

**Calendar No. 266**118TH CONGRESS  
1ST SESSION**S. 2973****[Report No. 118–122]**

To amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under the Medicare and Medicaid programs, and for other purposes.

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**IN THE SENATE OF THE UNITED STATES**

SEPTEMBER 28 (legislative day, SEPTEMBER 22), 2023

Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on Finance

DECEMBER 7, 2023

Reported by Mr. WYDEN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

To amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under the Medicare and Medicaid programs, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the  
3 “Modernizing and Ensuring PBM Accountability Act”.

4 (b) **TABLE OF CONTENTS.**—The table of contents of  
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Arrangements with pharmacy benefit managers with respect to prescription drug plans and MA–PD plans.
- Sec. 3. Ensuring fair assessment of pharmacy performance and quality under Medicare part D.
- Sec. 4. Promoting transparency for pharmacies under Medicare part D.
- Sec. 5. Preventing the use of abusive spread pricing in Medicaid.
- Sec. 6. Ensuring accurate payments to pharmacies under Medicaid.
- Sec. 7. OIG study and report on drug price mark-ups in Medicare part D.
- Sec. 8. Resolving P&T committee conflicts of interest.
- Sec. 9. Enhancing PBM transparency requirements.
- Sec. 10. Facilitating midyear formulary changes for biosimilars.
- Sec. 11. Strengthening pharmacy access for seniors.
- Sec. 12. Beneficiary-focused listening sessions to improve prescription drug plan transparency, access, and choice.
- Sec. 13. Reporting on enforcement and oversight of pharmacy access requirements.
- Sec. 14. GAO study on price-related compensation across the supply chain.
- Sec. 15. Reports on inappropriate pharmacy rejections.
- Sec. 16. GAO study on drug shortages.
- Sec. 17. Report on biosimilar and generic access under Medicare part D.
- Sec. 18. Medicare Improvement Fund.

6 **SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MAN-**  
7 **AGERS WITH RESPECT TO PRESCRIPTION**  
8 **DRUG PLANS AND MA–PD PLANS.**

9 (a) **IN GENERAL.**—

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

1       “(h) REQUIREMENTS RELATING TO PHARMACY BEN-  
2 EFIT MANAGERS.—For plan years beginning on or after  
3 January 1, 2026:

4           “(1) AGREEMENTS WITH PHARMACY BENEFIT  
5 MANAGERS.—Each contract entered into with a  
6 PDP sponsor under this part with respect to a pre-  
7 scription drug plan offered by such sponsor shall  
8 provide that any pharmacy benefit manager acting  
9 on behalf of such sponsor has a written agreement  
10 with the PDP sponsor under which the pharmacy  
11 benefit manager agrees to meet the following re-  
12 quirements:

13           “(A) NO INCOME OTHER THAN BONA FIDE  
14 SERVICE FEES.—

15           “(i) IN GENERAL.—The pharmacy  
16 benefit manager and any affiliate of such  
17 pharmacy benefit manager shall not derive  
18 any remuneration with respect to any serv-  
19 ices provided in connection with the utiliza-  
20 tion of covered part D drugs from any en-  
21 tity or individual other than bona fide serv-  
22 ice fees, subject to clauses (ii) and (iii).

23           “(ii) INCENTIVE PAYMENTS.—For the  
24 purposes of this subsection, an incentive  
25 payment paid by a PDP sponsor to a phar-

1 macy benefit manager that is performing  
2 services on behalf of such sponsor shall be  
3 deemed a 'bona fide service fee' if such  
4 payment is a flat dollar amount, is con-  
5 sistent with fair market value, and is re-  
6 lated to services actually performed by the  
7 pharmacy benefit manager or affiliate of  
8 such pharmacy benefit manager in connec-  
9 tion with the utilization of covered part D  
10 drugs.

11 “(iii) CLARIFICATION ON REBATES  
12 AND DISCOUNTS USED TO LOWER COSTS  
13 FOR COVERED PART D DRUGS.—Rebates,  
14 discounts, and other price concessions re-  
15 ceived from manufacturers, even if such  
16 price concessions are calculated as a per-  
17 centage of a drug's price, shall not be con-  
18 sidered a violation of the requirements of  
19 clause (i) if they are fully passed through  
20 to a PDP sponsor and exclusively used to  
21 lower costs for prescription drugs under  
22 this part, including in cases where a PDP  
23 sponsor is acting as a pharmacy benefit  
24 manager on behalf of a prescription drug  
25 plan offered by such PDP sponsor.

1           “(iv) EVALUATION OF REMUNERATION  
2           ARRANGEMENTS.—Remuneration arrange-  
3           ments between pharmacy benefit managers  
4           or affiliates of such pharmacy benefit man-  
5           agers, as applicable, and other entities in-  
6           volved in the dispensing or utilization of  
7           covered part D drugs (including PDP  
8           sponsors, manufacturers, pharmacies, and  
9           other entities as determined appropriate by  
10          the Secretary) shall be subject to review by  
11          the Secretary and the Office of the Inspee-  
12          tor General of the Department of Health  
13          and Human Services. The Secretary, in  
14          consultation with the Office of the Inspee-  
15          tor General, shall evaluate whether remu-  
16          neration under such arrangements is con-  
17          sistent with fair market value through re-  
18          views and assessments of such remunera-  
19          tion, as determined appropriate.

20          “(B) TRANSPARENCY REGARDING GUARAN-  
21          TEES AND COST PERFORMANCE EVALUA-  
22          TIONS.—The pharmacy benefit manager shall—

23                 “(i) define, interpret, and apply, in a  
24                 fully transparent and consistent manner  
25                 for purposes of calculating or otherwise

1 evaluating pharmacy benefit manager per-  
2 formance against pricing guarantees or  
3 similar cost performance measurements re-  
4 lated to rebates, discounts, price conces-  
5 sions, or net costs, terms such as—

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

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

16 “(III) ‘specialty drug’;

17 “(IV) ‘rebate’; and

18 “(V) ‘discount’;

19 “(ii) identify any drugs, claims, or  
20 price concessions excluded from any prie-  
21 ing guarantee or other cost performance  
22 calculation or evaluation in a clear and  
23 consistent manner; and

24 “(iii) where a pricing guarantee or  
25 other cost performance measure is based

1 on a pricing benchmark other than the  
2 wholesale acquisition cost (as defined in  
3 section 1847A(c)(6)(B)) of a drug, cal-  
4 culate and provide a wholesale acquisition  
5 cost-based equivalent to the pricing guar-  
6 antee or other cost performance measure  
7 in the written agreement.

8 “(C) PROVISION OF INFORMATION.—

9 “(i) IN GENERAL.—Not later than  
10 July 1 of each year, beginning in 2026, the  
11 pharmacy benefit manager shall submit to  
12 the PDP sponsor, and to the Secretary, a  
13 report, in accordance with this subpara-  
14 graph, and shall make such report avail-  
15 able to such sponsor at no cost to such  
16 sponsor in a format specified by the Sec-  
17 retary under paragraph (4). Each such re-  
18 port shall include, with respect to such  
19 PDP sponsor and each plan offered by  
20 such sponsor, the following information  
21 with respect to the previous plan year:

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

1           “(aa) the brand name, ge-  
2           neric or non-proprietary name,  
3           and National Drug Code;

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

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

22          “(dd) the average wholesale  
23          acquisition cost, listed as cost per  
24          day’s supply; cost per dosage

1 unit, and cost per typical course  
2 of treatment (as applicable);

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

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

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

22 “(hh) all other direct or in-  
23 direct remuneration on the drug  
24 as reported under the Detailed  
25 DIR Report (or any successor re-

1 port) submitted by such sponsor  
2 to the Centers for Medicare &  
3 Medicaid Services;

4 “(ii) the average pharmacy  
5 reimbursement amount paid by  
6 the plan for the drug in the ag-  
7 gregate and disaggregated by dis-  
8 pensing channel identified in item  
9 (cc);

10 “(jj) the average National  
11 Average Drug Acquisition Cost  
12 (NADAC) for retail community  
13 pharmacies; and

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

21 “(H) In the case of a pharmacy  
22 benefit manager that has an affiliate  
23 that is a retail, mail order, or spe-  
24 cialty pharmacy, with respect to drugs

1 covered by such plan that were dis-  
2 pensed, the following information:

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

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

19 “(cc) The interquartile  
20 range of the total combined costs  
21 paid by the plan and plan enroll-  
22 ees, per dosage unit, per course  
23 of treatment, per 30-day supply,  
24 and per 90-day supply for each  
25 drug dispensed by pharmacies

1 that are an affiliate of the phar-  
2 macy benefit manager and that  
3 are included in the pharmacy  
4 network of such plan.

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

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

22 “(ff) A list of covered part  
23 D drugs subject to an agreement  
24 with a covered entity under sec-  
25 tion 340B of the Public Health

1 Service Act for which the phar-  
2 macy benefit manager or an affil-  
3 iate of the pharmacy benefit  
4 manager had a contract or other  
5 arrangement with such a covered  
6 entity in the service area of such  
7 plan.

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

14 “(aa) A list of currently  
15 marketed generic drugs approved  
16 under section 505(j) of the Fed-  
17 eral Food, Drug, and Cosmetic  
18 Act pursuant to an application  
19 that references such listed drug  
20 that are not covered by the plan,  
21 are covered on the same for-  
22 mulary tier or a formulary tier  
23 typically associated with higher  
24 cost-sharing than the listed drug,  
25 or are subject to utilization man-

1           agement that the listed drug is  
2           not subject to.

3           “(bb) The estimated average  
4           beneficiary cost-sharing under  
5           the plan for a 30-day supply of  
6           the listed drug.

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

19          “(dd) A written justification  
20          for providing more favorable cov-  
21          erage of the listed drug than the  
22          generic drugs described in item  
23          (aa).

24          “(ee) The number of cur-  
25          rently marketed generic drugs

1 approved under section 505(j) of  
2 the Federal Food, Drug, and  
3 Cosmetic Act pursuant to an ap-  
4 plication that references such  
5 listed drug.

6 “(IV) Where a reference product  
7 (as defined in section 351(i) of the  
8 Public Health Service Act) is covered  
9 by the plan, the following information:

10 “(aa) A list of currently  
11 marketed biosimilar biological  
12 products licensed under section  
13 351(k) of the Public Health  
14 Service Act pursuant to an appli-  
15 cation that refers to such ref-  
16 erence product that are not cov-  
17 ered by the plan, are covered on  
18 the same formulary tier or a for-  
19 mulary tier typically associated  
20 with higher cost-sharing than the  
21 reference product, or are subject  
22 to utilization management that  
23 the reference product is not sub-  
24 ject to.

1           “(bb) The estimated average  
2 beneficiary cost-sharing under  
3 the plan for a 30-day supply of  
4 the reference product.

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

19           “(dd) A written justification  
20 for providing more favorable cov-  
21 erage of the reference product  
22 than the biosimilar biological  
23 product described in item (aa).

24           “(ee) The number of cur-  
25 rently marketed biosimilar bio-

1 logical products licensed under  
2 section 351(k) of the Public  
3 Health Service Act, pursuant to  
4 an application that refers to such  
5 reference product.

6 “(V) Total gross spending on  
7 covered part D drugs by the plan, not  
8 net of rebates, fees, discounts, or  
9 other direct or indirect remuneration.

10 “(VI) The total amount retained  
11 by the pharmacy benefit manager or  
12 an affiliate of such pharmacy benefit  
13 manager in revenue related to utiliza-  
14 tion of prescription drugs under that  
15 plan, inclusive of bona fide service  
16 fees.

17 “(VII) The total spending on cov-  
18 ered part D drugs net of rebates, fees,  
19 discounts, or other direct and indirect  
20 remuneration by the plan.

21 “(VIII) An explanation of any  
22 benefit design parameters under such  
23 plan that encourage plan enrollees to  
24 fill prescriptions at pharmacies that  
25 are an affiliate of such pharmacy ben-

1           efit manager, such as mail and spe-  
2           cialty home delivery programs, and re-  
3           tail and mail auto-refill programs.

4           “(IX) A list of all brokers, con-  
5           sultants, advisors, and auditors that  
6           receive compensation from the phar-  
7           macy benefit manager or an affiliate  
8           of such pharmacy benefit manager for  
9           referrals, consulting, auditing, or  
10          other services offered to PDP spon-  
11          sors related to pharmacy benefit man-  
12          agement services.

13          “(X) A list of all affiliates of the  
14          pharmacy benefit manager.

