

AMENDMENT TO H.R. 2484
OFFERED BY M____.

Page 7, line 13, strike “1,786,000,000” and insert
“2,189,000,000”.

Add at the end the following new section:

1 SEC. ____ . MODERNIZING AND ENSURING PBM ACCOUNT-
2 ABILITY.

3 (a) IN GENERAL.—

4 (1) PRESCRIPTION DRUG PLANS.—Section
5 1860D–12 of the Social Security Act (42 U.S.C.
6 1395w–112) is amended by adding at the end the
7 following new subsection:

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

11 “(1) AGREEMENTS WITH PHARMACY BENEFIT
12 MANAGERS.—Each contract entered into with a
13 PDP sponsor under this part with respect to a pre-
14 scription drug plan offered by such sponsor shall
15 provide that any pharmacy benefit manager acting
16 on behalf of such sponsor has a written agreement
17 with the PDP sponsor under which the pharmacy

1 benefit manager, and any affiliates of such phar-
2 macy benefit manager, as applicable, agree to meet
3 the following requirements:

4 “(A) NO INCOME OTHER THAN BONA FIDE
5 SERVICE FEES.—

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

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

1 value (as specified by the Secretary), is re-
2 lated to services actually performed by the
3 pharmacy benefit manager or affiliate of
4 such pharmacy benefit manager, on behalf
5 of the PDP sponsor making such payment,
6 in connection with the utilization of cov-
7 ered part D drugs, and meets additional
8 requirements, if any, as determined appro-
9 priate by the Secretary.

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

1 acting as a pharmacy benefit manager on
2 behalf of a prescription drug plan offered
3 by such PDP sponsor.

4 “(iv) EVALUATION OF REMUNERATION
5 ARRANGEMENTS.—Components of subsets
6 of remuneration arrangements (such as
7 fees or other forms of compensation paid
8 to or retained by the pharmacy benefit
9 manager or affiliate of such pharmacy ben-
10 efit manager), as determined appropriate
11 by the Secretary, between pharmacy ben-
12 efit managers or affiliates of such phar-
13 macy benefit managers, as applicable, and
14 other entities involved in the dispensing or
15 utilization of covered part D drugs (includ-
16 ing PDP sponsors, manufacturers, phar-
17 macies, and other entities as determined
18 appropriate by the Secretary) shall be sub-
19 ject to review by the Secretary, in con-
20 sultation with the Office of the Inspector
21 General of the Department of Health and
22 Human Services, as determined appro-
23 priate by the Secretary. The Secretary, in
24 consultation with the Office of the Inspec-
25 tor General, shall review whether remu-

1 neration under such arrangements is con-
2 sistent with fair market value (as specified
3 by the Secretary) through reviews and as-
4 sessments of such remuneration, as deter-
5 mined appropriate.

6 “(v) DISGORGEMENT.—The pharmacy
7 benefit manager shall disgorge any remu-
8 neration paid to such pharmacy benefit
9 manager or an affiliate of such pharmacy
10 benefit manager in violation of this sub-
11 paragraph to the PDP sponsor.

12 “(vi) ADDITIONAL REQUIREMENTS.—
13 The pharmacy benefit manager shall—

14 “(I) enter into a written agree-
15 ment with any affiliate of such phar-
16 macy benefit manager, under which
17 the affiliate shall identify and disgorge
18 any remuneration described in clause
19 (v) to the pharmacy benefit manager;
20 and

21 “(II) attest, subject to any re-
22 quirements determined appropriate by
23 the Secretary, that the pharmacy ben-
24 efit manager has entered into a writ-
25 ten agreement described in subclause

1 (I) with any relevant affiliate of the
2 pharmacy benefit manager.

