

119TH CONGRESS
1ST SESSION

H. R. 4317

To assure pharmacy access and choice for Medicare beneficiaries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 10, 2025

Mr. CARTER of Georgia (for himself, Mrs. DINGELL, Mr. MURPHY, Ms. ROSS, Mr. ARRINGTON, Mrs. HARSHBARGER, Mr. VICENTE GONZALEZ of Texas, Mr. ALLEN, Mr. KRISHNAMOORTHY, Mr. ROSE, Mr. TRAN, and Ms. MALLIOTAKIS) 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 assure pharmacy access and choice for Medicare beneficiaries, 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 Benefit
5 Manager Reform Act of 2025” or the “PBM Reform Act
6 of 2025”.

1 **SEC. 2. ASSURING PHARMACY ACCESS AND CHOICE FOR**
2 **MEDICARE BENEFICIARIES.**

3 (a) IN GENERAL.—Section 1860D–4(b)(1) of the So-
4 cial Security Act (42 U.S.C. 1395w–104(b)(1)) is amend-
5 ed by striking subparagraph (A) and inserting the fol-
6 lowing:

7 “(A) IN GENERAL.—

8 “(i) PARTICIPATION OF ANY WILLING
9 PHARMACY.—A PDP sponsor offering a
10 prescription drug plan shall permit any
11 pharmacy that meets the standard contract
12 terms and conditions under such plan to
13 participate as a network pharmacy of such
14 plan.

15 “(ii) CONTRACT TERMS AND CONDI-
16 TIONS.—

17 “(I) IN GENERAL.—Notwith-
18 standing any other provision of law,
19 for plan years beginning on or after
20 January 1, 2029, in accordance with
21 clause (i), contract terms and condi-
22 tions offered by such PDP sponsor
23 shall be reasonable and relevant ac-
24 cording to standards established by
25 the Secretary under subclause (II).

1 “(II) STANDARDS.—Not later
2 than the first Monday in April of
3 2028, the Secretary shall establish
4 standards for reasonable and relevant
5 contract terms and conditions for pur-
6 poses of this clause.

7 “(III) REQUEST FOR INFORMA-
8 TION.—Not later than April 1, 2027,
9 for purposes of establishing the stand-
10 ards under subclause (II), the Sec-
11 retary shall issue a request for infor-
12 mation to seek input on trends in pre-
13 scription drug plan and network phar-
14 macy contract terms and conditions,
15 current prescription drug plan and
16 network pharmacy contracting prac-
17 tices, whether pharmacy reimburse-
18 ment and dispensing fees paid by
19 PDP sponsors to network pharmacies
20 sufficiently cover the ingredient and
21 operational costs of such pharmacies,
22 the use and application of pharmacy
23 quality measures by PDP sponsors for
24 network pharmacies, PDP sponsor re-
25 strictions or limitations on the dis-

1 pensing of covered part D drugs by
 2 network pharmacies (or any subsets of
 3 such pharmacies), PDP sponsor au-
 4 diting practices for network phar-
 5 macies, areas in current regulations or
 6 program guidance related to con-
 7 tracting between prescription drug
 8 plans and network pharmacies requir-
 9 ing clarification or additional speci-
 10 ficity, factors for consideration in de-
 11 termining the reasonableness and rel-
 12 evance of contract terms and condi-
 13 tions between prescription drug plans
 14 and network pharmacies, and other
 15 issues as determined appropriate by
 16 the Secretary.”.

17 (b) ESSENTIAL RETAIL PHARMACIES.—Section
 18 1860D–42 of the Social Security Act (42 U.S.C. 1395w–
 19 152) is amended by adding at the end the following new
 20 subsection:

21 “(e) ESSENTIAL RETAIL PHARMACIES.—

22 “(1) IN GENERAL.—With respect to plan years
 23 beginning on or after January 1, 2028, the Sec-
 24 retary shall publish reports, at least once every 2

1 years until 2034, and periodically thereafter, that
2 provide information, to the extent feasible, on—

3 “(A) trends in ingredient cost reimburse-
4 ment, dispensing fees, incentive payments and
5 other fees paid by PDP sponsors offering pre-
6 scription drug plans and MA organizations of-
7 fering MA–PD plans under this part to essen-
8 tial retail pharmacies (as defined in paragraph
9 (2)) with respect to the dispensing of covered
10 part D drugs, including a comparison of such
11 trends between essential retail pharmacies and
12 pharmacies that are not essential retail phar-
13 macies;

14 “(B) trends in amounts paid to PDP spon-
15 sors offering prescription drug plans and MA
16 organizations offering MA–PD plans under this
17 part by essential retail pharmacies with respect
18 to the dispensing of covered part D drugs, in-
19 cluding a comparison of such trends between
20 essential retail pharmacies and pharmacies that
21 are not essential retail pharmacies;

22 “(C) trends in essential retail pharmacy
23 participation in pharmacy networks and pre-
24 ferred pharmacy networks for prescription drug
25 plans offered by PDP sponsors and MA–PD

plans offered by MA organizations under this part, including a comparison of such trends between essential retail pharmacies and pharmacies that are not essential retail pharmacies;

“(D) trends in the number of essential retail pharmacies, including variation in such trends by geographic region or other factors;

“(E) a comparison of cost-sharing for covered part D drugs dispensed by essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations under this part and cost-sharing for covered part D drugs dispensed by other network pharmacies for such plans located in similar geographic areas that are not essential retail pharmacies;

“(F) a comparison of the volume of covered part D drugs dispensed by essential retail pharmacies that are network pharmacies for prescription drug plans offered by PDP sponsors and MA–PD plans offered by MA organizations under this part and such volume of dispensing by network pharmacies for such plans located in similar geographic areas that are not

1 essential retail pharmacies, including informa-
2 tion on any patterns or trends in such compari-
3 son specific to certain types of covered part D
4 drugs, such as generic drugs or drugs specified
5 as specialty drugs by a PDP sponsor under a
6 prescription drug plan or an MA organization
7 under an MA–PD plan; and

8 “(G) a comparison of the information de-
9 scribed in subparagraphs (A) through (F) be-
10 tween essential retail pharmacies that are net-
11 work pharmacies for prescription drug plans of-
12 fered by PDP sponsors under this part and es-
13 sential retail pharmacies that are network phar-
14 macies for MA–PD plans offered by MA organi-
15 zations under this part.

16 “(2) DEFINITION OF ESSENTIAL RETAIL PHAR-
17 MACY.—In this subsection, the term ‘essential retail
18 pharmacy’ means, with respect to a plan year, a re-
19 tail pharmacy that—

20 “(A) is not a pharmacy that is an affiliate
21 as defined in paragraph (4); and

22 “(B) is located in—

23 “(i) a medically underserved area (as
24 designated pursuant to section

1 330(b)(3)(A) of the Public Health Service
2 Act);

3 “(ii) a rural area in which there is no
4 other retail pharmacy within 10 miles, as
5 determined by the Secretary;

6 “(iii) a suburban area in which there
7 is no other retail pharmacy within 2 miles,
8 as determined by the Secretary; or

9 “(iv) an urban area in which there is
10 no other retail pharmacy within 1 mile, as
11 determined by the Secretary.

12 “(3) LIST OF ESSENTIAL RETAIL PHAR-
13 MACIES.—

14 “(A) PUBLICATION OF LIST OF ESSENTIAL
15 RETAIL PHARMACIES.—For each plan year (be-
16 ginning with plan year 2028), the Secretary
17 shall publish, on a publicly available internet
18 website of the Centers for Medicare & Medicaid
19 Services, a list of pharmacies that meet the cri-
20 teria described in subparagraphs (A) and (B) of
21 paragraph (2) to be considered an essential re-
22 tail pharmacy.

23 “(B) REQUIRED SUBMISSIONS FROM PDP
24 SPONSORS.—For each plan year (beginning
25 with plan year 2028), each PDP sponsor offer-

1 ing a prescription drug plan and each MA orga-
2 nization offering an MA–PD plan shall submit
3 to the Secretary, for the purposes of deter-
4 mining retail pharmacies that meet the criterion
5 specified in subparagraph (A) of paragraph (2),
6 a list of retail pharmacies that are affiliates of
7 such sponsor or organization, or are affiliates of
8 a pharmacy benefit manager acting on behalf of
9 such sponsor or organization, at a time, and in
10 a form and manner, specified by the Secretary.

11 “(C) REPORTING BY PDP SPONSORS AND
12 MA ORGANIZATIONS.—For each plan year be-
13 ginning with plan year 2027, each PDP sponsor
14 offering a prescription drug plan and each MA
15 organization offering an MA–PD plan under
16 this part shall submit to the Secretary informa-
17 tion on incentive payments and other fees paid
18 by such sponsor or organization to pharmacies,
19 insofar as any such payments or fees are not
20 otherwise reported, at a time, and in a form
21 and manner, specified by the Secretary.

22 “(D) IMPLEMENTATION.—Notwithstanding
23 any other provision of law, the Secretary may
24 implement this paragraph by program instruc-
25 tion or otherwise.

1 “(E) NONAPPLICATION OF PAPERWORK
2 REDUCTION ACT.—Chapter 35 of title 44,
3 United States Code, shall not apply to the im-
4 plementation of this paragraph.

5 “(4) DEFINITION OF AFFILIATE; PHARMACY
6 BENEFIT MANAGER.—In this subsection, the terms
7 ‘affiliate’ and ‘pharmacy benefit manager’ have the
8 meaning given those terms in section 1860D–
9 12(h)(7).”.

10 (c) ENFORCEMENT.—

11 (1) IN GENERAL.—Section 1860D–4(b)(1) of
12 the Social Security Act (42 U.S.C. 1395w–
13 104(b)(1)) is amended by adding at the end the fol-
14 lowing new subparagraph:

15 “(F) ENFORCEMENT OF STANDARDS FOR
16 REASONABLE AND RELEVANT CONTRACT TERMS
17 AND CONDITIONS.—

18 “(i) ALLEGATION SUBMISSION PROC-
19 ESS.—

20 “(I) IN GENERAL.—Not later
21 than January 1, 2028, the Secretary
22 shall establish a process through
23 which a pharmacy may submit to the
24 Secretary an allegation of a violation
25 by a PDP sponsor offering a prescrip-

1 tion drug plan of the standards for
2 reasonable and relevant contract
3 terms and conditions under subpara-
4 graph (A)(ii), or of subclause (VIII)
5 of this clause.