15          “(XI) A summary document sub-  
16          mitted in a standardized template de-  
17          veloped by the Secretary that includes  
18          such information described in sub-  
19          clauses (I) through (X).

20          “(ii) WRITTEN EXPLANATION OF CON-  
21          TRACTS OR AGREEMENTS WITH DRUG  
22          MANUFACTURERS.—

23          “(I) IN GENERAL.—The phar-  
24          macy benefit manager shall, not later  
25          than 30 days after the finalization of

1 any contract or agreement between  
2 such pharmacy benefit manager or an  
3 affiliate of such pharmacy benefit  
4 manager and a drug manufacturer (or  
5 subsidiary, agent, or entity affiliated  
6 with such drug manufacturer) that  
7 makes rebates, discounts, payments,  
8 or other financial incentives related to  
9 one or more prescription drugs of the  
10 manufacturer directly or indirectly  
11 contingent upon coverage, formulary  
12 placement, or utilization management  
13 conditions on any other prescription  
14 drugs, submit to the PDP sponsor a  
15 written explanation of such contract  
16 or agreement.

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

20 “(aa) include the manufac-  
21 turer subject to the contract or  
22 agreement, all prescription drugs  
23 subject to the contract or agree-  
24 ment and the manufacturers of  
25 such drugs, and a high-level de-

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

5 “(bb) be certified by the  
6 Chief Executive Officer, Chief Fi-  
7 nancial Officer, or General Coun-  
8 sel of such pharmacy benefit  
9 manager, affiliate of such phar-  
10 macy benefit manager, or an in-  
11 dividual delegated with the au-  
12 thority to sign on behalf of one of  
13 these officers, who reports di-  
14 rectly to the officer.

15 “(D) AUDIT RIGHTS.—

16 “(i) IN GENERAL.—Not less than once  
17 a year, at the request of the PDP sponsor,  
18 the pharmacy benefit manager shall allow  
19 for an audit of the pharmacy benefit man-  
20 ager to ensure compliance with all terms  
21 and conditions under the written agree-  
22 ment and the accuracy of information re-  
23 ported under subparagraph (C).

24 “(ii) AUDITOR.—The PDP sponsor  
25 shall have the right to select an auditor.

1 The pharmacy benefit manager shall not  
2 impose any limitations on the selection of  
3 such auditor.

4 “(iii) PROVISION OF INFORMATION.—

5 The pharmacy benefit manager shall make  
6 available to such auditor all records, data,  
7 contracts, and other information necessary  
8 to confirm the accuracy of information  
9 provided under subparagraph (C), subject  
10 to reasonable restrictions on how such in-  
11 formation must be reported to prevent re-  
12 disclosure of such information.

13 “(iv) TIMING.—The pharmacy benefit

14 manager must provide information under  
15 clause (iii) and other information, data,  
16 and records relevant to the audit to such  
17 auditor within 6 months of the initiation of  
18 the audit and respond to requests for addi-  
19 tional information from such auditor with-  
20 in 30 days after the request for additional  
21 information.

22 “(v) INFORMATION FROM AFFILI-

23 ATES.—The pharmacy benefit manager  
24 shall be responsible for providing to such  
25 auditor information required to be reported

1 under subparagraph (C) that is owned or  
2 held by an affiliate of such pharmacy ben-  
3 efit manager.

4 “(E) ENFORCEMENT.—The pharmacy ben-  
5 efit manager shall—

6 “(i) disgorge to a PDP sponsor (or, in  
7 a case where the PDP sponsor is an affil-  
8 iate of such pharmacy benefit manager, to  
9 the Secretary) any payment, remuneration,  
10 or other amount received by the pharmacy  
11 benefit manager or an affiliate of such  
12 pharmacy benefit manager in violation of  
13 subparagraph (A) or the written agreement  
14 entered into with such sponsor under this  
15 part with respect to a prescription drug  
16 plan;

17 “(ii) reimburse the PDP sponsor for  
18 any civil money penalty imposed on the  
19 PDP sponsor as a result of the failure of  
20 the pharmacy benefit manager to meet the  
21 requirements of this paragraph that are  
22 applicable to the pharmacy benefit man-  
23 ager under the agreement; and

24 “(iii) be subject to punitive remedies  
25 for breach of contract for failure to comply

1                   with the requirements applicable under this  
2                   paragraph:

3                   “(2) CERTIFICATION OF COMPLIANCE.—Each  
4                   PDP sponsor shall furnish to the Secretary (in a  
5                   time and manner specified by the Secretary) an an-  
6                   nual certification of compliance with this subsection,  
7                   as well as such information as the Secretary deter-  
8                   mines necessary to carry out this subsection:

9                   “(3) RULE OF CONSTRUCTION.—Nothing in  
10                  this subsection shall be construed as prohibiting pay-  
11                  ments related to reimbursement for ingredient costs  
12                  to any entity that acquires prescription drugs, such  
13                  as a pharmacy or wholesaler:

14                  “(4) STANDARD FORMATS.—Not later than  
15                  June 1, 2025, the Secretary shall specify standard,  
16                  machine-readable formats for pharmacy benefit  
17                  managers to submit annual reports required under  
18                  paragraph (1)(C)(i):

19                  “(5) CONFIDENTIALITY.—

20                  “(A) IN GENERAL.—Information disclosed  
21                  by a pharmacy benefit manager or PDP spon-  
22                  sor under this subsection that is not otherwise  
23                  publicly available or available for purchase shall  
24                  not be disclosed by the Secretary or a PDP  
25                  sponsor receiving the information, except that

1 the Secretary may disclose the information for  
2 the following purposes:

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

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

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

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

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

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

23 “(B) RESTRICTION ON USE OF INFORMA-  
24 TION.—The Secretary, the Comptroller General,  
25 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 a specific pharmacy benefit  
6            manager, affiliate, manufacturer or wholesaler,  
7            PDP sponsor, or plan, or contract prices, re-  
8            bates, discounts, or other remuneration for spe-  
9            cific drugs in a manner that may allow the  
10          identification of specific contracting parties.

11          “(6) DEFINITIONS.—For purposes of this sub-  
12          section:

13                “(A) AFFILIATE.—The term ‘affiliate’  
14                means any entity that is owned by, controlled  
15                by, or related under a common ownership struc-  
16                ture with a pharmacy benefit manager or PDP  
17                sponsor, or that acts as a contractor or agent  
18                to such pharmacy benefit manager or PDP  
19                sponsor, insofar as such contractor or agent  
20                performs any of the functions described under  
21                subparagraph (C).

22                “(B) BONA FIDE SERVICE FEE.—The term  
23                ‘bona fide service fee’ means a fee that is reflec-  
24                tive of the fair market value for a bona fide,  
25                itemized service actually performed on behalf of

1 an entity, that the entity would otherwise per-  
 2 form (or contract for) in the absence of the  
 3 service arrangement and that are not passed on  
 4 in whole or in part to a client or customer,  
 5 whether or not the entity takes title to the  
 6 drug. Such fee must be a flat dollar amount  
 7 and shall not be directly or indirectly based on,  
 8 or contingent upon—

9 “(i) drug price, such as wholesale ac-  
 10 quisition cost or drug benchmark price  
 11 (such as average wholesale price);

12 “(ii) discounts, rebates, fees, or other  
 13 direct or indirect remuneration amounts  
 14 with respect to covered part D drugs dis-  
 15 pensed to enrollees in a prescription drug  
 16 plan, except as permitted pursuant to  
 17 paragraph (1)(A)(ii);

18 “(iii) coverage or formulary placement  
 19 decisions or the volume or value of any re-  
 20 ferrals or business generated between the  
 21 parties to the arrangement; or

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

24 “(C) PHARMACY BENEFIT MANAGER.—The  
 25 term ‘pharmacy benefit manager’ means any

1 person or entity that, either directly or through  
2 an intermediary, acts as a price negotiator or  
3 group purchaser on behalf of a PDP sponsor or  
4 prescription drug plan; or manages the pre-  
5 scription drug benefits provided by such spon-  
6 sor or plan, including the processing and pay-  
7 ment of claims for prescription drugs; the per-  
8 formance of drug utilization review; the proe-  
9 cessed of drug prior authorization requests; the  
10 adjudication of appeals or grievances related to  
11 the prescription drug benefit; contracting with  
12 network pharmacies; controlling the cost of cov-  
13 ered part D drugs; or the provision of related  
14 services. Such term includes any person or enti-  
15 ty that carries out one or more of the activities  
16 described in the preceding sentence, irrespective  
17 of whether such person or entity calls itself a  
18 ‘pharmacy benefit manager.’”.

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) REQUIREMENTS RELATING TO PHAR-  
24 MACY BENEFIT MANAGERS.—For plan years be-

1           ginning on or after January 1, 2026, section  
2           1860D-12(h).”.

3           ~~(3) FUNDING.—~~

4                   (A) SECRETARY.—In addition to amounts  
5           otherwise available, there is appropriated to the  
6           Centers for Medicare & Medicaid Services Pro-  
7           gram Management Account, out of any money  
8           in the Treasury not otherwise appropriated,  
9           \$20,000,000 for fiscal year 2026, to remain  
10          available until expended, to carry out the  
11          amendments made by this subsection.

12                   (B) OIG.—In addition to amounts other-  
13          wise available, there is appropriated to the In-  
14          spector General of the Department of Health  
15          and Human Services, out of any money in the  
16          Treasury not otherwise appropriated,  
17          \$5,000,000 for fiscal year 2026, to remain  
18          available until expended, to carry out the  
19          amendments made by this subsection.

20          (b) GAO STUDY AND REPORT ON CERTAIN REPORT-  
21          ING REQUIREMENTS.—

22                   (1) STUDY.—The Comptroller General of the  
23          United States (in this subsection referred to as the  
24          “Comptroller General”) shall conduct a study on  
25          Federal and State reporting requirements for health

1 plans and pharmacy benefit managers related to the  
2 transparency of prescription drug costs and prices.  
3 Such study shall include an analysis of the following:

4 (A) Federal statutory and regulatory re-  
5 porting requirements for health plans and phar-  
6 macy benefit managers related to prescription  
7 drug costs and prices.

8 (B) Selected States' statutory and regu-  
9 latory reporting requirements for health plans  
10 and pharmacy benefit managers related to pre-  
11 scription drug costs and prices.

12 (C) The extent to which the statutory and  
13 regulatory reporting requirements identified in  
14 subparagraphs (A) and (B) overlap and con-  
15 flict.

16 (D) The resources required by health plans  
17 and pharmacy benefit managers to comply with  
18 the reporting requirements described in sub-  
19 paragraphs (A) and (B).

20 (E) Other items determined appropriate by  
21 the Comptroller General.

22 (2) REPORT.—Not later than 2 years after the  
23 date on which information is first required to be re-  
24 ported under section 1860D–12(h)(1)(C) of the So-  
25 cial Security Act, as added by subsection (a)(1), the

1 Comptroller General shall submit to Congress a re-  
2 port containing the results of the study conducted  
3 under paragraph ~~(1)~~, together with recommenda-  
4 tions for legislation and administrative actions that  
5 would streamline and reduce the burden associated  
6 with the reporting requirements for health plans and  
7 pharmacy benefit managers described in paragraph  
8 ~~(1)~~.

9 ~~(c) MEDPAC REPORTS ON AGREEMENTS WITH~~  
10 ~~PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE-~~  
11 ~~SCRIPTION DRUG PLANS AND MA-PD PLANS.—The~~  
12 Medicare Payment Advisory Commission shall submit to  
13 Congress the following reports:

14 ~~(1) Not later than March 31, 2027, a report re-~~  
15 ~~garding agreements with pharmacy benefit managers~~  
16 ~~with respect to prescription drug plans and MA-PD~~  
17 ~~plans. Such report shall include—~~

18 ~~(A) a description of trends and patterns,~~  
19 ~~including relevant averages, totals, and other~~  
20 ~~figures for each of the types of information sub-~~  
21 ~~mitted;~~

22 ~~(B) an analysis of any differences in agree-~~  
23 ~~ments and their effects on plan enrollee out-of-~~  
24 ~~poCKET spending and average pharmacy reim-~~  
25 ~~bursement, and any other impacts; and~~



1           “(A) established or adopted by the Sec-  
 2           retary under paragraph (2) and included on the  
 3           list described in subparagraph (B) of such  
 4           paragraph; and

5           “(B) relevant to the performance of such  
 6           pharmacy based on the type of pharmacy (in-  
 7           cluding retail, mail order, specialty, long term  
 8           care, and home infusion or other types of phar-  
 9           macies); drugs dispensed by such pharmacy;  
 10          and pharmacy services used to dispense and  
 11          manage drugs by such pharmacy.

