan for all such drugs;

8 “(II) the total amount received,
9 or expected to be received, by the plan
10 from any applicable entity in rebates,
11 fees, alternative discounts, or other
12 remuneration; and

13 “(III) to the extent feasible, in-
14 formation on the total amount of re-
15 muneration for such drugs, including
16 copayment assistance dollars paid, co-
17 payment cards applied, or other dis-
18 counts provided by each drug manu-
19 facturer (or entity administering co-
20 payment assistance on behalf of such
21 drug manufacturer) to participants
22 and beneficiaries;

23 “(iv) amounts paid directly or indi-
24 rectly in rebates, fees, or any other type of
25 compensation (as defined in section

1 408(b)(2)(B)(ii)(dd)(AA) of the Employee
2 Retirement Income Security Act (29
3 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to bro-
4 kerage firms, brokers, consultants, advi-
5 sors, or any other individual or firm, for—

6 “(I) the referral of the group
7 health plan’s business to an entity
8 providing pharmacy benefit manage-
9 ment services, including the identity
10 of the recipient of such amounts;

11 “(II) consideration of the entity
12 providing pharmacy benefit manage-
13 ment services by the group health
14 plan; or

15 “(III) the retention of the entity
16 by the group health plan;

17 “(v) an explanation of any benefit de-
18 sign parameters that encourage or require
19 participants and beneficiaries in such plan
20 to fill prescriptions at mail order, specialty,
21 or retail pharmacies that are affiliated with
22 or under common ownership with the enti-
23 ty providing pharmacy benefit management
24 services under such plan, including manda-
25 tory mail and specialty home delivery pro-

grams, retail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

“(vi) total gross spending on all drugs under the plan during the reporting period.

“(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

“(4) PRIVACY REQUIREMENTS.—

“(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan shall report infor-

1 mation under paragraph (1) in a manner con-
2 sistent with the privacy regulations promul-
3 gated under section 13402(a) of the Health In-
4 formation Technology for Economic and Clin-
5 ical Health Act (42 U.S.C. 17932(a)) and con-
6 sistent with the privacy regulations promul-
7 gated under the Health Insurance Portability
8 and Accountability Act of 1996 in part 160 and
9 subparts A and E of part 164 of title 45, Code
10 of Federal Regulations (or successor regula-
11 tions) (referred to in this paragraph as the
12 ‘HIPAA privacy regulations’) and shall restrict
13 the use and disclosure of such information ac-
14 cording to such privacy regulations and such
15 HIPAA privacy regulations.

16 “(B) ADDITIONAL REQUIREMENTS.—

17 “(i) IN GENERAL.—An entity pro-
18 viding pharmacy benefit management serv-
19 ices on behalf of a group health plan that
20 submits a report under paragraph (1) shall
21 ensure that such report contains only sum-
22 mary health information, as defined in sec-
23 tion 164.504(a) of title 45, Code of Fed-
24 eral Regulations (or successor regulations).

1 “(ii) RESTRICTIONS.—In carrying out
2 this subsection, a group health plan shall
3 comply with section 164.504(f) of title 45,
4 Code of Federal Regulations (or a suc-
5 cessor regulation), and a plan sponsor shall
6 act in accordance with the terms of the
7 agreement described in such section.

8 “(C) RULE OF CONSTRUCTION.—

9 “(i) Nothing in this section shall be
10 construed to modify the requirements for
11 the creation, receipt, maintenance, or
12 transmission of protected health informa-
13 tion under the HIPAA privacy regulations.

14 “(ii) Nothing in this section shall be
15 construed to affect the application of any
16 Federal or State privacy or civil rights law,
17 including the HIPAA privacy regulations,
18 the Genetic Information Nondiscrimination
19 Act of 2008 (Public Law 110–233) (in-
20 cluding the amendments made by such
21 Act), the Americans with Disabilities Act
22 of 1990 (42 U.S.C. 12101 et sec), section
23 504 of the Rehabilitation Act of 1973 (29
24 U.S.C. 794), section 1557 of the Patient
25 Protection and Affordable Care Act (42

1 U.S.C. 18116), title VI of the Civil Rights
2 Act of 1964 (42 U.S.C. 2000d), and title
3 VII of the Civil Rights Act of 1964 (42
4 U.S.C. 2000e).