6 “(II) FREQUENCY OF SUBMIS-
7 SION.—

8 “(aa) IN GENERAL.—Except
9 as provided in item (bb), the alle-
10 gation submission process under
11 this clause shall allow pharmacies
12 to submit any allegations of vio-
13 lations described in subclause (I)
14 not more frequently than once
15 per plan year per contract be-
16 tween a pharmacy and a PDP
17 sponsor.

18 “(bb) ALLEGATIONS RELAT-
19 ING TO CONTRACT MODIFICA-
20 TIONS.—In the case where a con-
21 tract between a pharmacy and a
22 PDP sponsor is modified fol-
23 lowing the submission of allega-
24 tions by a pharmacy with respect
25 to such contract and plan year,

1 the allegation submission process
2 under this clause shall allow such
3 pharmacy to submit an additional
4 allegation related to those modi-
5 fications with respect to such
6 contract and plan year.

7 “(III) ACCESS TO RELEVANT
8 DOCUMENTS AND MATERIALS.—A
9 PDP sponsor subject to an allegation
10 under this clause—

11 “(aa) shall provide docu-
12 ments or materials, as specified
13 by the Secretary, including con-
14 tract offers made by such spon-
15 sor to such pharmacy or cor-
16 respondence related to such of-
17 fers, to the Secretary at a time,
18 and in a form and manner, speci-
19 fied by the Secretary; and

20 “(bb) shall not prohibit or
21 otherwise limit the ability of a
22 pharmacy to submit such docu-
23 ments or materials to the Sec-
24 retary for the purpose of submit-
25 ting an allegation or providing

1 evidence for such an allegation
2 under this clause.

3 “(IV) STANDARDIZED TEM-
4 PLATE.—The Secretary shall establish
5 a standardized template for phar-
6 macies to use for the submission of al-
7 legations described in subclause (I).
8 Such template shall require that the
9 submission include a certification by
10 the pharmacy that the information in-
11 cluded is accurate, complete, and true
12 to the best of the knowledge, informa-
13 tion, and belief of such pharmacy.

14 “(V) PREVENTING FRIVOLOUS
15 ALLEGATIONS.—In the case where the
16 Secretary determines that a pharmacy
17 has submitted frivolous allegations
18 under this clause on a routine basis,
19 the Secretary may temporarily pro-
20 hibit such pharmacy from using the
21 allegation submission process under
22 this clause, as determined appropriate
23 by the Secretary.

24 “(VI) EXEMPTION FROM FREE-
25 DOM OF INFORMATION ACT.—Allega-

1 tions submitted under this clause shall
2 be exempt from disclosure under sec-
3 tion 552 of title 5, United States
4 Code.

5 “(VII) RULE OF CONSTRUC-
6 TION.—Nothing in this clause shall be
7 construed as limiting the ability of a
8 pharmacy to pursue other legal ac-
9 tions or remedies, consistent with ap-
10 plicable Federal or State law, with re-
11 spect to a potential violation of a re-
12 quirement described in this subpara-
13 graph.

14 “(VIII) ANTI-RETALIATION AND
15 ANTI-COERCION.—Consistent with ap-
16 plicable Federal or State law, a PDP
17 sponsor shall not—

18 “(aa) retaliate against a
19 pharmacy for submitting any al-
20 legations under this clause; or

21 “(bb) coerce, intimidate,
22 threaten, or interfere with the
23 ability of a pharmacy to submit
24 any such allegations.

1 “(ii) INVESTIGATION.—The Secretary
2 shall investigate, as determined appro-
3 priate by the Secretary, allegations sub-
4 mitted pursuant to clause (i).

5 “(iii) ENFORCEMENT.—

6 “(I) IN GENERAL.—In the case
7 where the Secretary determines that a
8 PDP sponsor offering a prescription
9 drug plan has violated the standards
10 for reasonable and relevant contract
11 terms and conditions under subpara-
12 graph (A)(ii), the Secretary may use
13 authorities under sections 1857(g)
14 and 1860D–12(b)(3)(E) to impose
15 civil monetary penalties or other inter-
16 mediate sanctions.

17 “(II) APPLICATION OF CIVIL
18 MONETARY PENALTIES.—The provi-
19 sions of section 1128A (other than
20 subsections (a) and (b)) shall apply to
21 a civil monetary penalty under this
22 clause in the same manner as such
23 provisions apply to a penalty or pro-
24 ceeding under section 1128A(a).”.

1 (2) CONFORMING AMENDMENT.—Section
 2 1857(g)(1) of the Social Security Act (42 U.S.C.
 3 1395w–27(g)(1)) is amended—

4 (A) in subparagraph (J), by striking “or”
 5 after the semicolon;

6 (B) by redesignating subparagraph (K) as
 7 subparagraph (L);

8 (C) by inserting after subparagraph (J),
 9 the following new subparagraph:

10 “(K) fails to comply with the standards for
 11 reasonable and relevant contract terms and con-
 12 ditions under subparagraph (A)(ii) of section
 13 1860D–4(b)(1); or”;

14 (D) in subparagraph (L), as redesignated
 15 by subparagraph (B), by striking “through (J)”
 16 and inserting “through (K)”; and

17 (E) in the flush matter following subpara-
 18 graph (L), as so redesignated, by striking “sub-
 19 paragraphs (A) through (K)” and inserting
 20 “subparagraphs (A) through (L)”.

21 (d) ACCOUNTABILITY OF PHARMACY BENEFIT MAN-
 22 AGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT
 23 CONTRACT TERMS AND CONDITIONS.—

24 (1) IN GENERAL.—Section 1860D–12(b) of the
 25 Social Security Act (42 U.S.C. 1395w–112) is

1 amended by adding at the end the following new
2 paragraph:

3 “(9) ACCOUNTABILITY OF PHARMACY BENEFIT
4 MANAGERS FOR VIOLATIONS OF REASONABLE AND
5 RELEVANT CONTRACT TERMS AND CONDITIONS.—

6 For plan years beginning on or after January 1,
7 2028, each contract entered into with a PDP spon-
8 sor under this part with respect to a prescription
9 drug plan offered by such sponsor shall provide that
10 any pharmacy benefit manager acting on behalf of
11 such sponsor has a written agreement with the PDP
12 sponsor under which the pharmacy benefit manager
13 agrees to reimburse the PDP sponsor for any
14 amounts paid by such sponsor under section 1860D–
15 4(b)(1)(F)(iii)(I) to the Secretary as a result of a
16 violation described in such section if such violation
17 is related to a responsibility delegated to the phar-
18 macy benefit manager by such PDP sponsor.”.

19 (2) MA–PD PLANS.—Section 1857(f)(3) of the
20 Social Security Act (42 U.S.C. 1395w–27(f)(3)) is
21 amended by adding at the end the following new
22 subparagraph:

23 “(F) ACCOUNTABILITY OF PHARMACY
24 BENEFIT MANAGERS FOR VIOLATIONS OF REA-
25 SONABLE AND RELEVANT CONTRACT TERMS.—

1 For plan years beginning on or after January
2 1, 2028, section 1860D–12(b)(9).”.

3 (e) BIENNIAL REPORT ON ENFORCEMENT AND
4 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—
5 Section 1860D–42 of the Social Security Act (42 U.S.C.
6 1395w–152), as amended by subsection (b), is amended
7 by adding at the end the following new subsection:

8 “(f) BIENNIAL REPORT ON ENFORCEMENT AND
9 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

10 “(1) IN GENERAL.—Not later than 2 years
11 after the date of enactment of this subsection, and
12 at least once every 2 years thereafter, the Secretary
13 shall publish a report on enforcement and oversight
14 actions and activities undertaken by the Secretary
15 with respect to the requirements under section
16 1860D–4(b)(1).

17 “(2) LIMITATION.—A report under paragraph
18 (1) shall not disclose—

19 “(A) identifiable information about individ-
20 uals or entities unless such information is oth-
21 erwise publicly available; or

22 “(B) trade secrets with respect to any enti-
23 ties.”.

24 (f) FUNDING.—In addition to amounts otherwise
25 available, there is appropriated to the Centers for Medi-

1 care & Medicaid Services Program Management Account,
 2 out of any money in the Treasury not otherwise appro-
 3 priated, \$188,000,000 for fiscal year 2025, to remain
 4 available until expended, to carry out this section.

5 **SEC. 3. MODERNIZING AND ENSURING PBM ACCOUNT-**
 6 **ABILITY.**

7 (a) IN GENERAL.—

8 (1) PRESCRIPTION DRUG PLANS.—Section
 9 1860D–12 of the Social Security Act (42 U.S.C.
 10 1395w–112) is amended by adding at the end the
 11 following new subsection:

12 “(h) REQUIREMENTS RELATING TO PHARMACY BEN-
 13 EFIT MANAGERS.—For plan years beginning on or after
 14 January 1, 2028:

15 “(1) AGREEMENTS WITH PHARMACY BENEFIT
 16 MANAGERS.—Each contract entered into with a
 17 PDP sponsor under this part with respect to a pre-
 18 scription drug plan offered by such sponsor shall
 19 provide that any pharmacy benefit manager acting
 20 on behalf of such sponsor has a written agreement
 21 with the PDP sponsor under which the pharmacy
 22 benefit manager, and any affiliates of such phar-
 23 macy benefit manager, as applicable, agree to meet
 24 the following requirements:

1 “(A) NO INCOME OTHER THAN BONA FIDE
2 SERVICE FEES.—

3 “(i) IN GENERAL.—The pharmacy
4 benefit manager and any affiliate of such
5 pharmacy benefit manager shall not derive
6 any remuneration with respect to any serv-
7 ices provided on behalf of any entity or in-
8 dividual, in connection with the utilization
9 of covered part D drugs, from any such en-
10 tity or individual other than bona fide serv-
11 ice fees, subject to clauses (ii) and (iii).