12          “(2) STANDARDIZED PHARMACY PERFORMANCE  
 13          MEASURES.—

14                 “(A) MEASURES.—

15                         “(i) IN GENERAL.—Notwithstanding  
 16                         any other provision of law, the Secretary  
 17                         shall establish (or adopt pursuant to clause  
 18                         (iii)) standardized pharmacy performance  
 19                         measures that may be used by a PDP  
 20                         sponsor offering a prescription drug plan  
 21                         and an MA organization offering an MA-  
 22                         PD plan for the purpose of determining in-  
 23                         centive payments, price concessions, or fees  
 24                         or other remuneration described in para-  
 25                         graph (1).

1           “(ii) REQUIREMENTS.—The measures  
2           under clause (i) shall focus on pharmacy  
3           performance and quality of care based on  
4           the type of pharmacy, as determined by  
5           the Secretary. Such measures shall be evi-  
6           dence-based, feasible, appropriate and rea-  
7           sonable.

8           “(iii) ADOPTION OF MEASURE.—In  
9           lieu of establishing some or all of the  
10          measures under this paragraph, the Sec-  
11          retary may adopt measures that are en-  
12          dorsed by one or more multi-stakeholder  
13          consensus organizations (such as the Phar-  
14          macy Quality Alliance), that has participa-  
15          tion from pharmacies (including retail and  
16          specialty pharmacies not owned or affili-  
17          ated with a plan, pharmacy benefit man-  
18          ager, or other pharmacy), health plans,  
19          pharmacy benefit managers, and the Cen-  
20          ters for Medicare & Medicaid Services. Any  
21          measure adopted under this clause shall be  
22          deemed to meet the requirements under  
23          clause (ii).

24          “(B) MAINTENANCE OF LIST.—

1           “(i) IN GENERAL.—The Secretary  
2           shall maintain, and publish on a publicly  
3           available internet website, a list of meas-  
4           ures established or adopted under this  
5           paragraph. Such list shall initially be pub-  
6           lished no later than June 1, 2024.

7           “(ii) UPDATE.—The Secretary shall  
8           periodically evaluate measures, and how  
9           measures are applied by type of pharmacy  
10          and update the measures on the list under  
11          clause (i) so that such measures meet the  
12          requirements under subparagraph (A)(ii).

13          “(3) NONAPPLICATION OF PAPERWORK REDUC-  
14          TION ACT.—Chapter 35 of title 44, United States  
15          Code, shall not apply to any data collection under-  
16          taken by the Secretary under this subsection.”.

17          (b) FUNDING.—In addition to amounts otherwise  
18          available, there is appropriated to the Centers for Medi-  
19          care & Medicaid Services Program Management Account,  
20          out of any money in the Treasury not otherwise appro-  
21          priated, \$4,000,000 for fiscal year 2025, to remain avail-  
22          able until expended, to carry out the amendment made  
23          by subsection (a).

1 **SEC. 4. PROMOTING TRANSPARENCY FOR PHARMACIES**  
 2 **UNDER MEDICARE PART D.**

3 (a) **TRANSPARENCY FOR PHARMACIES.**—Section  
 4 1860D–2(f) of the Social Security Act (42 U.S.C. 1395w–  
 5 102(f)), as added by section 3, is amended by adding at  
 6 the end the following new paragraph:

7 “(4) **TRANSPARENCY FOR PHARMACIES.**—

8 “(A) **IN GENERAL.**—For plan years begin-  
 9 ning on or after January 1, 2025, a PDP spon-  
 10 sor offering a prescription drug plan and an  
 11 MA organization offering an MA–PD plan, with  
 12 respect to payment made by such PDP sponsor  
 13 or such MA organization to a pharmacy for a  
 14 covered part D drug dispensed by such phar-  
 15 macy during a plan year, shall promptly fur-  
 16 nish, upon paying a claim for a covered part D  
 17 drug from a pharmacy, to such pharmacy infor-  
 18 mation related to such claim, such as the Net-  
 19 work Reimbursement ID, fees, pharmacy price  
 20 concessions, discounts, incentives, or any other  
 21 forms of remuneration that affect payment and  
 22 pricing of the claim.

23 “(B) **STANDARDIZED FORMAT.**—The PDP  
 24 sponsor and the MA organization shall furnish  
 25 the information described in subparagraph (A)  
 26 in a standardized format (as specified by the

1 Secretary) that includes all fields needed to  
 2 price the claim for a covered part D drug dis-  
 3 pensed by such pharmacy.

4 “(C) AVAILABILITY OF INFORMATION TO  
 5 THE SECRETARY.—A PDP sponsor offering a  
 6 prescription drug plan or an MA organization  
 7 offering an MA-PD plan shall make the infor-  
 8 mation described in subparagraph (A) available  
 9 to the Secretary upon request.

10 “(D) IMPLEMENTATION.—Notwithstanding  
 11 any other provision of law, the Secretary shall  
 12 implement this paragraph by program instruc-  
 13 tion or otherwise.”.

14 (b) FUNDING.—In addition to amounts otherwise  
 15 available, there is appropriated to the Centers for Medi-  
 16 care & Medicaid Services Program Management Account,  
 17 out of any money in the Treasury not otherwise appro-  
 18 priated, \$2,000,000 for fiscal year 2025, to remain avail-  
 19 able until expended, to carry out the amendment made  
 20 by subsection (a).

21 **SEC. 5. PREVENTING THE USE OF ABUSIVE SPREAD PRIC-**  
 22 **ING IN MEDICAID.**

23 (a) IN GENERAL.—Section 1927(e) of the Social Se-  
 24 curity Act (42 U.S.C. 1396r-8(e)) is amended by adding  
 25 at the end the following:

1           ~~“(6) TRANSPARENT PRESCRIPTION DRUG PASS-~~  
2           ~~THROUGH PRICING REQUIRED.—~~A contract between  
3           the State and a pharmacy benefit manager (referred  
4           to in this paragraph as a ‘PBM’), or a contract be-  
5           tween the State and a managed care entity or other  
6           specified entity (as such terms are defined in section  
7           ~~1903(m)(9)(D)~~ and collectively referred to in this  
8           paragraph as the ‘entity’) that includes provisions  
9           making the entity responsible for coverage of covered  
10          outpatient drugs dispensed to individuals enrolled  
11          with the entity, shall require that payment for such  
12          drugs and related administrative services (as appli-  
13          cable), including payments made by a PBM on be-  
14          half of the State or entity, is based on a transparent  
15          prescription drug pass-through pricing model under  
16          which—

17                   ~~“(A) any payment made by the entity or~~  
18                   the PBM (as applicable) for such a drug—

19                           ~~“(i) is limited to—~~

20                                   ~~“(I) ingredient cost; and~~

21                                   ~~“(II) a professional dispensing~~  
22                                   fee that is not less than the profes-  
23                                   sional dispensing fee that the State  
24                                   plan or waiver would pay if the plan

1 or waiver was making the payment di-  
2 rectly;

3 “(ii) is passed through in its entirety  
4 by the entity or PBM to the pharmacy or  
5 provider that dispenses the drug (and shall  
6 not be reduced or denied retroactively  
7 under post-adjudication processes); and

8 “(iii) is made in a manner that is con-  
9 sistent with sections 447.502, 447.512,  
10 447.514, and 447.518 of title 42, Code of  
11 Federal Regulations (or any successor reg-  
12 ulation) as if such requirements applied di-  
13 rectly to the entity or the PBM, except  
14 that any payment by the entity or the  
15 PBM for the ingredient cost of such drug  
16 purchased by a covered entity (as defined  
17 in subsection (a)(5)(B)) may exceed the  
18 actual acquisition cost (as defined in  
19 447.502 of title 42, Code of Federal Regu-  
20 lations, or any successor regulation) for  
21 such drug if—

22 “(I) such drug was subject to an  
23 agreement under section 340B of the  
24 Public Health Service Act;

1           “(H) such payment for the ingre-  
2           dient cost of such drug does not ex-  
3           ceed the maximum payment that  
4           would have been made by the entity or  
5           the PBM for the ingredient cost of  
6           such drug if such drug had not been  
7           purchased by such covered entity; and

8           “(III) such covered entity reports  
9           to the Secretary (in a form and man-  
10          ner specified by the Secretary); on an  
11          annual basis and with respect to pay-  
12          ments for the ingredient costs of such  
13          drugs so purchased by such covered  
14          entity that are in excess of the actual  
15          acquisition costs for such drugs; the  
16          aggregate amount of such excess;

17          “(B) payment to the entity or the PBM  
18          (as applicable) for administrative services per-  
19          formed by the entity or PBM is limited to the  
20          fair market value of such services;

21          “(C) the entity or the PBM (as applicable)  
22          shall make available to the State, and the Sec-  
23          retary upon request, all costs and payments re-  
24          lated to covered outpatient drugs and accom-  
25          panying administrative services incurred; re-

1 received, or made by the entity or the PBM, in-  
 2 cluding ingredient costs, professional dispensing  
 3 fees, administrative fees, post-sale and post-in-  
 4 voice fees, discounts, or related adjustments  
 5 such as direct and indirect remuneration fees,  
 6 and any and all other remuneration; and

7 “(D) any form of spread pricing whereby  
 8 any amount charged or claimed by the entity or  
 9 the PBM (as applicable) that exceeds the  
 10 amount paid to the pharmacies or providers on  
 11 behalf of the State or entity, including any  
 12 post-sale or post-invoice fees, discounts, or re-  
 13 lated adjustments such as direct and indirect  
 14 remuneration fees or assessments (after allow-  
 15 ing for an administrative fee as described in  
 16 subparagraph (B)) is not allowable for purposes  
 17 of claiming Federal matching payments under  
 18 this title.”.

19 (b) DEFINITION OF PHARMACY BENEFIT MAN-  
 20 AGER.—Section 1927(k) of the Social Security Act (42  
 21 U.S.C. 1396r-8(k)) is amended by adding at the end the  
 22 following new paragraph:

23 “(12) PHARMACY BENEFIT MANAGER.—The  
 24 term ‘pharmacy benefit manager’ means any person  
 25 or entity that, either directly or through an inter-

1       mediary, acts as a price negotiator or group pur-  
 2       chaser on behalf of a State, managed care entity or  
 3       other specified entity (as such terms are defined in  
 4       section 1903(m)(9)(D)), or manages the prescription  
 5       drug benefits provided by such State, managed care  
 6       entity, or other specified entity, including the pro-  
 7       cessing and payment of claims for prescription drugs,  
 8       the performance of drug utilization review, the pro-  
 9       cessing of drug prior authorization requests, the man-  
 10      aging of appeals or grievances related to the pre-  
 11      scription drug benefits, contracting with pharmacies,  
 12      controlling the cost of covered outpatient drugs, or  
 13      the provision of services related thereto. Such term  
 14      includes any person or entity that carries out 1 or  
 15      more of the activities described in the preceding sen-  
 16      tence, irrespective of whether such person or entity  
 17      calls itself a ‘pharmacy benefit manager.’”.

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

20           (1) in paragraph (2)(A)(xiii)—

21                   (A) by striking “and (III)” and inserting  
 22                   “(III)”;

23                   (B) by inserting before the period at the  
 24                   end the following: “, and (IV) if the entity, or  
 25                   a pharmacy benefit manager acting on behalf of

1 the entity under a contract or other arrange-  
2 ment between the entity and the pharmacy ben-  
3 efit manager, performs any of the activities de-  
4 scribed in section 1927(k)(12), such activities  
5 shall comply with the requirements of section  
6 1927(e)(6)”; and

7 (C) by moving the left margin 2 ems to the  
8 left; and

9 (2) by adding at the end the following new  
10 paragraph:

11 “(10) No payment shall be made under this title to  
12 a State with respect to expenditures incurred by the State  
13 for payment for services provided by an other specified  
14 entity (as defined in paragraph (9)(D)(iii)) unless such  
15 services are provided in accordance with a contract be-  
16 tween the State and such entity which satisfies the re-  
17 quirements of paragraph (2)(A)(xiii).”.

18 (d) EFFECTIVE DATE.—The amendments made by  
19 this section apply to contracts between States and man-  
20 aged care entities, other specified entities, or pharmacy  
21 benefit managers that have an effective date beginning on  
22 or after the date that is 18 months after the date of enact-  
23 ment of this Act.