3 “(B) TRANSPARENCY REGARDING GUARAN-
4 TEES AND COST PERFORMANCE EVALUA-
5 TIONS.—The pharmacy benefit manager shall—

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

14 “(I) ‘generic drug’, in a manner
15 consistent with the definition of the
16 term under section 423.4 of title 42,
17 Code of Federal Regulations, or a suc-
18 cessor regulation;

19 “(II) ‘brand name drug’, in a
20 manner consistent with the definition
21 of the term under section 423.4 of
22 title 42, Code of Federal Regulations,
23 or a successor regulation;

24 “(III) ‘specialty drug’;

25 “(IV) ‘rebate’; and

1 “(V) ‘discount’;

2 “(ii) identify any drugs, claims, or
3 price concessions excluded from any pric-
4 ing guarantee or other cost performance
5 measure in a clear and consistent manner;
6 and

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

15 “(C) PROVISION OF INFORMATION.—

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

1 PDP sponsor and each plan offered by
2 such sponsor, the following information
3 with respect to the previous plan year:

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

7 “(aa) the brand name, ge-
8 neric or non-proprietary name,
9 and National Drug Code;

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

19 “(cc) the number of pre-
20 scription claims described in item
21 (bb) by each type of dispensing
22 channel through which the drug
23 was dispensed, including retail,
24 mail order, specialty pharmacy,
25 long term care pharmacy, home

1 infusion pharmacy, or other types
2 of pharmacies or providers;

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

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

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

21 “(gg) total rebates paid by
22 the manufacturer on the drug as
23 reported under the Detailed DIR
24 Report (or any successor report)
25 submitted by such sponsor to the

1 Centers for Medicare & Medicaid
2 Services;

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

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

16 “(jj) the average National
17 Average Drug Acquisition Cost
18 (NADAC); and

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

1 “(II) In the case of a pharmacy
2 benefit manager that has an affiliate
3 that is a retail, mail order, or spe-
4 cialty pharmacy, with respect to drugs
5 covered by such plan that were dis-
6 pensed, the following information:

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

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

23 “(cc) The interquartile
24 range of the total combined costs
25 paid by the plan and plan enroll-

1 ees, per dosage unit, per course
2 of treatment, per 30-day supply,
3 and per 90-day supply for each
4 drug dispensed by pharmacies
5 that are an affiliate of the phar-
6 macy benefit manager and that
7 are included in the pharmacy
8 network of such plan.

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

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

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

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

21 “(aa) A list of currently
22 marketed generic drugs approved
23 under section 505(j) of the Fed-
24 eral Food, Drug, and Cosmetic
25 Act pursuant to an application

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

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

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

1 “(dd) A written justification
2 for providing more favorable cov-
3 erage of the listed drug than the
4 generic drugs described in item
5 (aa).

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

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

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

1 mulary tier typically associated
2 with higher cost-sharing than the
3 reference product, or are subject
4 to utilization management that
5 the reference product is not sub-
6 ject to.

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

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

1 “(dd) A written justification
2 for providing more favorable cov-
3 erage of the reference product
4 than the biosimilar biological
5 product described in item (aa).

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

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

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

24 “(VII) The total spending on cov-
25 ered part D drugs net of rebates, fees,

1 discounts, or other direct and indirect
2 remuneration by the plan.

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

11 “(IX) The following information:

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

22 “(bb) The amount of com-
23 pensation provided by such phar-
24 macy benefit manager or affiliate

1 to each such broker, consultant,
2 advisor, and auditor.

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

9 “(X) A list of all affiliates of the
10 pharmacy benefit manager.

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

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

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

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

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

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

1 the terms of such contract or
2 agreement and how such terms
3 apply to such drugs; and

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

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

22 “(D) AUDIT RIGHTS.—

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

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

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

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

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

1 the audit and respond to requests for addi-
2 tional information from such auditor with-
3 in 30 days after the request for additional
4 information.

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

13 “(2) ENFORCEMENT.—

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

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

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

1 money penalty imposed on the PDP spon-
2 sor as a result of the failure of the phar-
3 macy benefit manager or affiliate to meet
4 the requirements of paragraph (1) that are
5 applicable to the pharmacy benefit man-
6 ager or affiliate under the agreement; and
7 “(iii) require, in a written agreement
8 with any such pharmacy benefit manager
9 acting on behalf of such sponsor or affil-
10 iate of such pharmacy benefit manager,
11 that such pharmacy benefit manager or af-
12 filiate be subject to punitive remedies for
13 breach of contract for failure to comply
14 with the requirements applicable under
15 paragraph (1).

16 “(B) REPORTING OF ALLEGED VIOLA-
17 TIONS.—The Secretary shall make available and
18 maintain a mechanism for manufacturers, PDP
19 sponsors, pharmacies, and other entities that
20 have contractual relationships with pharmacy
21 benefit managers or affiliates of such pharmacy
22 benefit managers to report, on a confidential
23 basis, alleged violations of paragraph (1)(A) or
24 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.—Notwithstanding
19 any other provision of law, the Secretary may
20 implement this paragraph by program instruc-
21 tion or otherwise.