12 “(ii) INCENTIVE PAYMENTS.—For the
13 purposes of this subsection, an incentive
14 payment (as determined by the Secretary)
15 paid by a PDP sponsor to a pharmacy
16 benefit manager that is performing serv-
17 ices on behalf of such sponsor shall be
18 deemed a ‘bona fide service fee’ (even if
19 such payment does not otherwise meet the
20 definition of such term under paragraph
21 (7)(B)) if such payment is a flat dollar
22 amount, is consistent with fair market
23 value (as specified by the Secretary), is re-
24 lated to services actually performed by the
25 pharmacy benefit manager or affiliate of

1 such pharmacy benefit manager, on behalf
2 of the PDP sponsor making such payment,
3 in connection with the utilization of cov-
4 ered part D drugs, and meets additional
5 requirements, if any, as determined appro-
6 priate by the Secretary.

7 “(iii) CLARIFICATION ON REBATES
8 AND DISCOUNTS USED TO LOWER COSTS
9 FOR COVERED PART D DRUGS.—Rebates,
10 discounts, and other price concessions re-
11 ceived by a pharmacy benefit manager or
12 an affiliate of a pharmacy benefit manager
13 from manufacturers, even if such price
14 concessions are calculated as a percentage
15 of a drug’s price, shall not be considered a
16 violation of the requirements of clause (i)
17 if they are fully passed through to a PDP
18 sponsor and are compliant with all regu-
19 latory and subregulatory requirements re-
20 lated to direct and indirect remuneration
21 for manufacturer rebates under this part,
22 including in cases where a PDP sponsor is
23 acting as a pharmacy benefit manager on
24 behalf of a prescription drug plan offered
25 by such PDP sponsor.

“(iv) EVALUATION OF REMUNERATION
ARRANGEMENTS.—Components of subsets
of remuneration arrangements (such as
fees or other forms of compensation paid
to or retained by the pharmacy benefit
manager or affiliate of such pharmacy ben-
efit manager), as determined appropriate
by the Secretary, between pharmacy ben-
efit managers or affiliates of such phar-
macy benefit managers, as applicable, and
other entities involved in the dispensing or
utilization of covered part D drugs (includ-
ing PDP sponsors, manufacturers, and
pharmacies) shall be subject to review by
the Secretary, in consultation with the Of-
fice of the Inspector General of the De-
partment of Health and Human Services,
as determined appropriate by the Sec-
retary. The Secretary, in consultation with
the Office of the Inspector General, shall
review whether remuneration under such
arrangements is consistent with fair mar-
ket value (as specified by the Secretary)
through reviews and assessments of such
remuneration, as determined appropriate.

1 “(v) DISGORGEMENT.—The pharmacy
2 benefit manager shall disgorge any remuneration paid to such pharmacy benefit
3 manager or an affiliate of such pharmacy
4 benefit manager in violation of this sub-
5 paragraph to the PDP sponsor.
6

7 “(vi) ADDITIONAL REQUIREMENTS.—
8 The pharmacy benefit manager shall—

9 “(I) enter into a written agree-
10 ment with any affiliate of such pharmacy benefit manager, under which
11 the affiliate shall identify and disgorge
12 any remuneration described in clause
13 (v) to the pharmacy benefit manager;
14 and
15

16 “(II) attest, subject to any re-
17 quirements determined appropriate by
18 the Secretary, that the pharmacy ben-
19 efit manager has entered into a writ-
20 ten agreement described in subclause
21 (I) with any relevant affiliate of the
22 pharmacy benefit manager.

23 “(B) TRANSPARENCY REGARDING GUARAN-
24 TEES AND COST PERFORMANCE EVALUA-
25 TIONS.—The pharmacy benefit manager shall—

1 “(i) define, interpret, and apply, in a
2 fully transparent and consistent manner
3 for purposes of calculating or otherwise
4 evaluating pharmacy benefit manager per-
5 formance against pricing guarantees or
6 similar cost performance measurements re-
7 lated to rebates, discounts, price conces-
8 sions, or net costs, terms such as—

9 “(I) ‘generic drug’, in a manner
10 consistent with the definition of the
11 term under section 423.4 of title 42,
12 Code of Federal Regulations, or a suc-
13 cessor regulation;

14 “(II) ‘brand name drug’, in a
15 manner consistent with the definition
16 of the term under section 423.4 of
17 title 42, Code of Federal Regulations,
18 or a successor regulation;

19 “(III) ‘specialty drug’;

20 “(IV) ‘rebate’; and

21 “(V) ‘discount’;

22 “(ii) identify any drugs, claims, or
23 price concessions excluded from any pric-
24 ing guarantee or other cost performance

1 measure in a clear and consistent manner;
2 and

3 “(iii) where a pricing guarantee or
4 other cost performance measure is based
5 on a pricing benchmark other than the
6 wholesale acquisition cost (as defined in
7 section 1847A(c)(6)(B)) of a drug, cal-
8 culate and provide a wholesale acquisition
9 cost-based equivalent to the pricing guar-
10 antee or other cost performance measure.

11 “(C) PROVISION OF INFORMATION.—

12 “(i) IN GENERAL.—Not later than
13 July 1 of each year, beginning in 2028, the
14 pharmacy benefit manager shall submit to
15 the PDP sponsor, and to the Secretary, a
16 report, in accordance with this subpara-
17 graph, and shall make such report avail-
18 able to such sponsor at no cost to such
19 sponsor in a format specified by the Sec-
20 retary under paragraph (5). Each such re-
21 port shall include, with respect to such
22 PDP sponsor and each plan offered by
23 such sponsor, the following information
24 with respect to the previous plan year:

1 “(I) A list of all drugs covered by
2 the plan that were dispensed includ-
3 ing, with respect to each such drug—

4 “(aa) the brand name, ge-
5 neric or non-proprietary name,
6 and National Drug Code;

7 “(bb) the number of plan
8 enrollees for whom the drug was
9 dispensed, the total number of
10 prescription claims for the drug
11 (including original prescriptions
12 and refills, counted as separate
13 claims), and the total number of
14 dosage units of the drug dis-
15 pensed;

16 “(cc) the number of pre-
17 scription claims described in item
18 (bb) by each type of dispensing
19 channel through which the drug
20 was dispensed, including retail,
21 mail order, specialty pharmacy,
22 long-term care pharmacy, home
23 infusion pharmacy, or other types
24 of pharmacies or providers;

1 “(dd) the average wholesale
2 acquisition cost, listed as cost per
3 day’s supply, cost per dosage
4 unit, and cost per typical course
5 of treatment (as applicable);

6 “(ee) the average wholesale
7 price for the drug, listed as price
8 per day’s supply, price per dos-
9 age unit, and price per typical
10 course of treatment (as applica-
11 ble);

12 “(ff) the total out-of-pocket
13 spending by plan enrollees on
14 such drug after application of
15 any benefits under the plan, in-
16 cluding plan enrollee spending
17 through copayments, coinsurance,
18 and deductibles;

19 “(gg) total rebates paid by
20 the manufacturer on the drug as
21 reported under the Detailed DIR
22 Report (or any successor report)
23 submitted by such sponsor to the
24 Centers for Medicare & Medicaid
25 Services;

1 “(hh) all other direct or in-
2 direct remuneration on the drug
3 as reported under the Detailed
4 DIR Report (or any successor re-
5 port) submitted by such sponsor
6 to the Centers for Medicare &
7 Medicaid Services;

8 “(ii) the average pharmacy
9 reimbursement amount paid by
10 the plan for the drug in the ag-
11 gregate and disaggregated by dis-
12 pensing channel identified in item
13 (cc);

14 “(jj) the average National
15 Average Drug Acquisition Cost
16 (NADAC); and

17 “(kk) total manufacturer-de-
18 rived revenue, inclusive of bona
19 fide service fees, attributable to
20 the drug and retained by the
21 pharmacy benefit manager and
22 any affiliate of such pharmacy
23 benefit manager.

24 “(II) In the case of a pharmacy
25 benefit manager that has an affiliate

1 that is a retail, mail order, or spe-
2 cialty pharmacy, with respect to drugs
3 covered by such plan that were dis-
4 pensed, the following information:

5 “(aa) The percentage of
6 total prescriptions that were dis-
7 pensed by pharmacies that are an
8 affiliate of the pharmacy benefit
9 manager for each drug.

10 “(bb) The interquartile
11 range of the total combined costs
12 paid by the plan and plan enroll-
13 ees, per dosage unit, per course
14 of treatment, per 30-day supply,
15 and per 90-day supply for each
16 drug dispensed by pharmacies
17 that are not an affiliate of the
18 pharmacy benefit manager and
19 that are included in the phar-
20 macy network of such plan.

21 “(cc) The interquartile
22 range of the total combined costs
23 paid by the plan and plan enroll-
24 ees, per dosage unit, per course
25 of treatment, per 30-day supply,

1 and per 90-day supply for each
2 drug dispensed by pharmacies
3 that are an affiliate of the phar-
4 macy benefit manager and that
5 are included in the pharmacy
6 network of such plan.

7 “(dd) The lowest total com-
8 bined cost paid by the plan and
9 plan enrollees, per dosage unit,
10 per course of treatment, per 30-
11 day supply, and per 90-day sup-
12 ply, for each drug that is avail-
13 able from any pharmacy included
14 in the pharmacy network of such
15 plan.

16 “(ee) The difference between
17 the average acquisition cost of
18 the affiliate, such as a pharmacy
19 or other entity that acquires pre-
20 scription drugs, that initially ac-
21 quires the drug and the amount
22 reported under subclause (I)(jj)
23 for each drug.

24 “(ff) A list inclusive of the
25 brand name, generic or non-pro-

1 proprietary name, and National
2 Drug Code of covered part D
3 drugs subject to an agreement
4 with a covered entity under sec-
5 tion 340B of the Public Health
6 Service Act for which the phar-
7 macy benefit manager or an affil-
8 iate of the pharmacy benefit
9 manager had a contract or other
10 arrangement with such a covered
11 entity in the service area of such
12 plan.