1 **SEC. 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES**  
2 **UNDER MEDICAID.**

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

5 (1) by striking “and” after the semicolon at the  
6 end of paragraph (1)(A)(i) and all that precedes it  
7 through “(1)” and inserting the following:

8 “(1) **DETERMINING PHARMACY ACTUAL ACQUI-**  
9 **SITION COSTS.**—The Secretary shall conduct a sur-  
10 vey of retail community pharmacy drug prices to de-  
11 termine the national average drug acquisition cost as  
12 follows:

13 “(A) **USE OF VENDOR.**—The Secretary  
14 may contract services for—

15 “(i) with respect to retail community  
16 pharmacies, the determination of retail  
17 survey prices of the national average drug  
18 acquisition cost for covered outpatient  
19 drugs that represent a nationwide average  
20 of consumer purchase prices for such  
21 drugs, net of all discounts and rebates (to  
22 the extent any information with respect to  
23 such discounts and rebates is available)  
24 based on a monthly survey of such phar-  
25 macies; and”;

1           (2) 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 in the State that receives any pay-  
7 ment, reimbursement, administrative fee, dis-  
8 count, or rebate related to the dispensing of  
9 covered outpatient drugs to individuals receiv-  
10 ing benefits under this title, regardless of  
11 whether such payment, reimbursement, admin-  
12 istrative fee, discount, or rebate is received  
13 from the State or a managed care entity or  
14 other specified entity (as such terms are defined  
15 in section 1903(m)(9)(D)) directly or from a  
16 pharmacy benefit manager or another entity  
17 that has a contract with the State or a man-  
18 aged care entity or other specified entity (as so  
19 defined), shall respond to surveys of retail  
20 prices conducted under this paragraph.

21           “(G) SURVEY INFORMATION.—Information  
22 on national drug acquisition prices obtained  
23 under this paragraph shall be made publicly  
24 available and shall include at least the fol-  
25 lowing:

1           “(i) The monthly response rate to the  
2           survey including a list of pharmacies not in  
3           compliance with subparagraph (F).

4           “(ii) The sampling frame and number  
5           of pharmacies sampled monthly.

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

12          “(H) PENALTIES.—The Secretary may en-  
13          force non-compliance with this paragraph by a  
14          pharmacy through the establishment of pen-  
15          alties or the suspension of payments under this  
16          title, in full or in part, until compliance with  
17          this paragraph has been completed.”;

18          (3) in paragraph (2)—

19                 (A) in subparagraph (A), by inserting “,  
20                 including payment rates under Medicaid man-  
21                 aged care entities or other specified entities (as  
22                 such terms are defined in section  
23                 1903(m)(9)(D)),” after “under this title”; and

1           (B) in subparagraph (B), by inserting  
 2           “and the basis for such dispensing fees” before  
 3           the semicolon; and

4           (4) in paragraph (4), by inserting “, and  
 5           \$5,000,000 for fiscal year 2024 and each fiscal year  
 6           thereafter,” after “2010”.

7           (b) **EFFECTIVE DATE.**—The amendments made by  
 8 this section take effect on the first day of the first quarter  
 9 that begins on or after the date that is 18 months after  
 10 the date of enactment of this Act.

11 **SEC. 7. OIG STUDY AND REPORT ON DRUG PRICE MARK-**  
 12 **UPS IN MEDICARE PART D.**

13           Section 1860D–42 of the Social Security Act (42  
 14 U.S.C. 1395w–152) is amended by adding at the end the  
 15 following new subsection:

16           “(e) **OIG STUDY AND REPORT ON DRUG PRICE**  
 17 **MARK-UPS UNDER THIS PART.**—

18           “(1) **STUDY.**—The Inspector General of the De-  
 19 partment of Health and Human Services (in this  
 20 subsection referred to as the ‘Inspector General’)  
 21 shall conduct a study on the impact of related party  
 22 transactions within select vertically integrated enti-  
 23 ties on the negotiated price (as defined in section  
 24 1860D–2(d)(1)(B)) paid by part D plan sponsors

1 for covered part D drugs. Such study may include  
2 an analysis of the following:

3 “(A) Acquisition costs by the affiliate with-  
4 in such vertically integrated entities that ini-  
5 tially acquires the prescription drug for a sam-  
6 ple of covered part D drugs, including at least  
7 5 generic drugs, brand drugs, specialty brand  
8 drugs, and specialty generic drugs.

9 “(B) The methodologies and negotiation  
10 processes used to calculate transfer prices or  
11 other transactions between related parties with  
12 respect to such covered part D drugs.

13 “(C) The impact of the transactions de-  
14 scribed in subparagraph (B) on the negotiated  
15 price, net of direct and indirect remuneration,  
16 for such covered part D drugs.

17 “(D) The margin captured by different af-  
18 filiates within such vertically integrated entities  
19 through the transactions described in subpara-  
20 graph (B).

21 “(E) An assessment of the impact of the  
22 transactions described in subparagraph (B) on  
23 costs to individuals enrolled in a prescription  
24 drug plan or an MA-PD plan and program  
25 spending on prescription drugs under this part.

1           “(F) Other issues determined to be rel-  
2           evant and appropriate by the Inspector General.

3           ~~“(2) REPORT.—~~Not later than 3 years after the  
4           date of enactment of this subsection, the Inspector  
5           General shall submit to the Committee on Finance  
6           of the Senate and the Committee on Energy and  
7           Commerce and the Committee on Ways and Means  
8           of the House of Representatives a report containing  
9           the results of the study conducted under paragraph  
10          (1), together with recommendations for such legisla-  
11          tion and administrative action as the Inspector Gen-  
12          eral determines appropriate.

13          ~~“(3) FUNDING.—~~In addition to amounts other-  
14          wise available, there is appropriated to the Inspector  
15          General, out of any money in the Treasury not oth-  
16          erwise appropriated, \$5,200,000 for fiscal year  
17          2024, to remain available until expended, to carry  
18          out this subsection.”.

19 **SEC. 8. RESOLVING P&T COMMITTEE CONFLICTS OF INTER-**  
20 **EST.**

21          Section ~~1860D-4(b)(3)(A)(ii)(I)~~ of the Social Secu-  
22          rity Act (~~42 U.S.C. 1395w-104(b)(3)(A)(ii)(I)~~) is amend-  
23          ed by inserting the following before the semicolon: “(and,  
24          for 2025 and each subsequent year, any pharmacy benefit

1 manager acting under contract with such sponsor offering  
 2 such plan)”.  
 3

3 **SEC. 9. ENHANCING PBM TRANSPARENCY REQUIREMENTS.**

4 (a) IN GENERAL.—Section 1150A of the Social Secu-  
 5 rity Act (42 U.S.C. 1320b–23) is amended—

6 (1) by striking subsection (a) and inserting the  
 7 following:

8 “(a) PROVISION OF INFORMATION.—

9 “(1) IN GENERAL.—The following entities shall  
 10 provide the information described in subsection (b)  
 11 to the Secretary and, in the case of an entity de-  
 12 scribed in subparagraph (B) or an affiliate of such  
 13 entity described in subparagraph (C), to the health  
 14 benefits plan with which the entity is under contract,  
 15 at such times, and in such form and manner, as the  
 16 Secretary shall specify:

17 “(A) A health benefits plan.

18 “(B) Any entity that provides pharmacy  
 19 benefits management services on behalf of a  
 20 health benefits plan (in this section referred to  
 21 as a ‘PBM’) that manages prescription drug  
 22 coverage under a contract with—

23 “(i) a PDP sponsor of a prescription  
 24 drug plan or an MA organization offering

1 an MA-PD plan under part D of title  
2 XVIII; or

3 “(ii) a qualified health benefits plan  
4 offered through an exchange established by  
5 a State under section 1311 of the Patient  
6 Protection and Affordable Care Act.

7 “(C) Any affiliate of an entity described in  
8 subparagraph (B) that acts as a price nego-  
9 tiator or group purchaser on behalf of such  
10 PBM, PDP sponsor, MA organization, or quali-  
11 fied health benefits plan.

12 “(2) AFFILIATE DEFINED.—In this section, the  
13 term ‘affiliate’ means any entity that is owned by,  
14 controlled by, or related under a common ownership  
15 structure with a PBM (including an entity owned or  
16 controlled by the PDP sponsor of a prescription  
17 drug plan, MA organization offering an MA-PD  
18 plan, or qualified health benefits plan for which such  
19 entity is acting as a price negotiator or group pur-  
20 chaser).”;

21 (2) in subsection (b)—

22 (A) in paragraph (2), by inserting “and  
23 percentage” after “and the aggregate amount”;  
24 and

1           (B) by adding at the end the following new  
2           paragraph:

3           “(4) The amount (in the aggregate and  
4           disaggregated by type) of all fees the PBM or an af-  
5           filiate of the PBM receives from all pharmaceutical  
6           manufacturers in connection with patient utilization  
7           under the plan; and the amount and percentage (in  
8           the aggregate and disaggregated by type) of such  
9           fees that are passed through to the plan sponsor or  
10          issuer.”; and

11          (3) by adding at the end the following new sub-  
12          section:

13          “(e) ANNUAL REPORT.—The Secretary shall make  
14          publicly available on the internet website of the Centers  
15          for Medicare & Medicaid Services an annual report that  
16          summarizes the trends observed with respect to data re-  
17          ported under subsection (b).”.

18          (b) EFFECTIVE DATE.—The amendments made by  
19          this section shall apply to plan or contract years beginning  
20          on or after January 1, 2027.

21          (c) IMPLEMENTATION.—Notwithstanding any other  
22          provision of law, the Secretary may implement the amend-  
23          ments made by this section by program instruction or oth-  
24          erwise.

1 (d) NON-APPLICATION OF THE PAPERWORK REDUC-  
 2 TION ACT.—Chapter 35 of title 44, United States Code  
 3 (commonly referred to as the “Paperwork Reduction Act  
 4 of 1995”), shall not apply to the implementation of the  
 5 amendments made by this section.

6 **SEC. 10. FACILITATING MIDYEAR FORMULARY CHANGES**  
 7 **FOR BIOSIMILARS.**

8 (a) IN GENERAL.—Section 1860D–4(b) of the Social  
 9 Security Act (42 U.S.C. 1395w–104(b)) is amended by  
 10 adding at the end the following new paragraph:

11 “(5) MID-YEAR CHANGES IN FORMULARIES  
 12 PERMITTED FOR CERTAIN BIOSIMILAR BIOLOGICAL  
 13 PRODUCTS AND THE REFERENCE PRODUCT OF SUCH  
 14 BIOSIMILARS.—If a PDP sponsor of a prescription  
 15 drug plan uses a formulary (including the use of  
 16 tiered cost-sharing), the following shall apply:

17 “(A) IN GENERAL.—For plan year 2025,  
 18 and subsequent plan years, in the case of a cov-  
 19 ered part D drug that is the reference biological  
 20 product (as defined in section 351(i) of the  
 21 Public Health Service Act) with respect to a  
 22 biosimilar biological product (defined as a bio-  
 23 logical product licensed under section 351(k) of  
 24 such Act), the PDP sponsor may, with respect  
 25 to a formulary, at any time after the first 60

1 days of the plan year, subject to paragraph  
2 (3)(E), change the preferred or tiered cost-shar-  
3 ing status of such reference biological product  
4 if such PDP sponsor adds, before or at the  
5 same time, to such formulary such biosimilar  
6 biological product at the same or a higher pre-  
7 ferred status, or to the same or lower cost-shar-  
8 ing tier, as that of such reference biological  
9 product immediately prior to such change.

10 “(B) REQUEST FOR APPROVAL OF  
11 CHANGE.—Prior to making a change described  
12 in subparagraph (A), the PDP sponsor shall  
13 submit to the Secretary a request to make such  
14 change. If the Secretary approves the request  
15 or has not provided a decision to the PDP  
16 sponsor regarding such request within 30 days  
17 of receiving such request, such PDP sponsor  
18 may make such change.”

19 (b) ADMINISTRATION.—

20 (1) IMPLEMENTATION.—Notwithstanding any  
21 other provision of law, the Secretary of Health and  
22 Human Services may implement the amendment  
23 made by subsection (a) by program instruction or  
24 otherwise.

1           (2) ~~NON-APPLICATION OF THE PAPERWORK RE-~~  
 2           ~~DUCTION ACT.~~—Chapter 35 of title 44, United  
 3           States Code (commonly referred to as the “Paper-  
 4           work Reduction Act of 1995”), shall not apply to the  
 5           implementation of the amendment made by sub-  
 6           section (a).