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

24 “(A) prohibiting flat dispensing fees or re-
25 imbursement or payment for ingredient costs

1 (including customary, industry-standard dis-
2 counts directly related to drug acquisition that
3 are retained by pharmacies or wholesalers) to
4 entities that acquire or dispense prescription
5 drugs; or

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

10 “(5) STANDARD FORMATS.—

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

16 “(B) IMPLEMENTATION.—Notwithstanding
17 any other provision of law, the Secretary may
18 implement this paragraph by program instruc-
19 tion or otherwise.

20 “(6) CONFIDENTIALITY.—

21 “(A) IN GENERAL.—Information disclosed
22 by a pharmacy benefit manager, an affiliate of
23 a pharmacy benefit manager, a PDP sponsor,
24 or a pharmacy under this subsection that is not
25 otherwise publicly available or available for pur-

1 chase shall not be disclosed by the Secretary or
2 a PDP sponsor receiving the information, ex-
3 cept that the Secretary may disclose the infor-
4 mation for the following purposes:

5 “(i) As the Secretary determines nec-
6 essary to carry out this part.

7 “(ii) To permit the Comptroller Gen-
8 eral to review the information provided.

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

12 “(iv) To permit the Executive Direc-
13 tor of the Medicare Payment Advisory
14 Commission to review the information pro-
15 vided.

16 “(v) To the Attorney General for the
17 purposes of conducting oversight and en-
18 forcement under this title.

19 “(vi) To the Inspector General of the
20 Department of Health and Human Serv-
21 ices in accordance with its authorities
22 under the Inspector General Act of 1978
23 (section 406 of title 5, United States
24 Code), and other applicable statutes.

1 “(B) RESTRICTION ON USE OF INFORMA-
2 TION.—The Secretary, the Comptroller General,
3 the Director of the Congressional Budget Of-
4 fice, and the Executive Director of the Medicare
5 Payment Advisory Commission shall not report
6 on or disclose information disclosed pursuant to
7 subparagraph (A) to the public in a manner
8 that would identify—

9 “(i) a specific pharmacy benefit man-
10 ager, affiliate, pharmacy, manufacturer,
11 wholesaler, PDP sponsor, or plan; or

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

17 “(7) DEFINITIONS.—For purposes of this sub-
18 section:

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

23 “(i) owns or is owned by, controls or
24 is controlled by, or is otherwise related in

1 any ownership structure to such pharmacy
2 benefit manager or PDP sponsor; or

3 “(ii) acts as a contractor, principal, or
4 agent to such pharmacy benefit manager
5 or PDP sponsor, insofar as such con-
6 tractor, principal, or agent performs any of
7 the functions described under subpara-
8 graph (C).

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

22 “(i) drug price, such as wholesale ac-
23 quisition cost or drug benchmark price
24 (such as average wholesale price);

1 “(ii) the amount of discounts, rebates,
2 fees, or other direct or indirect remunera-
3 tion with respect to covered part D drugs
4 dispensed to enrollees in a prescription
5 drug plan, except as permitted pursuant to
6 paragraph (1)(A)(ii);

7 “(iii) coverage or formulary placement
8 decisions or the volume or value of any re-
9 ferrals or business generated between the
10 parties to the arrangement; or

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

13 “(C) PHARMACY BENEFIT MANAGER.—The
14 term ‘pharmacy benefit manager’ means any
15 person or entity that, either directly or through
16 an intermediary, acts as a price negotiator or
17 group purchaser on behalf of a PDP sponsor or
18 prescription drug plan, or manages the pre-
19 scription drug benefits provided by such spon-
20 sor or plan, including the processing and pay-
21 ment of claims for prescription drugs, the per-
22 formance of drug utilization review, the proc-
23 essing of drug prior authorization requests, the
24 adjudication of appeals or grievances related to
25 the prescription drug benefit, contracting with

1 network pharmacies, controlling the cost of cov-
2 ered part D drugs, or the provision of related
3 services. Such term includes any person or enti-
4 ty that carries out one or more of the activities
5 described in the preceding sentence, irrespective
6 of whether such person or entity calls itself a
7 ‘pharmacy benefit manager’.”.