13 “(III) Where a drug approved
14 under section 505(c) of the Federal
15 Food, Drug, and Cosmetic Act (re-
16 ferred to in this subclause as the ‘list-
17 ed drug’) is covered by the plan, the
18 following information:

19 “(aa) A list of currently
20 marketed generic drugs approved
21 under section 505(j) of the Fed-
22 eral Food, Drug, and Cosmetic
23 Act pursuant to an application
24 that references such listed drug
25 that are not covered by the plan,

1 are covered on the same for-
2 mulary tier or a formulary tier
3 typically associated with higher
4 cost-sharing than the listed drug,
5 or are subject to utilization man-
6 agement that the listed drug is
7 not subject to.

8 “(bb) The estimated average
9 beneficiary cost-sharing under
10 the plan for a 30-day supply of
11 the listed drug.

12 “(cc) Where a generic drug
13 listed under item (aa) is on a for-
14 mulary tier typically associated
15 with higher cost-sharing than the
16 listed drug, the estimated aver-
17 age cost-sharing that a bene-
18 ficiary would have paid for a 30-
19 day supply of each of the generic
20 drugs described in item (aa), had
21 the plan provided coverage for
22 such drugs on the same for-
23 mulary tier as the listed drug.

24 “(dd) A written justification
25 for providing more favorable cov-

1 erage of the listed drug than the
2 generic drugs described in item
3 (aa).

4 “(ee) The number of cur-
5 rently marketed generic drugs
6 approved under section 505(j) of
7 the Federal Food, Drug, and
8 Cosmetic Act pursuant to an ap-
9 plication that references such
10 listed drug.

11 “(IV) Where a reference product
12 (as defined in section 351(i) of the
13 Public Health Service Act) is covered
14 by the plan, the following information:

15 “(aa) A list of currently
16 marketed biosimilar biological
17 products licensed under section
18 351(k) of the Public Health
19 Service Act pursuant to an appli-
20 cation that refers to such ref-
21 erence product that are not cov-
22 ered by the plan, are covered on
23 the same formulary tier or a for-
24 mulary tier typically associated
25 with higher cost-sharing than the

1 reference product, or are subject
2 to utilization management that
3 the reference product is not sub-
4 ject to.

5 “(bb) The estimated average
6 beneficiary cost-sharing under
7 the plan for a 30-day supply of
8 the reference product.

9 “(cc) Where a biosimilar bi-
10 ological product listed under item
11 (aa) is on a formulary tier typi-
12 cally associated with higher cost-
13 sharing than the reference prod-
14 uct, the estimated average cost-
15 sharing that a beneficiary would
16 have paid for a 30-day supply of
17 each of the biosimilar biological
18 products described in item (aa),
19 had the plan provided coverage
20 for such products on the same
21 formulary tier as the reference
22 product.

23 “(dd) A written justification
24 for providing more favorable cov-
25 erage of the reference product

1 than the biosimilar biological
2 product described in item (aa).

3 “(ee) The number of cur-
4 rently marketed biosimilar bio-
5 logical products licensed under
6 section 351(k) of the Public
7 Health Service Act, pursuant to
8 an application that refers to such
9 reference product.

10 “(V) Total gross spending on
11 covered part D drugs by the plan, not
12 net of rebates, fees, discounts, or
13 other direct or indirect remuneration.

14 “(VI) The total amount retained
15 by the pharmacy benefit manager or
16 an affiliate of such pharmacy benefit
17 manager in revenue related to utiliza-
18 tion of covered part D drugs under
19 that plan, inclusive of bona fide serv-
20 ice fees.

21 “(VII) The total spending on cov-
22 ered part D drugs net of rebates, fees,
23 discounts, or other direct and indirect
24 remuneration by the plan.

1 “(VIII) An explanation of any
2 benefit design parameters under such
3 plan that encourage plan enrollees to
4 fill prescriptions at pharmacies that
5 are an affiliate of such pharmacy ben-
6 efit manager, such as mail and spe-
7 cialty home delivery programs, and re-
8 tail and mail auto-refill programs.

9 “(IX) The following information:

10 “(aa) A list of all brokers,
11 consultants, advisors, and audi-
12 tors that receive compensation
13 from the pharmacy benefit man-
14 ager or an affiliate of such phar-
15 macy benefit manager for refer-
16 rals, consulting, auditing, or
17 other services offered to PDP
18 sponsors related to pharmacy
19 benefit management services.

20 “(bb) The amount of com-
21 pensation provided by such phar-
22 macy benefit manager or affiliate
23 to each such broker, consultant,
24 advisor, and auditor.

1 “(cc) The methodology for
2 calculating the amount of com-
3 pensation provided by such phar-
4 macy benefit manager or affil-
5 iate, for each such broker, con-
6 sultant, advisor, and auditor.

7 “(X) A list of all affiliates of the
8 pharmacy benefit manager.

9 “(XI) A summary document sub-
10 mitted in a standardized template de-
11 veloped by the Secretary that includes
12 such information described in sub-
13 clauses (I) through (X).

14 “(ii) WRITTEN EXPLANATION OF CON-
15 TRACTS OR AGREEMENTS WITH DRUG
16 MANUFACTURERS.—

17 “(I) IN GENERAL.—The phar-
18 macy benefit manager shall, not later
19 than 30 days after the finalization of
20 any contract or agreement between
21 such pharmacy benefit manager or an
22 affiliate of such pharmacy benefit
23 manager and a drug manufacturer (or
24 subsidiary, agent, or entity affiliated
25 with such drug manufacturer) that

1 makes rebates, discounts, payments,
2 or other financial incentives related to
3 one or more covered part D drugs or
4 other prescription drugs, as applica-
5 ble, of the manufacturer directly or
6 indirectly contingent upon coverage,
7 formulary placement, or utilization
8 management conditions on any other
9 covered part D drugs or other pre-
10 scription drugs, as applicable, submit
11 to the PDP sponsor a written expla-
12 nation of such contract or agreement.

13 “(II) REQUIREMENTS.—A writ-
14 ten explanation under subclause (I)
15 shall—

16 “(aa) include the manufac-
17 turer subject to the contract or
18 agreement, all covered part D
19 drugs and other prescription
20 drugs, as applicable, subject to
21 the contract or agreement and
22 the manufacturers of such drugs,
23 and a high-level description of
24 the terms of such contract or

1 agreement and how such terms
2 apply to such drugs; and

3 “(bb) be certified by the
4 Chief Executive Officer, Chief Fi-
5 nancial Officer, or General Coun-
6 sel of such pharmacy benefit
7 manager, or affiliate of such
8 pharmacy benefit manager, as
9 applicable, or an individual dele-
10 gated with the authority to sign
11 on behalf of one of these officers,
12 who reports directly to the offi-
13 cer.

14 “(III) DEFINITION OF OTHER
15 PRESCRIPTION DRUGS.—For purposes
16 of this clause, the term ‘other pre-
17 scription drugs’ means prescription
18 drugs covered as supplemental bene-
19 fits under this part or prescription
20 drugs paid outside of this part.

21 “(D) AUDIT RIGHTS.—

22 “(i) IN GENERAL.—Not less than once
23 a year, at the request of the PDP sponsor,
24 the pharmacy benefit manager shall allow
25 for an audit of the pharmacy benefit man-

1 ager to ensure compliance with all terms
2 and conditions under the written agree-
3 ment described in this paragraph and the
4 accuracy of information reported under
5 subparagraph (C).

6 “(ii) AUDITOR.—The PDP sponsor
7 shall have the right to select an auditor.
8 The pharmacy benefit manager shall not
9 impose any limitations on the selection of
10 such auditor.

11 “(iii) PROVISION OF INFORMATION.—
12 The pharmacy benefit manager shall make
13 available to such auditor all records, data,
14 contracts, and other information necessary
15 to confirm the accuracy of information
16 provided under subparagraph (C), subject
17 to reasonable restrictions on how such in-
18 formation must be reported to prevent re-
19 disclosure of such information.

20 “(iv) TIMING.—The pharmacy benefit
21 manager must provide information under
22 clause (iii) and other information, data,
23 and records relevant to the audit to such
24 auditor within 6 months of the initiation of
25 the audit and respond to requests for addi-

1 tional information from such auditor with-
2 in 30 days after the request for additional
3 information.

4 “(v) INFORMATION FROM AFFILI-
5 ATES.—The pharmacy benefit manager
6 shall be responsible for providing to such
7 auditor information required to be reported
8 under subparagraph (C) or under clause
9 (iii) of this subparagraph that is owned or
10 held by an affiliate of such pharmacy ben-
11 efit manager.

12 “(2) ENFORCEMENT.—

13 “(A) IN GENERAL.—Each PDP sponsor
14 shall—

15 “(i) disgorge to the Secretary any
16 amounts disgorged to the PDP sponsor by
17 a pharmacy benefit manager under para-
18 graph (1)(A)(v);

19 “(ii) require, in a written agreement
20 with any pharmacy benefit manager acting
21 on behalf of such sponsor or affiliate of
22 such pharmacy benefit manager, that such
23 pharmacy benefit manager or affiliate re-
24 imburse the PDP sponsor for any civil
25 money penalty imposed on the PDP spon-

1 sor as a result of the failure of the phar-
2 macy benefit manager or affiliate to meet
3 the requirements of paragraph (1) that are
4 applicable to the pharmacy benefit man-
5 ager or affiliate under the agreement; and

6 “(iii) require, in a written agreement
7 with any such pharmacy benefit manager
8 acting on behalf of such sponsor or affil-
9 iate of such pharmacy benefit manager,
10 that such pharmacy benefit manager or af-
11 filiate be subject to punitive remedies for
12 breach of contract for failure to comply
13 with the requirements applicable under
14 paragraph (1).

15 “(B) REPORTING OF ALLEGED VIOLA-
16 TIONS.—The Secretary shall make available and
17 maintain a mechanism for manufacturers, PDP
18 sponsors, pharmacies, and other entities that
19 have contractual relationships with pharmacy
20 benefit managers or affiliates of such pharmacy
21 benefit managers to report, on a confidential
22 basis, alleged violations of paragraph (1)(A) or
23 subparagraph (C).