5 “(D) WRITTEN NOTICE.—Each plan year,
6 group health plans shall provide to each partici-
7 pant or beneficiary written notice informing the
8 participant or beneficiary of the requirement for
9 entities providing pharmacy benefit manage-
10 ment services on behalf of the group health
11 plan to submit reports to group health plans
12 under paragraph (1), as applicable, which may
13 include incorporating such notification in plan
14 documents provided to the participant or bene-
15 ficiary, or providing individual notification.

16 “(E) LIMITATION TO BUSINESS ASSOCI-
17 ATES.—A group health plan receiving a report
18 under paragraph (1) may disclose such informa-
19 tion only to the entity from which the report
20 was received or to that entity’s business associ-
21 ates as defined in section 160.103 of title 45,
22 Code of Federal Regulations (or successor regu-
23 lations) or as permitted by the HIPAA privacy
24 regulations.

1 “(F) CLARIFICATION REGARDING PUBLIC
2 DISCLOSURE OF INFORMATION.—Nothing in
3 this section shall prevent an entity providing
4 pharmacy benefit management services on be-
5 half of a group health plan, from placing rea-
6 sonable restrictions on the public disclosure of
7 the information contained in a report described
8 in paragraph (1), except that such plan or enti-
9 ty may not—

10 “(i) restrict disclosure of such report
11 to the Department of Health and Human
12 Services, the Department of Labor, or the
13 Department of the Treasury; or

14 “(ii) prevent disclosure for the pur-
15 poses of subsection (c), or any other public
16 disclosure requirement under this section.

17 “(G) LIMITED FORM OF REPORT.—The
18 Secretary shall define through rulemaking a
19 limited form of the report under paragraph (1)
20 required with respect to any group health plan
21 established by a plan sponsor that is, or is af-
22 filiated with, a drug manufacturer, drug whole-
23 saler, or other direct participant in the drug
24 supply chain, in order to prevent anti-competi-
25 tive behavior.

1 “(5) STANDARD FORMAT AND REGULATIONS.—

2 “(A) IN GENERAL.—Not later than 18
3 months after the date of enactment of this sec-
4 tion, the Secretary shall specify through rule-
5 making a standard format for entities providing
6 pharmacy benefit management services on be-
7 half of group health plans, to submit reports re-
8 quired under paragraph (1).

9 “(B) ADDITIONAL REGULATIONS.—Not
10 later than 18 months after the date of enact-
11 ment of this section, the Secretary shall,
12 through rulemaking, promulgate any other final
13 regulations necessary to implement the require-
14 ments of this section. In promulgating such
15 regulations, the Secretary shall, to the extent
16 practicable, align the reporting requirements
17 under this section with the reporting require-
18 ments under section 9825.

19 “(c) REQUIREMENT TO PROVIDE INFORMATION TO
20 PARTICIPANTS OR BENEFICIARIES.—A group health plan,
21 upon request of a participant or beneficiary, shall provide
22 to such participant or beneficiary—

23 “(1) the summary document described in sub-
24 section (b)(2)(B)(ii); and

1 “(2) the information described in subsection
2 (b)(2)(A)(i)(III) with respect to a claim made by or
3 on behalf of such participant or beneficiary.

4 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
5 tion shall be construed to permit a health insurance issuer,
6 group health plan, entity providing pharmacy benefit man-
7 agement services on behalf of a group health plan or
8 health insurance issuer, or other entity to restrict disclo-
9 sure to, or otherwise limit the access of, the Secretary to
10 a report described in subsection (b)(1) or information re-
11 lated to compliance with subsections (a), (b), or (c) of this
12 section or section 4980D(g) by such issuer, plan, or entity.