7   **SEC. 11. STRENGTHENING PHARMACY ACCESS FOR SEN-**  
 8                                   **IORES.**

9           Section ~~1860D-4(b)(1)~~ of the Social Security Act (~~42~~  
 10          ~~U.S.C. 1395w-104(b)(1)~~) is amended by adding at the  
 11          end the following new subparagraph:

12                               “(F) ~~LIMITED ACCESS DRUGS.~~—

13                               “(i) ~~LIMITATION ON RESTRICTIONS OR~~  
 14                               ~~LIMITS ON ACCESS.~~—For each plan year  
 15                               (beginning with plan year 2026), a PDP  
 16                               sponsor offering a prescription drug plan—

17                                       “(I) may not restrict or limit ac-  
 18                                       cess to any covered part D drug to a  
 19                                       subset of their network pharmacies;  
 20                                       other than with respect to a limited  
 21                                       access drug, as defined in clause (v);  
 22                                       and

23                                       “(II) shall document the ration-  
 24                                       ale for why a covered part D drug  
 25                                       meets the definition of a limited ac-

1           cess drug under clause (v), if such  
2           plan restricts or limits access to a lim-  
3           ited access drug to a subset of net-  
4           work pharmacies.

5           “(ii) ANNUAL SUBMISSION OF INFOR-  
6           MATION TO THE SECRETARY ON LIMITED  
7           ACCESS DRUGS.—For each plan year (be-  
8           ginning with plan year 2026), each PDP  
9           sponsor offering a prescription drug plan  
10          shall submit to the Secretary, at a time  
11          and in a manner specified by the Sec-  
12          retary, with respect to each prescription  
13          drug plan offered by the sponsor during  
14          such plan year—

15               “(I) a list of all covered part D  
16               drugs that the PDP sponsor des-  
17               ignated as a limited access drug;

18               “(II) for each covered part D  
19               drug included in the list described in  
20               subclause (I), a written rationale for  
21               why such drug meets the definition of  
22               a limited access drug;

23               “(III) a summary of the require-  
24               ments imposed on network pharmacies  
25               (including all accreditation require-

1           ments, if any) to ensure appropriate  
2           handling and dispensing of each cov-  
3           ered part D drug included in the list  
4           described in subclause (I);

5           “(IV) the percentages of each  
6           covered part D drug included in the  
7           list described in subclause (I) that is  
8           dispensed through retail pharmacies,  
9           specialty pharmacies, mail order phar-  
10          macies, or other dispensing channels  
11          as defined by the PDP sponsor, re-  
12          spectively;

13          “(V) the annual percentage of  
14          each covered part D drug included in  
15          the list described in subclause (I) that  
16          is dispensed through a pharmacy that  
17          is affiliated with the plan or is an af-  
18          filiate (as defined in section 1860D-  
19          12(h)(4)(A)) of a pharmacy benefit  
20          manager acting on behalf of such  
21          sponsor or such plan; and

22          “(VI) any other information de-  
23          termined appropriate by the Sec-  
24          retary.

1           “(iii) PHARMACY ACCESS TO LIMITED  
2           ACCESS DRUG INFORMATION.—For plan  
3           years beginning with plan year 2026, upon  
4           the request of a network pharmacy, a PDP  
5           sponsor of a prescription drug plan shall  
6           provide such pharmacy, not later than 14  
7           days after receiving such request, with the  
8           information described in subclauses (I),  
9           (II), and (III) of clause (ii).

10           “(iv) HHS ANNUAL REPORT ON LIM-  
11           ITED ACCESS DRUGS.—Not later than De-  
12           cember 31, 2028, and annually thereafter,  
13           the Secretary shall submit to the Com-  
14           mittee on Finance of the Senate, and the  
15           Committee on Ways and Means and the  
16           Committee on Energy and Commerce of  
17           the House of Representatives a report on  
18           compliance by PDP sponsors with the re-  
19           quirements under this subparagraph. Each  
20           such report shall include—

21                   “(I) a description of the patterns,  
22                   trends, variations, and rationales for  
23                   the designation by PDP sponsors of  
24                   certain covered part D drugs as lim-  
25                   ited access drugs, and the implications

1 of such designations on beneficiary ac-  
2 cess to such covered part D drugs;

3 “(II) a description of the infor-  
4 mation submitted to the Secretary  
5 under clause (ii) (in a manner that  
6 does not disclose the identity of a  
7 pharmacy, a PDP sponsor, a prescrip-  
8 tion drug plan, or pharmacy benefit  
9 manager, or any proprietary pricing  
10 information); and

11 “(III) any other information de-  
12 termined appropriate by the Sec-  
13 retary.

14 “(v) LIMITED ACCESS DRUG DE-  
15 FINED.—In this subparagraph, the term  
16 ‘limited access drug’ means a covered part  
17 D drug that meets at least one of the fol-  
18 lowing:

19 “(I) The Food and Drug Admin-  
20 istration has restricted distribution of  
21 such covered part D drug to certain  
22 facilities or physicians.

23 “(II) The dispensing of such cov-  
24 ered part D drug requires extraor-  
25 dinary special handling, provider co-

1                   ordination, or patient education that  
2                   cannot be met by a network phar-  
3                   macy.”.

4                   “(vii) IMPLEMENTATION.—Notwith-  
5                   standing any other provision of law, the  
6                   Secretary shall implement this subpara-  
7                   graph by program instruction or otherwise.

8                   “(viii) NONAPPLICATION OF PAPER-  
9                   WORK REDUCTION ACT.—Chapter 35 of  
10                  title 44, United States Code, shall not  
11                  apply to any data collection undertaken by  
12                  the Secretary under this subparagraph.”.

13 **SEC. 12. BENEFICIARY-FOCUSED LISTENING SESSIONS TO**  
14 **IMPROVE PRESCRIPTION DRUG PLAN TRANS-**  
15 **PARENCY, ACCESS, AND CHOICE.**

16                  Section 1860D-42 of the Social Security Act (42  
17 U.S.C. 1395w-152), as amended by section 7, is amended  
18 by adding at the end the following new subsection:

19                  “(f) BENEFICIARY-FOCUSED LISTENING SESSIONS  
20 TO IMPROVE PRESCRIPTION DRUG PLAN TRANS-  
21 PARENCY, ACCESS, AND CHOICE.—

22                  “(1) IN GENERAL.—Not later than December  
23 31, 2024, the Secretary shall hold at least one bene-  
24 ficiary-focused listening session to receive input on  
25 potential improvements to the experience with, and

1 transparency of, prescription drug plans under this  
2 part, as described in paragraph (2).

3 ~~“(2) BENEFICIARY-FOCUSED LISTENING SES-~~  
4 ~~SIONS.—~~Any beneficiary-focused listening session  
5 held under paragraph (1) shall be open to the public,  
6 including beneficiaries, caregivers of beneficiaries,  
7 consumer and patient advocacy organizations, health  
8 care providers, and other interested parties. Any  
9 such listening sessions may include an opportunity  
10 for the public to provide input to the Secretary on  
11 potential improvements to—

12 “(A) the information made available by  
13 prescription drug plans to individuals;

14 “(B) tools and mechanisms to assist enroll-  
15 ees of prescription drug plans in navigating  
16 plan complaint systems, as well as the efficiency  
17 and effectiveness of such systems;

18 “(C) tools and mechanisms to assist bene-  
19 ficiaries in selecting a prescription drug plan;

20 “(D) tools and mechanisms to assist en-  
21 rollees of prescription drug plans in navigating  
22 utilization management requirements of such  
23 plans, such as step therapy and prior authoriza-  
24 tion;

1           “(E) access to, and effectiveness and utili-  
 2           zation of, electronic real-time benefit tools (as  
 3           described in section 423.160(b)(7) of title 42,  
 4           Code of Federal Regulations, or any successor  
 5           regulation) and beneficiary real-time benefit  
 6           tools (as described in section 423.128(d)(4) of  
 7           title 42, Code of Federal Regulations, or any  
 8           successor regulation);

9           “(F) formulary management and oversight  
 10          by prescription drug plans; and

11          “(G) other subjects, as determined appro-  
 12          priate by the Secretary.”.

13 **SEC. 13. REPORTING ON ENFORCEMENT AND OVERSIGHT**  
 14 **OF PHARMACY ACCESS REQUIREMENTS.**

15          Section 1860D-42 of the Social Security Act (42  
 16 U.S.C. 1395w-152), as amended by section 12, is amend-  
 17 ed by adding at the end the following new subsection:

18          “(g) **BIENNIAL REPORT ON ENFORCEMENT AND**  
 19 **OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—**

20           “(1) **IN GENERAL.**—Not later than 2 years  
 21          after the date of enactment of this subsection, and  
 22          at least once every 2 years thereafter, the Secretary  
 23          shall publish a report on enforcement and oversight  
 24          actions and activities undertaken by the Secretary

1 with respect to the requirements under section  
2 1860D-4(b)(1).

3 “(2) LIMITATION.—A report under paragraph  
4 (1) shall not disclose—

5 “(A) identifiable information about individ-  
6 uals or entities unless such information is oth-  
7 erwise publicly available; or

8 “(B) trade secrets with respect to any enti-  
9 ties.”.

10 **SEC. 14. GAO STUDY ON PRICE-RELATED COMPENSATION**  
11 **ACROSS THE SUPPLY CHAIN.**

12 Section 1860D-42 of the Social Security Act (42  
13 U.S.C. 1395w-152), as amended by section 13, is amend-  
14 ed by adding at the end the following new subsection:

15 “(h) GAO STUDY AND REPORT ON PRICE-RELATED  
16 COMPENSATION AND PAYMENT STRUCTURES IN THE  
17 PRESCRIPTION DRUG SUPPLY CHAIN.—

18 “(1) STUDY.—The Comptroller General of the  
19 United States (in this subsection referred to as the  
20 ‘Comptroller General’) shall conduct a study describ-  
21 ing the use of compensation and payment structures  
22 related to a prescription drug’s price within the re-  
23 tail prescription drug supply chain in this part. Such  
24 study shall summarize information from Federal

1 agencies and industry experts, to the extent avail-  
2 able, with respect to the following:

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

11 “(i) pharmacy benefit managers;

12 “(ii) part D plan sponsors;

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 advise part D plan  
20 sponsors about pharmacy benefits or re-  
21 view part D plan sponsor contracts with  
22 pharmacy benefit managers; and

23 “(viii) other service providers that  
24 contract with any of the entities described  
25 in clauses (i) through (vii) that may use

1 price-related compensation and payment  
2 structures, such as rebate aggregators (or  
3 other entities that negotiate or process  
4 price concessions on behalf of pharmacy  
5 benefit managers, plan sponsors, or phar-  
6 macies).

7 “(B) The primary business models and  
8 compensation structures for each category of  
9 intermediary described in subparagraph (A).

10 “(C) Variation in price-related compensa-  
11 tion structures between affiliated entities (such  
12 as entities with common ownership, either full  
13 or partial, and subsidiary relationships) and un-  
14 affiliated entities.

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

23 “(E) Notable differences, if any, in the use  
24 and level of price-based compensation struc-  
25 tures over time and between different market

1 segments, such as under this part and the Med-  
2 icaid program under title XIX.

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

14 “(G) Other issues determined to be rel-  
15 evant and appropriate by the Comptroller Gen-  
16 eral.

17 “(2) REPORT.—Not later than 2 years after the  
18 date of enactment of this subsection, the Comp-  
19 troller General shall submit to Congress a report  
20 containing the results of the study conducted under  
21 paragraph (1), together with recommendations for  
22 such legislation and administrative action as the  
23 Comptroller General determines appropriate.”.