1 “(C) ANTI-RETALIATION AND ANTI-COER-
2 CION.—Consistent with applicable Federal or
3 State law, a PDP sponsor shall not—

4 “(i) retaliate against an individual or
5 entity for reporting an alleged violation
6 under subparagraph (B); or

7 “(ii) coerce, intimidate, threaten, or
8 interfere with the ability of an individual
9 or entity to report any such alleged viola-
10 tions.

11 “(3) CERTIFICATION OF COMPLIANCE.—

12 “(A) IN GENERAL.—Each PDP sponsor
13 shall furnish to the Secretary (at a time and in
14 a manner specified by the Secretary) an annual
15 certification of compliance with this subsection,
16 as well as such information as the Secretary de-
17 termines necessary to carry out this subsection.

18 “(B) IMPLEMENTATION.—The Secretary
19 may implement this paragraph by program in-
20 struction or otherwise.

21 “(4) RULE OF CONSTRUCTION.—Nothing in
22 this subsection shall be construed as—

23 “(A) prohibiting flat dispensing fees or re-
24 imbursement or payment for ingredient costs
25 (including customary, industry-standard dis-

1 counts directly related to drug acquisition that
2 are retained by pharmacies or wholesalers) to
3 entities that acquire or dispense prescription
4 drugs; or

5 “(B) modifying regulatory requirements or
6 sub-regulatory program instruction or guidance
7 related to pharmacy payment, reimbursement,
8 or dispensing fees.

9 “(5) STANDARD FORMATS.—

10 “(A) IN GENERAL.—Not later than June
11 1, 2027, the Secretary shall specify standard,
12 machine-readable formats for pharmacy benefit
13 managers to submit annual reports required
14 under paragraph (1)(C)(i).

15 “(B) IMPLEMENTATION.—The Secretary
16 may implement this paragraph by program in-
17 struction or otherwise.

18 “(6) CONFIDENTIALITY.—

19 “(A) IN GENERAL.—Information disclosed
20 by a pharmacy benefit manager, an affiliate of
21 a pharmacy benefit manager, a PDP sponsor,
22 or a pharmacy under this subsection that is not
23 otherwise publicly available or available for pur-
24 chase shall not be disclosed by the Secretary or
25 a PDP sponsor receiving the information, ex-

cept that the Secretary may disclose the information for the following purposes:

“(i) As the Secretary determines necessary to carry out this part.

“(ii) To permit the Comptroller General to review the information provided.

“(iii) To permit the Director of the Congressional Budget Office to review the information provided.

“(iv) To permit the Executive Director of the Medicare Payment Advisory Commission to review the information provided.

“(v) To the Attorney General for the purposes of conducting oversight and enforcement under this title.

“(vi) To the Inspector General of the Department of Health and Human Services in accordance with its authorities under the Inspector General Act of 1978 (section 406 of title 5, United States Code), and other applicable statutes.

“(B) RESTRICTION ON USE OF INFORMATION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Of-

1 fice, and the Executive Director of the Medicare
2 Payment Advisory Commission shall not report
3 on or disclose information disclosed pursuant to
4 subparagraph (A) to the public in a manner
5 that would identify—

6 “(i) a specific pharmacy benefit man-
7 ager, affiliate, pharmacy, manufacturer,
8 wholesaler, PDP sponsor, or plan; or

9 “(ii) contract prices, rebates, dis-
10 counts, or other remuneration for specific
11 drugs in a manner that may allow the
12 identification of specific contracting parties
13 or of such specific drugs.

14 “(7) DEFINITIONS.—For purposes of this sub-
15 section:

16 “(A) AFFILIATE.—The term ‘affiliate’
17 means, with respect to any pharmacy benefit
18 manager or PDP sponsor, any entity that, di-
19 rectly or indirectly—

20 “(i) owns or is owned by, controls or
21 is controlled by, or is otherwise related in
22 any ownership structure to such pharmacy
23 benefit manager or PDP sponsor; or

24 “(ii) acts as a contractor, principal, or
25 agent to such pharmacy benefit manager

1 or PDP sponsor, insofar as such con-
2 tractor, principal, or agent performs any of
3 the functions described under subpara-
4 graph (C).

5 “(B) BONA FIDE SERVICE FEE.—The term
6 ‘bona fide service fee’ means a fee that is reflec-
7 tive of the fair market value (as specified by the
8 Secretary, through notice and comment rule-
9 making) for a bona fide, itemized service actu-
10 ally performed on behalf of an entity, that the
11 entity would otherwise perform (or contract for)
12 in the absence of the service arrangement and
13 that is not passed on in whole or in part to a
14 client or customer, whether or not the entity
15 takes title to the drug. Such fee must be a flat
16 dollar amount and shall not be directly or indi-
17 rectly based on, or contingent upon—

18 “(i) drug price, such as wholesale ac-
19 quisition cost or drug benchmark price
20 (such as average wholesale price);

21 “(ii) the amount of discounts, rebates,
22 fees, or other direct or indirect remunera-
23 tion with respect to covered part D drugs
24 dispensed to enrollees in a prescription

1 drug plan, except as permitted pursuant to
2 paragraph (1)(A)(ii);

3 “(iii) coverage or formulary placement
4 decisions or the volume or value of any re-
5 ferrals or business generated between the
6 parties to the arrangement; or

7 “(iv) any other amounts or meth-
8 odologies prohibited by the Secretary.

9 “(C) PHARMACY BENEFIT MANAGER.—The
10 term ‘pharmacy benefit manager’ means any
11 person or entity that, either directly or through
12 an intermediary, acts as a price negotiator or
13 group purchaser on behalf of a PDP sponsor or
14 prescription drug plan, or manages the pre-
15 scription drug benefits provided by such spon-
16 sor or plan, including the processing and pay-
17 ment of claims for prescription drugs, the per-
18 formance of drug utilization review, the proc-
19 essing of drug prior authorization requests, the
20 adjudication of appeals or grievances related to
21 the prescription drug benefit, contracting with
22 network pharmacies, controlling the cost of cov-
23 ered part D drugs, or the provision of related
24 services. Such term includes any person or enti-
25 ty that carries out one or more of the activities

1 described in the preceding sentence, irrespective
2 of whether such person or entity calls itself a
3 ‘pharmacy benefit manager’.”.

4 (2) MA–PD PLANS.—Section 1857(f)(3) of the
5 Social Security Act (42 U.S.C. 1395w–27(f)(3)) is
6 amended by adding at the end the following new
7 subparagraph:

8 “(F) REQUIREMENTS RELATING TO PHAR-
9 MACY BENEFIT MANAGERS.—For plan years be-
10 ginning on or after January 1, 2028, section
11 1860D–12(h).”.

12 (3) NONAPPLICATION OF PAPERWORK REDUC-
13 TION ACT.—Chapter 35 of title 44, United States
14 Code, shall not apply to the implementation of this
15 subsection.

16 (4) FUNDING.—

17 (A) SECRETARY.—In addition to amounts
18 otherwise available, there is appropriated to the
19 Centers for Medicare & Medicaid Services Pro-
20 gram Management Account, out of any money
21 in the Treasury not otherwise appropriated,
22 \$113,000,000 for fiscal year 2025, to remain
23 available until expended, to carry out this sub-
24 section.

1 (B) OIG.—In addition to amounts other-
2 wise available, there is appropriated to the In-
3 spector General of the Department of Health
4 and Human Services, out of any money in the
5 Treasury not otherwise appropriated,
6 \$20,000,000 for fiscal year 2025, to remain
7 available until expended, to carry out this sub-
8 section.

9 (b) GAO STUDY AND REPORT ON PRICE-RELATED
10 COMPENSATION ACROSS THE SUPPLY CHAIN.—

11 (1) STUDY.—The Comptroller General of the
12 United States (in this subsection referred to as the
13 “Comptroller General”) shall conduct a study de-
14 scribing the use of compensation and payment struc-
15 tures related to a prescription drug’s price within
16 the retail prescription drug supply chain in part D
17 of title XVIII of the Social Security Act (42 U.S.C.
18 1395w–101 et seq.). Such study shall summarize in-
19 formation from Federal agencies and industry ex-
20 perts, to the extent available, with respect to the fol-
21 lowing:

22 (A) The type, magnitude, other features
23 (such as the pricing benchmarks used), and
24 prevalence of compensation and payment struc-
25 tures related to a prescription drug’s price,

1 such as calculating fee amounts as a percentage
2 of a prescription drug's price, between inter-
3 mediaries in the prescription drug supply chain,
4 including—

5 (i) pharmacy benefit managers;

6 (ii) PDP sponsors offering prescrip-
7 tion drug plans and Medicare Advantage
8 organizations offering MA–PD plans;

9 (iii) drug wholesalers;

10 (iv) pharmacies;

11 (v) manufacturers;

12 (vi) pharmacy services administrative
13 organizations;

14 (vii) brokers, auditors, consultants,
15 and other entities that—

16 (I) advise PDP sponsors offering
17 prescription drug plans and Medicare
18 Advantage organizations offering MA–
19 PD plans regarding pharmacy bene-
20 fits; or

21 (II) review PDP sponsor and
22 Medicare Advantage organization con-
23 tracts with pharmacy benefit man-
24 agers; and

1 (viii) other service providers that con-
2 tract with any of the entities described in
3 clauses (i) through (vii) that may use
4 price-related compensation and payment
5 structures, such as rebate aggregators (or
6 other entities that negotiate or process
7 price concessions on behalf of pharmacy
8 benefit managers, plan sponsors, or phar-
9 macies).

10 (B) The primary business models and com-
11 pensation structures for each category of inter-
12 mediary described in subparagraph (A).

13 (C) Variation in price-related compensation
14 structures between affiliated entities (such as
15 entities with common ownership, either full or
16 partial, and subsidiary relationships) and unaf-
17 filiated entities.

18 (D) Potential conflicts of interest among
19 contracting entities related to the use of pre-
20 scription drug price-related compensation struc-
21 tures, such as the potential for fees or other
22 payments set as a percentage of a prescription
23 drug's price to advantage formulary selection,
24 distribution, or purchasing of prescription drugs
25 with higher prices.