13 “(e) DEFINITIONS.—In this section:

14 “(1) APPLICABLE ENTITY.—The term ‘applica-
15 ble entity’ means—

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

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

1 a plan or issuer, or any entity described in sub-
2 paragraph (A); or

3 “(C) such other entity as the Secretary
4 may specify through rulemaking.

5 “(2) APPLICABLE GROUP PURCHASING ORGANI-
6 ZATION.—The term ‘applicable group purchasing or-
7 ganization’ means a group purchasing organization
8 that is affiliated with or under common ownership
9 with an entity providing pharmacy benefit manage-
10 ment services.

11 “(3) CONTRACTED COMPENSATION.—The term
12 ‘contracted compensation’ means the sum of any in-
13 gredient cost and dispensing fee for a drug (inclusive
14 of the out-of-pocket costs to the participant or bene-
15 ficiary), or another analogous compensation struc-
16 ture that the Secretary may specify through regula-
17 tions.

18 “(4) GROSS SPENDING.—The term ‘gross
19 spending’, with respect to prescription drug benefits
20 under a group health plan, means the amount spent
21 by a group health plan on prescription drug benefits,
22 calculated before the application of rebates, fees, al-
23 ternative discounts, or other remuneration.

24 “(5) NET SPENDING.—The term ‘net spending’,
25 with respect to prescription drug benefits under a

1 group health plan, means the amount spent by a
2 group health plan on prescription drug benefits, cal-
3 culated after the application of rebates, fees, alter-
4 native discounts, or other remuneration.

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

9 “(7) REMUNERATION.—The term ‘remunera-
10 tion’ has the meaning given such term by the Sec-
11 retary, through rulemaking, which shall be reeval-
12 ated by the Secretary every 5 years.

13 “(8) SPECIFIED LARGE EMPLOYER.—The term
14 ‘specified large employer’ means, in connection with
15 a group health plan established or maintained by a
16 single employer, with respect to a calendar year or
17 a plan year, as applicable, an employer who em-
18 ployed an average of at least 100 employees on busi-
19 ness days during the preceding calendar year or plan
20 year and who employs at least 1 employee on the
21 first day of the calendar year or plan year.

22 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-
23 ified large plan’ means a group health plan estab-
24 lished or maintained by a plan sponsor described in
25 clause (ii) or (iii) of section 3(16)(B) of the Em-

1 ployee Retirement Income Security Act of 1974 (29
 2 U.S.C. 1002(16)(B)) that had an average of at least
 3 100 participants on business days during the pre-
 4 ceding calendar year or plan year, as applicable.

5 “(10) WHOLESALE ACQUISITION COST.—The
 6 term ‘wholesale acquisition cost’ has the meaning
 7 given such term in section 1847A(c)(6)(B) of the
 8 Social Security Act (42 U.S.C. 1395w–
 9 3a(c)(6)(B)).”;

10 (2) EXCEPTION FOR CERTAIN GROUP HEALTH
 11 PLANS.—Section 9831(a)(2) of the Internal Revenue
 12 Code of 1986 is amended by inserting “other than
 13 with respect to section 9826,” before “any group
 14 health plan”.

15 (3) ENFORCEMENT.—Section 4980D of the In-
 16 ternal Revenue Code of 1986 is amended by adding
 17 at the end the following new subsection:

18 “(g) APPLICATION TO REQUIREMENTS IMPOSED ON
 19 CERTAIN ENTITIES PROVIDING PHARMACY BENEFIT
 20 MANAGEMENT SERVICES.—In the case of any requirement
 21 under section 9826 that applies with respect to an entity
 22 providing pharmacy benefit management services on be-
 23 half of a group health plan, any reference in this section
 24 to such group health plan (and the reference in subsection

1 (e)(1) to the employer) shall be treated as including a ref-
2 erence to such entity.”.

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

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

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