1 **SEC. 15. REPORTS ON INAPPROPRIATE PHARMACY REJEC-**  
 2 **TIONS.**

3 Section 1860D-42 of the Social Security Act (42  
 4 U.S.C. 1395w-152), as amended by section 14, is amend-  
 5 ed by adding at the end the following new subsection:

6 “(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS  
 7 INAPPROPRIATE PHARMACY REJECTIONS AND INAPPRO-  
 8 PRIATE COVERAGE DENIALS UNDER MEDICARE PART  
 9 D.—

10 “(1) IN GENERAL.—Not later than January 1,  
 11 2026, and at least once every 4 years thereafter, the  
 12 Secretary, in consultation with the Office of the In-  
 13 spector General of the Department of Health and  
 14 Human Services, shall post, on a publicly available  
 15 website, a report related to preventing, identifying,  
 16 or addressing inappropriate pharmacy rejections (as  
 17 defined in paragraph (2)(B)) and inappropriate cov-  
 18 erage denials (as defined in paragraph (2)(A)) under  
 19 this part. Such reports shall include—

20 “(A) a description of programs, reviews, or  
 21 initiatives underway to prevent, identify, or ad-  
 22 dress such rejections and denials, in accordance  
 23 with existing authorities;

24 “(B) a summary of data collected or other  
 25 information available with respect to such rejec-  
 26 tions and denials, including—

1           “(i) standards (if any such standards  
2           have been adopted) used by the Secretary  
3           for identifying PDP sponsors and MA or-  
4           ganizations with relatively high rates of  
5           such rejections or denials; and

6           “(ii) notable longitudinal trends or  
7           other patterns, as determined appropriate  
8           by the Secretary;

9           “(C) an overview of corrective actions  
10          taken and technical assistance provided by the  
11          Secretary in response to violations of existing  
12          requirements with respect to such rejections  
13          and denials; and

14          “(D) a description of barriers, if any, pre-  
15          venting the Secretary from taking administra-  
16          tive actions sufficient to identify and address  
17          such rejections and denials.

18          “(2) DEFINITIONS.—For purposes of this sub-  
19          section:

20                 “(A) INAPPROPRIATE COVERAGE DE-  
21                 NIAL.—The term ‘inappropriate coverage de-  
22                 nial’ means a denial of coverage of a covered  
23                 part D drug claim that violates the require-  
24                 ments of this part.

1           “(B) **INAPPROPRIATE PHARMACY REJEC-**  
 2           **TIONS.**—The term ‘inappropriate pharmacy re-  
 3           **jection’** means a rejection of a covered part D  
 4           drug claim that violates the requirements of  
 5           this part, such as through the application of  
 6           utilization management requirements that the  
 7           Secretary has not approved.”.

8 **SEC. 16. GAO STUDY ON DRUG SHORTAGES.**

9           Section 1860D–42 of the Social Security Act (42  
 10 U.S.C. 1395w–152), as amended by section 15, is amend-  
 11 ed by adding at the end the following new subsection:

12           “(j) **GAO STUDY AND REPORT ON DRUG SHORT-**  
 13 **AGES.**—

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 on fac-  
 17           tors contributing to shortages of covered part D  
 18           drugs across the outpatient prescription drug supply  
 19           chain. Such study shall include analysis of—

20           “(A) common features of and trends in  
 21           covered part D drugs that have experienced at  
 22           least 1 shortage (as defined under section 506C  
 23           of the Federal Food, Drug, and Cosmetic Act);

1           “(B) patterns, trends, and variations in  
2           the duration of shortages experienced by cov-  
3           ered part D drugs;

4           “(C) patterns, trends, and variations in the  
5           proximate causes and other potential causes of  
6           shortages experienced by covered part D drugs;

7           “(D) effects of such shortages on bene-  
8           ficiaries enrolled in prescription drug plans  
9           under this part, including with respect to access  
10          to covered part D drugs and out-of-pocket  
11          costs; and

12          “(E) other issues determined appropriate  
13          by the Comptroller General.

14          “(2) REPORT.—Not later than 2 years after the  
15          date of enactment of this subsection, the Comp-  
16          troller General shall submit to Congress a report  
17          containing the results of the study conducted under  
18          paragraph (1), together with recommendations for  
19          such legislation and administrative action as the  
20          Comptroller General determines appropriate.”.

21 **SEC. 17. REPORT ON BIOSIMILAR AND GENERIC ACCESS**  
22 **UNDER MEDICARE PART D.**

23          Section 1860D-42 of the Social Security Act (42  
24          U.S.C. 1395w-152), as amended by section 16, is amend-  
25          ed by adding at the end the following new subsection:

1       “(k) **OIG REPORT ON BIOSIMILAR AND GENERIC AC-**  
 2 **CESS UNDER PART D.—**

3           “(1) **STUDY.—**The Office of the Inspector Gen-  
 4 eral of the Department of Health and Human Serv-  
 5 ices (referred to in this subsection as the ‘Office of  
 6 the Inspector General’) shall conduct a study on bio-  
 7 similar and generic drug access and adoption under  
 8 prescription drug plans offered under this part, in-  
 9 cluding with respect to barriers to increased adop-  
 10 tion and utilization of lower-priced biosimilar and  
 11 generic utilization, plan features that discourage or  
 12 encourage the utilization of these products, and the  
 13 gross and net spending effects of policies that in-  
 14 creased adoption of these products under this part.

15           “(2) **REPORT.—**Not later than 1 year after the  
 16 date of enactment of this subsection, the Office of  
 17 the Inspector General shall publish a report on the  
 18 study conducted under paragraph (1).”.

19 **SEC. 18. MEDICARE IMPROVEMENT FUND.**

20       Section 1898(b)(1) of the Social Security Act (42  
 21 U.S.C. 1395iii(b)(1)) is amended by striking “during and  
 22 after fiscal year 2022, \$180,000,000” and inserting the  
 23 following: “during and after—

24           “(A) fiscal year 2022, \$180,000,000; and

25           “(B) fiscal year 2028, \$1,947,000,000”.

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) *SHORT TITLE.*—*This Act may be cited as the*  
 3 *“Modernizing and Ensuring PBM Accountability Act”.*

4 (b) *TABLE OF CONTENTS.*—*The table of contents of this*  
 5 *Act is as follows:*

*Sec. 1. Short title; table of contents.*

*Sec. 2. Arrangements with pharmacy benefit managers with respect to prescrip-*  
*tion drug plans and MA–PD plans.*

*Sec. 3. Ensuring fair assessment of pharmacy performance and quality under*  
*Medicare part D.*

*Sec. 4. Promoting transparency for pharmacies under Medicare part D.*

*Sec. 5. Preventing the use of abusive spread pricing in Medicaid.*

*Sec. 6. Ensuring accurate payments to pharmacies under Medicaid.*

*Sec. 7. OIG study and report on drug price mark-ups in Medicare part D.*

*Sec. 8. Resolving P&T committee conflicts of interest.*

*Sec. 9. Enhancing PBM transparency requirements.*

*Sec. 10. Facilitating midyear formulary changes for biosimilars.*

*Sec. 11. Strengthening pharmacy access for seniors.*

*Sec. 12. Beneficiary-focused listening sessions to improve prescription drug plan*  
*transparency, access, and choice.*

*Sec. 13. Reporting on enforcement and oversight of pharmacy access require-*  
*ments.*

*Sec. 14. GAO study on price-related compensation across the supply chain.*

*Sec. 15. Reports on inappropriate pharmacy rejections.*

*Sec. 16. GAO study on drug shortages.*

*Sec. 17. Report on biosimilar and generic access under Medicare part D.*

*Sec. 18. Medicare Improvement Fund.*

6 **SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MAN-**

7 **AGERS WITH RESPECT TO PRESCRIPTION**

8 **DRUG PLANS AND MA–PD PLANS.**

9 (a) *IN GENERAL.*—

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

1       “(h) *REQUIREMENTS RELATING TO PHARMACY BEN-*  
2 *EFIT MANAGERS.*—*For plan years beginning on or after*  
3 *January 1, 2026:*

4               “(1) *AGREEMENTS WITH PHARMACY BENEFIT*  
5 *MANAGERS.*—*Each contract entered into with a PDP*  
6 *sponsor under this part with respect to a prescription*  
7 *drug plan offered by such sponsor shall provide that*  
8 *any pharmacy benefit manager acting on behalf of*  
9 *such sponsor has a written agreement with the PDP*  
10 *sponsor under which the pharmacy benefit manager*  
11 *agrees to meet the following requirements:*

12                       “(A) *NO INCOME OTHER THAN BONA FIDE*  
13 *SERVICE FEES.*—

14                               “(i) *IN GENERAL.*—*The pharmacy ben-*  
15 *efit manager and any affiliate of such phar-*  
16 *macy benefit manager shall not derive any*  
17 *remuneration with respect to any services*  
18 *provided in connection with the utilization*  
19 *of covered part D drugs from any entity or*  
20 *individual other than bona fide service fees,*  
21 *subject to clauses (ii) and (iii).*

22                                       “(ii) *INCENTIVE PAYMENTS.*—*For the*  
23 *purposes of this subsection, an incentive*  
24 *payment paid by a PDP sponsor to a phar-*  
25 *macy benefit manager that is performing*

1            *services on behalf of such sponsor shall be*  
2            *deemed a ‘bona fide service fee’ if such pay-*  
3            *ment is a flat dollar amount, is consistent*  
4            *with fair market value, and is related to*  
5            *services actually performed by the phar-*  
6            *macy benefit manager or affiliate of such*  
7            *pharmacy benefit manager in connection*  
8            *with the utilization of covered part D drugs.*

9            *“(iii) CLARIFICATION ON REBATES AND*  
10           *DISCOUNTS USED TO LOWER COSTS FOR*  
11           *COVERED PART D DRUGS.—Rebates, dis-*  
12           *counts, and other price concessions received*  
13           *from manufacturers, even if such price con-*  
14           *cessions are calculated as a percentage of a*  
15           *drug’s price, shall not be considered a viola-*  
16           *tion of the requirements of clause (i) if they*  
17           *are fully passed through to a PDP sponsor*  
18           *and exclusively used to lower costs for pre-*  
19           *scription drugs under this part, including*  
20           *in cases where a PDP sponsor is acting as*  
21           *a pharmacy benefit manager on behalf of a*  
22           *prescription drug plan offered by such PDP*  
23           *sponsor.*

24           *“(iv) EVALUATION OF REMUNERATION*  
25           *ARRANGEMENTS.—Remuneration arrange-*

1            *ments between pharmacy benefit managers*  
2            *or affiliates of such pharmacy benefit man-*  
3            *agers, as applicable, and other entities in-*  
4            *volved in the dispensing or utilization of*  
5            *covered part D drugs (including PDP spon-*  
6            *sors, manufacturers, pharmacies, and other*  
7            *entities as determined appropriate by the*  
8            *Secretary) shall be subject to review by the*  
9            *Secretary and the Office of the Inspector*  
10           *General of the Department of Health and*  
11           *Human Services. The Secretary, in con-*  
12           *sultation with the Office of the Inspector*  
13           *General, shall evaluate whether remunera-*  
14           *tion under such arrangements is consistent*  
15           *with fair market value through reviews and*  
16           *assessments of such remuneration, as deter-*  
17           *mined appropriate.*

18            *“(B) TRANSPARENCY REGARDING GUARAN-*  
19            *TEES AND COST PERFORMANCE EVALUATIONS.—*  
20            *The pharmacy benefit manager shall—*

21                    *“(i) define, interpret, and apply, in a*  
22                    *fully transparent and consistent manner for*  
23                    *purposes of calculating or otherwise evalu-*  
24                    *ating pharmacy benefit manager perform-*  
25                    *ance against pricing guarantees or similar*

1 *cost performance measurements related to*  
2 *rebates, discounts, price concessions, or net*  
3 *costs, terms such as—*

4 *“(I) ‘generic drug’, in a manner*  
5 *consistent with the definition of the*  
6 *term under section 423.4 of title 42,*  
7 *Code of Federal Regulations, or a suc-*  
8 *cessor regulation;*

9 *“(II) ‘brand name drug’, in a*  
10 *manner consistent with the definition*  
11 *of the term under section 423.4 of title*  
12 *42, Code of Federal Regulations, or a*  
13 *successor regulation;*

14 *“(III) ‘specialty drug’;*

15 *“(IV) ‘rebate’; and*

16 *“(V) ‘discount’;*

17 *“(ii) identify any drugs, claims, or*  
18 *price concessions excluded from any pricing*  
19 *guarantee or other cost performance calcula-*  
20 *tion or evaluation in a clear and consistent*  
21 *manner; and*

22 *“(iii) where a pricing guarantee or*  
23 *other cost performance measure is based on*  
24 *a pricing benchmark other than the whole-*  
25 *sale acquisition cost (as defined in section*

1           1847A(c)(6)(B)) of a drug, calculate and  
2           provide a wholesale acquisition cost-based  
3           equivalent to the pricing guarantee or other  
4           cost performance measure in the written  
5           agreement.