1 (E) Notable differences, if any, in the use
2 and level of price-based compensation struc-
3 tures over time and between different market
4 segments, such as under part D of title XVIII
5 of the Social Security Act (42 U.S.C. 1395w-
6 101 et seq.) and the Medicaid program under
7 title XIX of such Act (42 U.S.C. 1396 et seq.).

8 (F) The effects of drug price-related com-
9 pensation structures and alternative compensa-
10 tion structures on Federal health care programs
11 and program beneficiaries, including with re-
12 spect to cost-sharing, premiums, Federal out-
13 lays, biosimilar and generic drug adoption and
14 utilization, drug shortage risks, and the poten-
15 tial for fees set as a percentage of a drug's
16 price to advantage the formulary selection, dis-
17 tribution, or purchasing of drugs with higher
18 prices.

19 (G) Other issues determined to be relevant
20 and appropriate by the Comptroller General.

21 (2) REPORT.—Not later than 2 years after the
22 date of enactment of this section, the Comptroller
23 General shall submit to Congress a report containing
24 the results of the study conducted under paragraph
25 (1), together with recommendations for such legisla-

1 tion and administrative action as the Comptroller
2 General determines appropriate.

3 (c) MEDPAC REPORTS ON AGREEMENTS WITH
4 PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE-
5 SCRIPTION DRUG PLANS AND MA–PD PLANS.—

6 (1) IN GENERAL.—The Medicare Payment Ad-
7 visory Commission shall submit to Congress the fol-
8 lowing reports:

9 (A) INITIAL REPORT.—Not later than the
10 first March 15 occurring after the date that is
11 2 years after the date on which the Secretary
12 makes the data available to the Commission, a
13 report regarding agreements with pharmacy
14 benefit managers with respect to prescription
15 drug plans and MA–PD plans. Such report
16 shall include, to the extent practicable—

17 (i) a description of trends and pat-
18 terns, including relevant averages, totals,
19 and other figures for the types of informa-
20 tion submitted;

21 (ii) an analysis of any differences in
22 agreements and their effects on plan en-
23 rollee out-of-pocket spending and average
24 pharmacy reimbursement, and other im-
25 pacts; and

1 (iii) any recommendations the Com-
2 mission determines appropriate.

3 (B) FINAL REPORT.—Not later than 2
4 years after the date on which the Commission
5 submits the initial report under subparagraph
6 (A), a report describing any changes with re-
7 spect to the information described in subpara-
8 graph (A) over time, together with any rec-
9 ommendations the Commission determines ap-
10 propriate.

11 (2) FUNDING.—In addition to amounts other-
12 wise available, there is appropriated to the Medicare
13 Payment Advisory Commission, out of any money in
14 the Treasury not otherwise appropriated,
15 \$1,000,000 for fiscal year 2025, to remain available
16 until expended, to carry out this subsection.

17 **SEC. 4. OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT**
18 **SERVICES.**

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

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

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

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

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

23 “(2) provide the entity providing pharmacy ben-
24 efit management services on behalf of a group health
25 plan or health insurance issuer relevant information

1 necessary to make the reports described in sub-
2 section (b).

3 “(b) REPORTS.—

4 “(1) IN GENERAL.—For plan years beginning
5 on or after the effective date, in the case of any con-
6 tract between a group health plan or a health insur-
7 ance issuer offering group health insurance coverage
8 offered in connection with such a plan and an entity
9 providing pharmacy benefit management services on
10 behalf of such plan or issuer, including an extension
11 or renewal of such a contract, entered into on or
12 after the effective date, the entity providing phar-
13 macy benefit management services on behalf of such
14 a group health plan or health insurance issuer, not
15 less frequently than every 6 months (or, at the re-
16 quest of a group health plan, not less frequently
17 than quarterly, and under the same conditions,
18 terms, and cost of the semiannual report under this
19 subsection), shall submit to the group health plan a
20 report in accordance with this section. Each such re-
21 port shall be made available to such group health
22 plan in plain language, in a machine-readable for-
23 mat, and as the Secretary may determine, other for-
24 mats. Each such report shall include the information
25 described in paragraph (2).

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

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

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

18 “(I) the contracted compensation
19 paid by the group health plan or
20 health insurance issuer for each cov-
21 ered drug (identified by the National
22 Drug Code) to the entity providing
23 pharmacy benefit management serv-
24 ices or other applicable entity on be-

1 half of the group health plan or health
2 insurance issuer;

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 or health insurance issuer, for
9 each covered drug (identified by the
10 National Drug Code);

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

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

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

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

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

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

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

22 “(bb) the total number of—
23 “(AA) prescription
24 claims (including original
25 prescriptions and refills);

1 “(BB) participants and
2 beneficiaries for whom a
3 claim for such drug was
4 filed through the applicable
5 dispensing channel;

6 “(CC) dosage units and
7 dosage units per fill of such
8 drug; and

9 “(DD) days supply of
10 such drug per fill;

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

18 “(VIII) the total amount of out-
19 of-pocket spending by participants
20 and beneficiaries on such drug, in-
21 cluding spending through copayments,
22 coinsurance, and deductibles, but not
23 including any amounts spent by par-
24 ticipants and beneficiaries on drugs
25 not covered under the plan or cov-

1 erage, or for which no claim is sub-
2 mitted under the plan or coverage;

3 “(IX) the total net spending on
4 the drug;

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

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

17 “(aa) for claims incurred
18 during the reporting period; and

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

22 “(XII) to the extent feasible, in-
23 formation on the total amount of re-
24 muneration for such drug, including
25 copayment assistance dollars paid, co-

1 payment cards applied, or other dis-
2 counts provided by each drug manu-
3 facturer (or entity administering co-
4 payment assistance on behalf of such
5 drug manufacturer), to the partici-
6 pants and beneficiaries enrolled in
7 such plan or coverage;

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

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

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

23 “(III) the total amount received,
24 or expected to be received, by the enti-
25 ty providing pharmacy benefit man-

1 agement services, from applicable en-
2 tities, in rebates, fees, alternative dis-
3 counts, or other remuneration from
4 such entities—

5 “(aa) for claims incurred
6 during the reporting period; and

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

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

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

22 “(VI) if applicable, a description
23 of the formulary tiers and utilization
24 mechanisms (such as prior authoriza-

tion or step therapy) employed for
drugs in that class; and

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

“(iii) with respect to any drug for
which gross spending under the group
health plan or health insurance coverage
exceeded \$10,000 during the reporting pe-
riod or, in the case that gross spending
under the group health plan or coverage
exceeded \$10,000 during the reporting pe-
riod with respect to fewer than 50 drugs,
with respect to the 50 prescription drugs
with the highest spending during the re-
porting period—

1 “(I) a list of all other drugs in
2 the same therapeutic class as such
3 drug;

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

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

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

24 “(I) an explanation of any ben-
25 efit design parameters that encourage

1 or require participants and bene-
2 ficiaries in the plan or coverage to fill
3 prescriptions at mail order, specialty,
4 or retail pharmacies;

5 “(II) the percentage of total pre-
6 scriptions dispensed by such phar-
7 macies to participants or beneficiaries
8 in such plan or coverage; and

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

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

20 “(bb) the median amount
21 charged to such plan or issuer,
22 and the interquartile range of the
23 costs, per dosage unit, per 30-
24 day supply, and per 90-day sup-
25 ply, including amounts paid by

1 the participants and bene-
2 ficiaries, when the same drug is
3 dispensed by other pharmacies
4 that are not affiliated with or
5 under common ownership with
6 the entity and that are included
7 in the pharmacy network of such
8 plan or coverage;

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

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

24 “(B) with respect to any group health
25 plan, including group health insurance coverage

1 offered in connection with such a plan, regard-
2 less of whether the plan or coverage is offered
3 by a specified large employer or whether it is a
4 specified large plan—

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

20 “(ii) a summary document for plans
21 and issuers to provide to participants and
22 beneficiaries, which shall be made available
23 to participants or beneficiaries upon re-
24 quest to their group health plan (including
25 in the case of group health insurance cov-

1 erage offered in connection with such a
2 plan), that—

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

14 “(II) contains only aggregate in-
15 formation; and

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

22 “(iii) with respect to drugs covered by
23 such plan or coverage during such report-
24 ing period—

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

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

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

18 “(iv) amounts paid directly or indi-
19 rectly in rebates, fees, or any other type of
20 compensation (as defined in section
21 408(b)(2)(B)(ii)(dd)(AA) of the Employee
22 Retirement Income Security Act) to bro-
23 kerage firms, brokers, consultants, advi-
24 sors, or any other individual or firm, for—

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

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

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

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

1 cost-sharing assistance incentives directly
2 or indirectly funded by such entity; and

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

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

21 “(4) PRIVACY REQUIREMENTS.—

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

erage shall report information under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the ‘HIPAA privacy regulations’) and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

“(B) ADDITIONAL REQUIREMENTS.—

“(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage that submits a report under paragraph (1) shall ensure that such report contains only summary 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 dislo-
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;

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 seq.), 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.”.