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

12 “(F) REQUIREMENTS RELATING TO PHAR-
13 MACY BENEFIT MANAGERS.—For plan years be-
14 ginning on or after January 1, 2028, section
15 1860D–12(h).”.

16 (3) NONAPPLICATION OF PAPERWORK REDUC-
17 TION ACT.—Chapter 35 of title 44, United States
18 Code, shall not apply to the implementation of this
19 subsection.

20 (4) FUNDING.—

21 (A) SECRETARY.—In addition to amounts
22 otherwise available, there is appropriated to the
23 Centers for Medicare & Medicaid Services Pro-
24 gram Management Account, out of any money
25 in the Treasury not otherwise appropriated,

1 \$113,000,000 for fiscal year 2025, to remain
2 available until expended, to carry out this sub-
3 section.

4 (B) OIG.—In addition to amounts other-
5 wise available, there is appropriated to the In-
6 specter General of the Department of Health
7 and Human Services, out of any money in the
8 Treasury not otherwise appropriated,
9 \$20,000,000 for fiscal year 2025, to remain
10 available until expended, to carry out this sub-
11 section.

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

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

1 (A) The type, magnitude, other features
2 (such as the pricing benchmarks used), and
3 prevalence of compensation and payment struc-
4 tures related to a prescription drug's price,
5 such as calculating fee amounts as a percentage
6 of a prescription drug's price, between inter-
7 mediaries in the prescription drug supply chain,
8 including—

- 9 (i) pharmacy benefit managers;
10 (ii) PDP sponsors offering prescrip-
11 tion drug plans and Medicare Advantage
12 organizations offering MA–PD plans;
13 (iii) drug wholesalers;
14 (iv) pharmacies;
15 (v) manufacturers;
16 (vi) pharmacy services administrative
17 organizations;
18 (vii) brokers, auditors, consultants,
19 and other entities that—

20 (I) advise PDP sponsors offering
21 prescription drug plans and Medicare
22 Advantage organizations offering MA–
23 PD plans regarding pharmacy bene-
24 fits; or

1 (II) review PDP sponsor and
2 Medicare Advantage organization con-
3 tracts with pharmacy benefit man-
4 agers; and

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

14 (B) The primary business models and com-
15 pensation structures for each category of inter-
16 mediary described in subparagraph (A).

17 (C) Variation in price-related compensation
18 structures between affiliated entities (such as
19 entities with common ownership, either full or
20 partial, and subsidiary relationships) and unaf-
21 filiated entities.

22 (D) Potential conflicts of interest among
23 contracting entities related to the use of pre-
24 scription drug price-related compensation struc-
25 tures, such as the potential for fees or other

1 payments set as a percentage of a prescription
2 drug's price to advantage formulary selection,
3 distribution, or purchasing of prescription drugs
4 with higher prices.

5 (E) Notable differences, if any, in the use
6 and level of price-based compensation struc-
7 tures over time and between different market
8 segments, such as under part D of title XVIII
9 of the Social Security Act (42 U.S.C. 1395w-
10 101 et seq.) and the Medicaid program under
11 title XIX of such Act (42 U.S.C. 1396 et seq.).

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

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

1 (2) REPORT.—Not later than 2 years after the
2 date of enactment of this section, the Comptroller
3 General shall submit to Congress a report containing
4 the results of the study conducted under paragraph
5 (1), together with recommendations for such legisla-
6 tion and administrative action as the Comptroller
7 General determines appropriate.

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

11 (1) IN GENERAL.—The Medicare Payment Ad-
12 visory Commission shall submit to Congress the fol-
13 lowing reports:

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

22 (i) a description of trends and pat-
23 terns, including relevant averages, totals,
24 and other figures for the types of informa-
25 tion submitted;

1 (ii) an analysis of any differences in
2 agreements and their effects on plan en-
3 rollee out-of-pocket spending and average
4 pharmacy reimbursement, and other im-
5 pacts; and

6 (iii) any recommendations the Com-
7 mission determines appropriate.

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

16 (2) FUNDING.—In addition to amounts other-
17 wise available, there is appropriated to the Medicare
18 Payment Advisory Commission, out of any money in
19 the Treasury not otherwise appropriated,
20 \$1,000,000 for fiscal year 2025, to remain available
21 until expended, to carry out this subsection.