6           “(C) PROVISION OF INFORMATION.—

7                   “(i) IN GENERAL.—Not later than July  
8                   1 of each year, beginning in 2026, the phar-  
9                   macy benefit manager shall submit to the  
10                  PDP sponsor, and to the Secretary, a re-  
11                  port, in accordance with this subparagraph,  
12                  and shall make such report available to  
13                  such sponsor at no cost to such sponsor in  
14                  a format specified by the Secretary under  
15                  paragraph (4). Each such report shall in-  
16                  clude, with respect to such PDP sponsor  
17                  and each plan offered by such sponsor, the  
18                  following information with respect to the  
19                  previous plan year:

20                           “(I) A list of all drugs covered by  
21                           the plan that were dispensed including,  
22                           with respect to each such drug—

23                                   “(aa) the brand name, ge-  
24                                   neric or non-proprietary name,  
25                                   and National Drug Code;

1           “(bb) the number of plan en-  
2           rollees for whom the drug was dis-  
3           pensed, the total number of pre-  
4           scription claims for the drug (in-  
5           cluding original prescriptions and  
6           refills, counted as separate  
7           claims), and the total number of  
8           dosage units of the drug dis-  
9           pensed;

10           “(cc) the number of prescrip-  
11           tion claims described in item (bb)  
12           by each type of dispensing chan-  
13           nel through which the drug was  
14           dispensed, including retail, mail  
15           order, specialty pharmacy, long  
16           term care pharmacy, home infu-  
17           sion pharmacy, or other types of  
18           pharmacies or providers;

19           “(dd) the average wholesale  
20           acquisition cost, listed as cost per  
21           day’s supply, cost per dosage unit,  
22           and cost per typical course of  
23           treatment (as applicable);

24           “(ee) the average wholesale  
25           price for the drug, listed as cost

1            *per day's supply, cost per dosage*  
2            *unit, and cost per typical course*  
3            *of treatment (as applicable);*

4            *“(ff) the total out-of-pocket*  
5            *spending by plan enrollees on*  
6            *such drug after application of any*  
7            *benefits under the plan, including*  
8            *plan enrollee spending through co-*  
9            *payments, coinsurance, and*  
10           *deductibles;*

11           *“(gg) total rebates paid by*  
12           *the manufacturer on the drug as*  
13           *reported under the Detailed DIR*  
14           *Report (or any successor report)*  
15           *submitted by such sponsor to the*  
16           *Centers for Medicare & Medicaid*  
17           *Services;*

18           *“(hh) all other direct or indi-*  
19           *rect remuneration on the drug as*  
20           *reported under the Detailed DIR*  
21           *Report (or any successor report)*  
22           *submitted by such sponsor to the*  
23           *Centers for Medicare & Medicaid*  
24           *Services;*

1           “(i) the average pharmacy  
2 reimbursement amount paid by  
3 the plan for the drug in the aggre-  
4 gate and disaggregated by dis-  
5 pensing channel identified in item  
6 (cc);

7           “(jj) the average National  
8 Average Drug Acquisition Cost  
9 (NADAC) for retail community  
10 pharmacies; and

11           “(kk) total manufacturer-de-  
12 rived revenue, inclusive of bona  
13 fide service fees, retained by the  
14 pharmacy benefit manager and  
15 any affiliate of such pharmacy  
16 benefit manager attributable to  
17 the drug.

18           “(II) In the case of a pharmacy  
19 benefit manager that has an affiliate  
20 that is a retail, mail order, or spe-  
21 cialty pharmacy, with respect to drugs  
22 covered by such plan that were dis-  
23 pensed, the following information:

24           “(aa) The percentage of total  
25 prescriptions that were dispensed

1 by pharmacies that are an affil-  
2 iate of the pharmacy benefit man-  
3 ager for each drug.

4 “(bb) The interquartile range  
5 of the total combined costs paid  
6 by the plan and plan enrollees,  
7 per dosage unit, per course of  
8 treatment, per 30-day supply, and  
9 per 90-day supply for each drug  
10 dispensed by pharmacies that are  
11 not an affiliate of the pharmacy  
12 benefit manager and that are in-  
13 cluded in the pharmacy network  
14 of such plan.

15 “(cc) The interquartile range  
16 of the total combined costs paid  
17 by the plan and plan enrollees,  
18 per dosage unit, per course of  
19 treatment, per 30-day supply, and  
20 per 90-day supply for each drug  
21 dispensed by pharmacies that are  
22 an affiliate of the pharmacy ben-  
23 efit manager and that are in-  
24 cluded in the pharmacy network  
25 of such plan.

1           “(dd) *The lowest total com-*  
2           *bined cost paid by the plan and*  
3           *plan enrollees, per dosage unit,*  
4           *per course of treatment, per 30-*  
5           *day supply, and per 90-day sup-*  
6           *ply, for each drug that is avail-*  
7           *able from any pharmacy included*  
8           *in the pharmacy network of such*  
9           *plan.*

10           “(ee) *The difference between*  
11           *the average acquisition cost of the*  
12           *affiliate, such as a pharmacy or*  
13           *other entity that acquires pre-*  
14           *scription drugs, that initially ac-*  
15           *quires the drug and the amount*  
16           *reported under subclause (I)(jj)*  
17           *for each drug.*

18           “(ff) *A list of covered part D*  
19           *drugs subject to an agreement*  
20           *with a covered entity under sec-*  
21           *tion 340B of the Public Health*  
22           *Service Act for which the phar-*  
23           *macy benefit manager or an affil-*  
24           *iate of the pharmacy benefit man-*  
25           *ager had a contract or other ar-*

1                    *rangement with such a covered en-*  
2                    *tity in the service area of such*  
3                    *plan.*

4                    *“(III) Where a drug approved*  
5                    *under section 505(c) of the Federal*  
6                    *Food, Drug, and Cosmetic Act (referred*  
7                    *to in this subclause as the ‘listed drug’)*  
8                    *is covered by the plan, the following*  
9                    *information:*

10                    *“(aa) A list of currently*  
11                    *marketed generic drugs approved*  
12                    *under section 505(j) of the Federal*  
13                    *Food, Drug, and Cosmetic Act*  
14                    *pursuant to an application that*  
15                    *references such listed drug that*  
16                    *are not covered by the plan, are*  
17                    *covered on the same formulary*  
18                    *tier or a formulary tier typically*  
19                    *associated with higher cost-shar-*  
20                    *ing than the listed drug, or are*  
21                    *subject to utilization management*  
22                    *that the listed drug is not subject*  
23                    *to.*

24                    *“(bb) The estimated average*  
25                    *beneficiary cost-sharing under the*

1                    *plan for a 30-day supply of the*  
2                    *listed drug.*

3                    *“(cc) Where a generic drug*  
4                    *listed under item (aa) is on a for-*  
5                    *mulary tier typically associated*  
6                    *with higher cost-sharing than the*  
7                    *listed drug, the estimated average*  
8                    *cost-sharing that a beneficiary*  
9                    *would have paid for a 30-day*  
10                   *supply of each of the generic drugs*  
11                   *described in item (aa), had the*  
12                   *plan provided coverage for such*  
13                   *drugs on the same formulary tier*  
14                   *as the listed drug.*

15                   *“(dd) A written justification*  
16                   *for providing more favorable cov-*  
17                   *erage of the listed drug than the*  
18                   *generic drugs described in item*  
19                   *(aa).*

20                   *“(ee) The number of cur-*  
21                   *rently marketed generic drugs ap-*  
22                   *proved under section 505(j) of the*  
23                   *Federal Food, Drug, and Cosmetic*  
24                   *Act pursuant to an application*  
25                   *that references such listed drug.*

1           “(IV) Where a reference product  
2           (as defined in section 351(i) of the  
3           Public Health Service Act) is covered  
4           by the plan, the following information:

5                   “(aa) A list of currently  
6                   marketed biosimilar biological  
7                   products licensed under section  
8                   351(k) of the Public Health Serv-  
9                   ice Act pursuant to an applica-  
10                  tion that refers to such reference  
11                  product that are not covered by  
12                  the plan, are covered on the same  
13                  formulary tier or a formulary tier  
14                  typically associated with higher  
15                  cost-sharing than the reference  
16                  product, or are subject to utiliza-  
17                  tion management that the ref-  
18                  erence product is not subject to.

19                   “(bb) The estimated average  
20                   beneficiary cost-sharing under the  
21                   plan for a 30-day supply of the  
22                   reference product.

23                   “(cc) Where a biosimilar bio-  
24                   logical product listed under item  
25                   (aa) is on a formulary tier typi-

1 *cally associated with higher cost-*  
2 *sharing than the listed drug, the*  
3 *estimated average cost-sharing*  
4 *that a beneficiary would have*  
5 *paid for a 30-day supply of each*  
6 *of the biosimilar biological prod-*  
7 *ucts described in item (aa), had*  
8 *the plan provided coverage for*  
9 *such products on the same for-*  
10 *mulary tier as the reference prod-*  
11 *uct.*

12 *“(dd) A written justification*  
13 *for providing more favorable cov-*  
14 *erage of the reference product than*  
15 *the biosimilar biological product*  
16 *described in item (aa).*

17 *“(ee) The number of cur-*  
18 *rently marketed biosimilar bio-*  
19 *logical products licensed under*  
20 *section 351(k) of the Public*  
21 *Health Service Act, pursuant to*  
22 *an application that refers to such*  
23 *reference product.*

24 *“(V) Total gross spending on cov-*  
25 *ered part D drugs by the plan, not net*

1                   of rebates, fees, discounts, or other di-  
2                   rect or indirect remuneration.

3                   “(VI) The total amount retained  
4                   by the pharmacy benefit manager or  
5                   an affiliate of such pharmacy benefit  
6                   manager in revenue related to utiliza-  
7                   tion of prescription drugs under that  
8                   plan, inclusive of bona fide service fees.

9                   “(VII) The total spending on cov-  
10                  ered part D drugs net of rebates, fees,  
11                  discounts, or other direct and indirect  
12                  remuneration by the plan.

13                  “(VIII) An explanation of any  
14                  benefit design parameters under such  
15                  plan that encourage plan enrollees to  
16                  fill prescriptions at pharmacies that  
17                  are an affiliate of such pharmacy ben-  
18                  efit manager, such as mail and spe-  
19                  cialty home delivery programs, and re-  
20                  tail and mail auto-refill programs.

21                  “(IX) A list of all brokers, con-  
22                  sultants, advisors, and auditors that  
23                  receive compensation from the phar-  
24                  macy benefit manager or an affiliate of  
25                  such pharmacy benefit manager for re-

1           *ferrals, consulting, auditing, or other*  
2           *services offered to PDP sponsors re-*  
3           *lated to pharmacy benefit management*  
4           *services.*

5                     “(X) *A list of all affiliates of the*  
6                     *pharmacy benefit manager.*

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

12                    “(ii) *WRITTEN EXPLANATION OF CON-*  
13                    *TRACTS OR AGREEMENTS WITH DRUG MANU-*  
14                    *FACTURERS.—*

15                    “(I) *IN GENERAL.—The pharmacy*  
16                    *benefit manager shall, not later than*  
17                    *30 days after the finalization of any*  
18                    *contract or agreement between such*  
19                    *pharmacy benefit manager or an affil-*  
20                    *iate of such pharmacy benefit manager*  
21                    *and a drug manufacturer (or sub-*  
22                    *sidary, agent, or entity affiliated with*  
23                    *such drug manufacturer) that makes*  
24                    *rebates, discounts, payments, or other*  
25                    *financial incentives related to one or*

1           *more prescription drugs of the manu-*  
2           *facturer directly or indirectly contin-*  
3           *gent upon coverage, formulary place-*  
4           *ment, or utilization management con-*  
5           *ditions on any other prescription*  
6           *drugs, submit to the PDP sponsor a*  
7           *written explanation of such contract or*  
8           *agreement.*

9                   “(II) *REQUIREMENTS.*—*A written*  
10           *explanation under subclause (I)*  
11           *shall—*

12                           “(aa) *include the manufac-*  
13                           *turer subject to the contract or*  
14                           *agreement, all prescription drugs*  
15                           *subject to the contract or agree-*  
16                           *ment and the manufacturers of*  
17                           *such drugs, and a high-level de-*  
18                           *scription of the terms of such con-*  
19                           *tract or agreement and how such*  
20                           *terms apply to such drugs; and*

21                           “(bb) *be certified by the Chief*  
22                           *Executive Officer, Chief Financial*  
23                           *Officer, or General Counsel of*  
24                           *such pharmacy benefit manager,*  
25                           *affiliate of such pharmacy benefit*