7 **SEC. 5. ENSURING ACCURATE PAYMENTS TO PHARMACIES**
 8 **UNDER MEDICAID.**

9 (a) IN GENERAL.—Section 1927(f) of the Social Se-
 10 curity Act (42 U.S.C. 1396r–8(f)) is amended—

11 (1) in paragraph (1)(A)—

12 (A) by redesignating clause (ii) as clause
 13 (iii); and

14 (B) by striking “and” after the semicolon
 15 at the end of clause (i) and all that precedes it
 16 through “(1)” and inserting the following:

17 “(1) DETERMINING PHARMACY ACTUAL ACQUI-
 18 SITION COSTS.—The Secretary shall conduct a sur-
 19 vey of retail community pharmacy drug prices and
 20 applicable non-retail pharmacy drug prices to deter-
 21 mine national average drug acquisition cost bench-
 22 marks (as such term is defined by the Secretary) as
 23 follows:

1 “(A) USE OF VENDOR.—The Secretary
2 may contract services for—

3 “(i) with respect to retail community
4 pharmacies, the determination of retail
5 survey prices of the national average drug
6 acquisition cost for covered outpatient
7 drugs that represent a nationwide average
8 of consumer purchase prices for such
9 drugs, net of all discounts, rebates, and
10 other price concessions (to the extent any
11 information with respect to such discounts,
12 rebates, and other price concessions is
13 available) based on a monthly survey of
14 such pharmacies;

15 “(ii) with respect to applicable non-re-
16 tail pharmacies—

17 “(I) the determination of survey
18 prices, separate from the survey prices
19 described in clause (i), of the non-re-
20 tail national average drug acquisition
21 cost for covered outpatient drugs that
22 represent a nationwide average of con-
23 sumer purchase prices for such drugs,
24 net of all discounts, rebates, and other
25 price concessions (to the extent any

1 information with respect to such dis-
2 counts, rebates, and other price con-
3 cessions is available) based on a
4 monthly survey of such pharmacies;
5 and

6 “(II) at the discretion of the Sec-
7 retary, for each type of applicable
8 non-retail pharmacy, the determina-
9 tion of survey prices, separate from
10 the survey prices described in clause
11 (i) or subclause (I) of this clause, of
12 the national average drug acquisition
13 cost for such type of pharmacy for
14 covered outpatient drugs that rep-
15 resent a nationwide average of con-
16 sumer purchase prices for such drugs,
17 net of all discounts, rebates, and other
18 price concessions (to the extent any
19 information with respect to such dis-
20 counts, rebates, and other price con-
21 cessions is available) based on a
22 monthly survey of such pharmacies;
23 and”;

1 (2) in subparagraph (B) of paragraph (1), by
2 striking “subparagraph (A)(ii)” and inserting “sub-
3 paragraph (A)(iii)”;

4 (3) in subparagraph (D) of paragraph (1), by
5 striking clauses (ii) and (iii) and inserting the fol-
6 lowing:

7 “(ii) The vendor must update the Sec-
8 retary no less often than monthly on the
9 survey prices for covered outpatient drugs.

10 “(iii) The vendor must differentiate,
11 in collecting and reporting survey data, for
12 all cost information collected, whether a
13 pharmacy is a retail community pharmacy
14 or an applicable non-retail pharmacy, in-
15 cluding whether such pharmacy is an affil-
16 iate (as defined in subsection (k)(14)),
17 and, in the case of an applicable non-retail
18 pharmacy, which type of applicable non-re-
19 tail pharmacy it is using the relevant phar-
20 macy type indicators included in the guid-
21 ance required by subsection (d)(2) of sec-
22 tion 44123 of the Act titled ‘An Act to
23 provide for reconciliation pursuant to title
24 II of H. Con. Res. 14.’”;

1 (4) by adding at the end of paragraph (1) the
2 following:

3 “(F) SURVEY REPORTING.—In order to
4 meet the requirement of section 1902(a)(54), a
5 State shall require that any retail community
6 pharmacy or applicable non-retail pharmacy in
7 the State that receives any payment, reimburse-
8 ment, administrative fee, discount, rebate, or
9 other price concession related to the dispensing
10 of covered outpatient drugs to individuals re-
11 ceiving benefits under this title, regardless of
12 whether such payment, reimbursement, admin-
13 istrative fee, discount, rebate, or other price
14 concession is received from the State or a man-
15 aged care entity or other specified entity (as
16 such terms are defined in section
17 1903(m)(9)(D)) directly or from a pharmacy
18 benefit manager or another entity that has a
19 contract with the State or a managed care enti-
20 ty or other specified entity (as so defined), shall
21 respond to surveys conducted under this para-
22 graph.

23 “(G) SURVEY INFORMATION.—Information
24 on national drug acquisition prices obtained
25 under this paragraph shall be made publicly

1 available in a form and manner to be deter-
2 mined by the Secretary and shall include at
3 least the following:

4 “(i) The monthly response rate to the
5 survey including a list of pharmacies not in
6 compliance with subparagraph (F).

7 “(ii) The sampling methodology and
8 number of pharmacies sampled monthly.

9 “(iii) Information on price concessions
10 to pharmacies, including discounts, re-
11 bates, and other price concessions, to the
12 extent that such information may be pub-
13 licly released and has been collected by the
14 Secretary as part of the survey.

15 “(H) PENALTIES.—

16 “(i) IN GENERAL.—Subject to clauses
17 (ii), (iii), and (iv), the Secretary shall en-
18 force the provisions of this paragraph with
19 respect to a pharmacy through the estab-
20 lishment of civil money penalties applicable
21 to a retail community pharmacy or an ap-
22 plicable non-retail pharmacy.

23 “(ii) BASIS FOR PENALTIES.—The
24 Secretary shall impose a civil money pen-
25 alty established under this subparagraph

on a retail community pharmacy or applicable non-retail pharmacy if—

“(I) the retail pharmacy or applicable non-retail pharmacy refuses or otherwise fails to respond to a request for information about prices in connection with a survey under this subsection;

“(II) knowingly provides false information in response to such a survey; or

“(III) otherwise fails to comply with the requirements established under this paragraph.

“(iii) PARAMETERS FOR PENALTIES.—

“(I) IN GENERAL.—A civil money penalty established under this subparagraph may be assessed with respect to each violation, and with respect to each non-compliant retail community pharmacy (including a pharmacy that is part of a chain) or non-compliant applicable non-retail pharmacy (including a pharmacy that

1 is part of a chain), in an amount not
2 to exceed \$100,000 for each such vio-
3 lation.

4 “(II) CONSIDERATIONS.—In de-
5 termining the amount of a civil money
6 penalty imposed under this subpara-
7 graph, the Secretary may consider the
8 size, business structure, and type of
9 pharmacy involved, as well as the type
10 of violation and other relevant factors,
11 as determined appropriate by the Sec-
12 retary.

13 “(iv) RULE OF APPLICATION.—The
14 provisions of section 1128A (other than
15 subsections (a) and (b)) shall apply to a
16 civil money penalty under this subpara-
17 graph in the same manner as such provi-
18 sions apply to a civil money penalty or pro-
19 ceeding under section 1128A(a).

20 “(I) LIMITATION ON USE OF AP-
21 PPLICABLE NON-RETAIL PHARMACY
22 PRICING INFORMATION.—No State
23 shall use pricing information reported
24 by applicable non-retail pharmacies
25 under subparagraph (A)(ii) to develop

1 or inform payment methodologies for
2 retail community pharmacies.”;

3 (5) in paragraph (2)—

4 (A) in subparagraph (A), by inserting “,
5 including payment rates and methodologies for
6 determining ingredient cost reimbursement
7 under managed care entities or other specified
8 entities (as such terms are defined in section
9 1903(m)(9)(D)),” after “under this title”; and

10 (B) in subparagraph (B), by inserting
11 “and the basis for such dispensing fees” before
12 the semicolon;

13 (6) by redesignating paragraph (4) as para-
14 graph (5);

15 (7) by inserting after paragraph (3) the fol-
16 lowing new paragraph:

17 “(4) OVERSIGHT.—

18 “(A) IN GENERAL.—The Inspector General
19 of the Department of Health and Human Serv-
20 ices shall conduct periodic studies of the survey
21 data reported under this subsection, as appro-
22 priate, including with respect to substantial
23 variations in acquisition costs or other applica-
24 ble costs, as well as with respect to how internal
25 transfer prices and related party transactions

1 may influence the costs reported by pharmacies
2 that are affiliates (as defined in subsection
3 (k)(14)) or are owned by, controlled by, or re-
4 lated under a common ownership structure with
5 a wholesaler, distributor, or other entity that
6 acquires covered outpatient drugs relative to
7 costs reported by pharmacies not affiliated with
8 such entities. The Inspector General shall pro-
9 vide periodic updates to Congress on the results
10 of such studies, as appropriate, in a manner
11 that does not disclose trade secrets or other
12 proprietary information.

13 “(B) APPROPRIATION.—There is appro-
14 priated to the Inspector General of the Depart-
15 ment of Health and Human Services, out of
16 any money in the Treasury not otherwise ap-
17 propriated, \$5,000,000 for fiscal year 2025, to
18 remain available until expended, to carry out
19 this paragraph.”; and

20 (8) in paragraph (5), as so redesignated—

21 (A) by inserting “, and \$9,000,000 for fis-
22 cal year 2025 and each fiscal year thereafter,”
23 after “2010”; and

24 (B) by inserting “Funds appropriated
25 under this paragraph for fiscal year 2025 and

1 any subsequent fiscal year shall remain avail-
2 able until expended.” after the period.

3 (b) DEFINITIONS.—Section 1927(k) of the Social Se-
4 curity Act (42 U.S.C. 1396r–8(k)) is amended—

5 (1) in the matter preceding paragraph (1), by
6 striking “In the section” and inserting “In this sec-
7 tion”; and

8 (2) by adding at the end the following new
9 paragraphs:

10 “(12) APPLICABLE NON-RETAIL PHARMACY.—

11 The term ‘applicable non-retail pharmacy’ means a
12 pharmacy that is licensed as a pharmacy by the
13 State and that is not a retail community pharmacy,
14 including a pharmacy that dispenses prescription
15 medications to patients primarily through mail and
16 specialty pharmacies. Such term does not include
17 nursing home pharmacies, long-term care facility
18 pharmacies, hospital pharmacies, clinics, charitable
19 or not-for-profit pharmacies, government phar-
20 macies, or low dispensing pharmacies (as defined by
21 the Secretary).

22 “(13) AFFILIATE.—The term ‘affiliate’ means
23 any entity that is owned by, controlled by, or related
24 under a common ownership structure with a phar-
25 macy benefit manager or a managed care entity or

1 other specified entity (as such terms are defined in
2 section 1903(m)(9)(D)).”.

3 (c) EFFECTIVE DATE.—

4 (1) IN GENERAL.—Subject to paragraph (2),
5 the amendments made by this section shall take ef-
6 fect on the first day of the first quarter that begins
7 on or after the date that is 6 months after the date
8 of enactment of this Act.

9 (2) DELAYED APPLICATION TO APPLICABLE
10 NON-RETAIL PHARMACIES.—The pharmacy survey
11 requirements established by the amendments to sec-
12 tion 1927(f) of the Social Security Act (42 U.S.C.
13 1396r–8(f)) made by this section shall apply to re-
14 tail community pharmacies beginning on the effec-
15 tive date described in paragraph (1), but shall not
16 apply to applicable non-retail pharmacies until the
17 first day of the first quarter that begins on or after
18 the date that is 18 months after the date of enact-
19 ment of this Act.

20 (d) IDENTIFICATION OF APPLICABLE NON-RETAIL
21 PHARMACIES.—

22 (1) IN GENERAL.—Not later than January 1,
23 2027, the Secretary of Health and Human Services
24 shall publish guidance specifying pharmacies that
25 meet the definition of applicable non-retail phar-

1 macies (as such term is defined in subsection
2 (k)(12) of section 1927 of the Social Security Act
3 (42 U.S.C. 1396r–8), as added by subsection (b)),
4 and that will be subject to the survey requirements
5 under subsection (f)(1) of such section, as amended
6 by subsection (a).

7 (2) INCLUSION OF PHARMACY TYPE INDICA-
8 TORS.—The guidance published under paragraph (1)
9 shall include pharmacy type indicators to distinguish
10 between different types of applicable non-retail phar-
11 macies, such as pharmacies that dispense prescrip-
12 tions primarily through the mail and pharmacies
13 that dispense prescriptions that require special han-
14 dling or distribution. An applicable non-retail phar-
15 macy may be identified through multiple pharmacy
16 type indicators.

17 (e) IMPLEMENTATION.—

18 (1) Implementation of the amendments made
19 by this section shall be exempt from the require-
20 ments of section 553 of title 5, United States Code.

21 (f) NONAPPLICATION OF PAPERWORK REDUCTION
22 ACT.—Chapter 35 of title 44, United States Code, shall
23 not apply to any data collection undertaken by the Sec-
24 retary of Health and Human Services under section

1 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)),
2 as amended by this section.

3 **SEC. 6. PREVENTING THE USE OF ABUSIVE SPREAD PRIC-**
4 **ING IN MEDICAID.**

5 (a) IN GENERAL.—Section 1927 of the Social Secu-
6 rity Act (42 U.S.C. 1396r–8) is amended—

7 (1) in subsection (e), by adding at the end the
8 following new paragraph:

9 “(6) TRANSPARENT PRESCRIPTION DRUG PASS-
10 THROUGH PRICING REQUIRED.—

11 “(A) IN GENERAL.—A contract between
12 the State and a pharmacy benefit manager (re-
13 ferred to in this paragraph as a ‘PBM’), or a
14 contract between the State and a managed care
15 entity or other specified entity (as such terms
16 are defined in section 1903(m)(9)(D) and col-
17 lectively referred to in this paragraph as the
18 ‘entity’) that includes provisions making the en-
19 tity responsible for coverage of covered out-
20 patient drugs dispensed to individuals enrolled
21 with the entity, shall require that payment for
22 such drugs and related administrative services
23 (as applicable), including payments made by a
24 PBM on behalf of the State or entity, is based

1 on a transparent prescription drug pass-
2 through pricing model under which—

3 “(i) any payment made by the entity
4 or the PBM (as applicable) for such a
5 drug—

6 “(I) is limited to—

7 “(aa) ingredient cost; and

8 “(bb) a professional dis-
9 pensing fee that is not less than
10 the professional dispensing fee
11 that the State would pay if the
12 State were making the payment
13 directly in accordance with the
14 State plan;

15 “(II) is passed through in its en-
16 tirety (except as reduced under Fed-
17 eral or State laws and regulations in
18 response to instances of waste, fraud,
19 or abuse) by the entity or PBM to the
20 pharmacy or provider that dispenses
21 the drug; and

22 “(III) is made in a manner that
23 is consistent with sections 447.502,
24 447.512, 447.514, and 447.518 of
25 title 42, Code of Federal Regulations

1 (or any successor regulation) as if
2 such requirements applied directly to
3 the entity or the PBM, except that
4 any payment by the entity or the
5 PBM for the ingredient cost of such
6 drug purchased by a covered entity
7 (as defined in subsection (a)(5)(B))
8 may exceed the actual acquisition cost
9 (as defined in 447.502 of title 42,
10 Code of Federal Regulations, or any
11 successor regulation) for such drug
12 if—

13 “(aa) such drug was subject
14 to an agreement under section
15 340B of the Public Health Serv-
16 ice Act;

17 “(bb) such payment for the
18 ingredient cost of such drug does
19 not exceed the maximum pay-
20 ment that would have been made
21 by the entity or the PBM for the
22 ingredient cost of such drug if
23 such drug had not been pur-
24 chased by such covered entity;
25 and

1 “(cc) such covered entity re-
2 ports to the Secretary (in a form
3 and manner specified by the Sec-
4 retary), on an annual basis and
5 with respect to payments for the
6 ingredient costs of such drugs so
7 purchased by such covered entity
8 that are in excess of the actual
9 acquisition costs for such drugs,
10 the aggregate amount of such ex-
11 cess;

12 “(ii) payment to the entity or the
13 PBM (as applicable) for administrative
14 services performed by the entity or PBM is
15 limited to an administrative fee that re-
16 flects the fair market value (as defined by
17 the Secretary) of such services;

18 “(iii) the entity or the PBM (as appli-
19 cable) makes available to the State, and
20 the Secretary upon request in a form and
21 manner specified by the Secretary, all costs
22 and payments related to covered outpatient
23 drugs and accompanying administrative
24 services (as described in clause (ii)) in-
25 curred, received, or made by the entity or

1 the PBM, broken down (as specified by the
2 Secretary), to the extent such costs and
3 payments are attributable to an individual
4 covered outpatient drug, by each such
5 drug, including any ingredient costs, pro-
6 fessional dispensing fees, administrative
7 fees (as described in clause (ii)), post-sale
8 and post-invoice fees, discounts, or related
9 adjustments such as direct and indirect re-
10 muneration fees, and any and all other re-
11 muneration, as defined by the Secretary;
12 and

13 “(iv) any form of spread pricing
14 whereby any amount charged or claimed by
15 the entity or the PBM (as applicable) that
16 exceeds the amount paid to the pharmacies
17 or providers on behalf of the State or enti-
18 ty, including any post-sale or post-invoice
19 fees, discounts, or related adjustments
20 such as direct and indirect remuneration
21 fees or assessments, as defined by the Sec-
22 retary, (after allowing for an administra-
23 tive fee as described in clause (ii)) is not
24 allowable for purposes of claiming Federal
25 matching payments under this title.

1 “(B) PUBLICATION OF INFORMATION.—
2 The Secretary shall publish, not less frequently
3 than on an annual basis and in a manner that
4 does not disclose the identity of a particular
5 covered entity or organization, information re-
6 ceived by the Secretary pursuant to subpara-
7 graph (A)(iii)(III) that is broken out by State
8 and by each of the following categories of cov-
9 ered entity within each such State:

10 “(i) Covered entities described in sub-
11 paragraph (A) of section 340B(a)(4) of the
12 Public Health Service Act.

13 “(ii) Covered entities described in sub-
14 paragraphs (B) through (K) of such sec-
15 tion.

16 “(iii) Covered entities described in
17 subparagraph (L) of such section.

18 “(iv) Covered entities described in
19 subparagraph (M) of such section.

20 “(v) Covered entities described in sub-
21 paragraph (N) of such section.

22 “(vi) Covered entities described in
23 subparagraph (O) of such section.”; and

(2) in subsection (k), as previously amended by this title, by adding at the end the following new paragraph:

“(14) PHARMACY BENEFIT MANAGER.—The term ‘pharmacy benefit manager’ means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a State, managed care entity (as defined in section 1903(m)(9)(D)), or other specified entity (as so defined), or manages the prescription drug benefits provided by a State, managed care entity, or other specified entity, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the managing of appeals or grievances related to the prescription drug benefits, contracting with pharmacies, controlling the cost of covered outpatient drugs, or the provision of services related thereto. Such term includes any person or entity that acts as a price negotiator (with regard to payment amounts to pharmacies and providers for a covered outpatient drug or the net cost of the drug) or group purchaser on behalf of a State, managed care entity, or other specified entity or that carries out 1 or more of the

1 other activities described in the preceding sentence,
2 irrespective of whether such person or entity calls
3 itself a pharmacy benefit manager.”.

4 (b) CONFORMING AMENDMENTS.—Section 1903(m)
5 of such Act (42 U.S.C. 1396b(m)) is amended—

6 (1) in paragraph (2)(A)(xiii)—

7 (A) by striking “and (III)” and inserting
8 “(III)”;

9 (B) by inserting before the period at the
10 end the following: “, and (IV) if the contract in-
11 cludes provisions making the entity responsible
12 for coverage of covered outpatient drugs, the
13 entity shall comply with the requirements of
14 section 1927(e)(6)”;

15 (C) by moving the margin 2 ems to the
16 left; and

17 (2) by adding at the end the following new
18 paragraph:

19 “(10) No payment shall be made under
20 this title to a State with respect to expenditures
21 incurred by the State for payment for services
22 provided by an other specified entity (as defined
23 in paragraph (9)(D)(iii)) unless such services
24 are provided in accordance with a contract be-

1 tween the State and such entity which satisfies
2 the requirements of paragraph (2)(A)(xiii).”.

3 (c) EFFECTIVE DATE.—The amendments made by
4 this section shall apply to contracts between States and
5 managed care entities, other specified entities, or phar-
6 macy benefit managers that have an effective date begin-
7 ning on or after the date that is 18 months after the date
8 of enactment of this Act.

9 (d) IMPLEMENTATION.—

10 (1) Implementation of the amendments made
11 by this section shall be exempt from the require-
12 ments of section 553 of title 5, United States Code.

13 (e) NONAPPLICATION OF PAPERWORK REDUCTION
14 ACT.—Chapter 35 of title 44, United States Code, shall
15 not apply to any data collection undertaken by the Sec-
16 retary of Health and Human Services under section
17 1927(e) of the Social Security Act (42 U.S.C. 1396r–
18 8(e)), as amended by this section.

○