1                    *manager, or an individual dele-*  
2                    *gated with the authority to sign*  
3                    *on behalf of one of these officers,*  
4                    *who reports directly to the officer.*

5                    *“(D) AUDIT RIGHTS.—*

6                    *“(i) IN GENERAL.—Not less than once*  
7                    *a year, at the request of the PDP sponsor,*  
8                    *the pharmacy benefit manager shall allow*  
9                    *for an audit of the pharmacy benefit man-*  
10                    *ager to ensure compliance with all terms*  
11                    *and conditions under the written agreement*  
12                    *and the accuracy of information reported*  
13                    *under subparagraph (C).*

14                    *“(ii) AUDITOR.—The PDP sponsor*  
15                    *shall have the right to select an auditor. The*  
16                    *pharmacy benefit manager shall not impose*  
17                    *any limitations on the selection of such*  
18                    *auditor.*

19                    *“(iii) PROVISION OF INFORMATION.—*  
20                    *The pharmacy benefit manager shall make*  
21                    *available to such auditor all records, data,*  
22                    *contracts, and other information necessary*  
23                    *to confirm the accuracy of information pro-*  
24                    *vided under subparagraph (C), subject to*  
25                    *reasonable restrictions on how such infor-*

1                    *mation must be reported to prevent redisclo-*  
2                    *sure of such information.*

3                    “(iv) *TIMING.*—*The pharmacy benefit*  
4                    *manager must provide information under*  
5                    *clause (iii) and other information, data,*  
6                    *and records relevant to the audit to such*  
7                    *auditor within 6 months of the initiation of*  
8                    *the audit and respond to requests for addi-*  
9                    *tional information from such auditor with-*  
10                    *in 30 days after the request for additional*  
11                    *information.*

12                    “(v) *INFORMATION FROM AFFILI-*  
13                    *ATES.*—*The pharmacy benefit manager*  
14                    *shall be responsible for providing to such*  
15                    *auditor information required to be reported*  
16                    *under subparagraph (C) that is owned or*  
17                    *held by an affiliate of such pharmacy ben-*  
18                    *efit manager.*

19                    “(E) *ENFORCEMENT.*—*The pharmacy ben-*  
20                    *efit manager shall—*

21                    “(i) *disgorge to a PDP sponsor (or, in*  
22                    *a case where the PDP sponsor is an affiliate*  
23                    *of such pharmacy benefit manager, to the*  
24                    *Secretary) any payment, remuneration, or*  
25                    *other amount received by the pharmacy ben-*

1            *efit manager or an affiliate of such phar-*  
2            *macy benefit manager in violation of sub-*  
3            *paragraph (A) or the written agreement en-*  
4            *tered into with such sponsor under this part*  
5            *with respect to a prescription drug plan;*

6            *“(ii) reimburse the PDP sponsor for*  
7            *any civil money penalty imposed on the*  
8            *PDP sponsor as a result of the failure of the*  
9            *pharmacy benefit manager to meet the re-*  
10           *quirements of this paragraph that are ap-*  
11           *plicable to the pharmacy benefit manager*  
12           *under the agreement; and*

13           *“(iii) be subject to punitive remedies*  
14           *for breach of contract for failure to comply*  
15           *with the requirements applicable under this*  
16           *paragraph.*

17           *“(2) CERTIFICATION OF COMPLIANCE.—Each*  
18           *PDP sponsor shall furnish to the Secretary (in a time*  
19           *and manner specified by the Secretary) an annual*  
20           *certification of compliance with this subsection, as*  
21           *well as such information as the Secretary determines*  
22           *necessary to carry out this subsection.*

23           *“(3) RULE OF CONSTRUCTION.—Nothing in this*  
24           *subsection shall be construed as prohibiting payments*  
25           *related to reimbursement for ingredient costs to any*

1        *entity that acquires prescription drugs, such as a*  
2        *pharmacy or wholesaler.*

3            *“(4) STANDARD FORMATS.—Not later than June*  
4        *1, 2025, the Secretary shall specify standard, ma-*  
5        *chine-readable formats for pharmacy benefit man-*  
6        *agers to submit annual reports required under para-*  
7        *graph (1)(C)(i).*

8            *“(5) CONFIDENTIALITY.—*

9            *“(A) IN GENERAL.—Information disclosed*  
10        *by a pharmacy benefit manager or PDP sponsor*  
11        *under this subsection that is not otherwise pub-*  
12        *licly available or available for purchase shall not*  
13        *be disclosed by the Secretary or a PDP sponsor*  
14        *receiving the information, except that the Sec-*  
15        *retary may disclose the information for the fol-*  
16        *lowing purposes:*

17            *“(i) As the Secretary determines nec-*  
18        *essary to carry out this part.*

19            *“(ii) To permit the Comptroller Gen-*  
20        *eral to review the information provided.*

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

1           “(iv) To permit the Executive Director  
2           of the Medicare Payment Advisory Commis-  
3           sion to review the information provided.

4           “(v) To the Attorney General for the  
5           purposes of conducting oversight and en-  
6           forcement under this title.

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

13          “(B) RESTRICTION ON USE OF INFORMA-  
14          TION.—The Secretary, the Comptroller General,  
15          the Director of the Congressional Budget Office,  
16          and the Executive Director of the Medicare Pay-  
17          ment Advisory Commission shall not report on  
18          or disclose information disclosed pursuant to  
19          subparagraph (A) to the public in a manner that  
20          would identify a specific pharmacy benefit man-  
21          ager, affiliate, manufacturer or wholesaler, PDP  
22          sponsor, or plan, or contract prices, rebates, dis-  
23          counts, or other remuneration for specific drugs  
24          in a manner that may allow the identification  
25          of specific contracting parties.

1           “(6) *DEFINITIONS.*—*For purposes of this sub-*  
2           *section:*

3           “(A) *AFFILIATE.*—*The term ‘affiliate’*  
4           *means any entity that is owned by, controlled*  
5           *by, or related under a common ownership struc-*  
6           *ture with a pharmacy benefit manager or PDP*  
7           *sponsor, or that acts as a contractor or agent to*  
8           *such pharmacy benefit manager or PDP sponsor,*  
9           *insofar as such contractor or agent performs any*  
10           *of the functions described under subparagraph*  
11           *(C).*

12           “(B) *BONA FIDE SERVICE FEE.*—*The term*  
13           *‘bona fide service fee’ means a fee that is reflec-*  
14           *tive of the fair market value for a bona fide,*  
15           *itemized service actually performed on behalf of*  
16           *an entity, that the entity would otherwise per-*  
17           *form (or contract for) in the absence of the serv-*  
18           *ice arrangement and that are not passed on in*  
19           *whole or in part to a client or customer, whether*  
20           *or not the entity takes title to the drug. Such fee*  
21           *must be a flat dollar amount and shall not be di-*  
22           *rectly or indirectly based on, or contingent*  
23           *upon—*

1           “(i) drug price, such as wholesale ac-  
2           quisition cost or drug benchmark price  
3           (such as average wholesale price);

4           “(ii) discounts, rebates, fees, or other  
5           direct or indirect remuneration amounts  
6           with respect to covered part D drugs dis-  
7           pensed to enrollees in a prescription drug  
8           plan, except as permitted pursuant to para-  
9           graph (1)(A)(ii);

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

14           “(iv) any other amounts or methodolo-  
15           gies prohibited by the Secretary.

16           “(C) PHARMACY BENEFIT MANAGER.—The  
17           term ‘pharmacy benefit manager’ means any  
18           person or entity that, either directly or through  
19           an intermediary, acts as a price negotiator or  
20           group purchaser on behalf of a PDP sponsor or  
21           prescription drug plan, or manages the prescrip-  
22           tion drug benefits provided by such sponsor or  
23           plan, including the processing and payment of  
24           claims for prescription drugs, the performance of  
25           drug utilization review, the processing of drug

1           *prior authorization requests, the adjudication of*  
2           *appeals or grievances related to the prescription*  
3           *drug benefit, contracting with network phar-*  
4           *macies, controlling the cost of covered part D*  
5           *drugs, or the provision of related services. Such*  
6           *term includes any person or entity that carries*  
7           *out one or more of the activities described in the*  
8           *preceding sentence, irrespective of whether such*  
9           *person or entity calls itself a ‘pharmacy benefit*  
10           *manager’.”*

11           (2) *MA–PD PLANS.*—Section 1857(f)(3) of the  
12           *Social Security Act (42 U.S.C. 1395w–27(f)(3)) is*  
13           *amended by adding at the end the following new sub-*  
14           *paragraph:*

15                     “(F) *REQUIREMENTS RELATING TO PHAR-*  
16                     *MACY BENEFIT MANAGERS.*—For plan years be-  
17                     *ginning on or after January 1, 2026, section*  
18                     *1860D–12(h).”*

19           (3) *FUNDING.*—

20                     (A) *SECRETARY.*—In addition to amounts  
21                     *otherwise available, there is appropriated to the*  
22                     *Centers for Medicare & Medicaid Services Pro-*  
23                     *gram Management Account, out of any money in*  
24                     *the Treasury not otherwise appropriated,*  
25                     *\$20,000,000 for fiscal year 2026, to remain*

1           *available until expended, to carry out the*  
2           *amendments made by this subsection.*

3           *(B) OIG.—In addition to amounts other-*  
4           *wise available, there is appropriated to the In-*  
5           *spector General of the Department of Health and*  
6           *Human Services, out of any money in the Treas-*  
7           *ury not otherwise appropriated, \$5,000,000 for*  
8           *fiscal year 2026, to remain available until ex-*  
9           *pended, to carry out the amendments made by*  
10          *this subsection.*

11          *(b) GAO STUDY AND REPORT ON CERTAIN REPORTING*  
12          *REQUIREMENTS.—*

13           *(1) STUDY.—The Comptroller General of the*  
14           *United States (in this subsection referred to as the*  
15           *“Comptroller General”)* shall conduct a study on *Fed-*  
16           *eral and State reporting requirements for health*  
17           *plans and pharmacy benefit managers related to the*  
18           *transparency of prescription drug costs and prices.*  
19           *Such study shall include an analysis of the following:*

20            *(A) Federal statutory and regulatory re-*  
21            *porting requirements for health plans and phar-*  
22            *macy benefit managers related to prescription*  
23            *drug costs and prices.*

24            *(B) Selected States’ statutory and regu-*  
25            *latory reporting requirements for health plans*

1           *and pharmacy benefit managers related to pre-*  
 2           *scription drug costs and prices.*

3           *(C) The extent to which the statutory and*  
 4           *regulatory reporting requirements identified in*  
 5           *subparagraphs (A) and (B) overlap and conflict.*

6           *(D) The resources required by health plans*  
 7           *and pharmacy benefit managers to comply with*  
 8           *the reporting requirements described in subpara-*  
 9           *graphs (A) and (B).*

10           *(E) Other items determined appropriate by*  
 11           *the Comptroller General.*

12           *(2) REPORT.—Not later than 2 years after the*  
 13           *date on which information is first required to be re-*  
 14           *ported under section 1860D–12(h)(1)(C) of the Social*  
 15           *Security Act, as added by subsection (a)(1), the*  
 16           *Comptroller General shall submit to Congress a report*  
 17           *containing the results of the study conducted under*  
 18           *paragraph (1), together with recommendations for leg-*  
 19           *islation and administrative actions that would*  
 20           *streamline and reduce the burden associated with the*  
 21           *reporting requirements for health plans and phar-*  
 22           *macy benefit managers described in paragraph (1).*

23           *(c) MEDPAC REPORTS ON AGREEMENTS WITH PHAR-*  
 24           *MACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIP-*  
 25           *TION DRUG PLANS AND MA-PD PLANS.—The Medicare*

1 *Payment Advisory Commission shall submit to Congress the*  
2 *following reports:*

3           (1) *Not later than March 31, 2027, a report re-*  
4 *garding agreements with pharmacy benefit managers*  
5 *with respect to prescription drug plans and MA-PD*  
6 *plans. Such report shall include—*

7                   (A) *a description of trends and patterns, in-*  
8 *cluding relevant averages, totals, and other fig-*  
9 *ures for each of the types of information sub-*  
10 *mitted;*

11                   (B) *an analysis of any differences in agree-*  
12 *ments and their effects on plan enrollee out-of-*  
13 *pocket spending and average pharmacy reim-*  
14 *bursement, and any other impacts; and*

15                   (C) *any recommendations the Commission*  
16 *determines appropriate.*

17           (2) *Not later than March 31, 2029, a report de-*  
18 *scribing any changes with respect to the information*  
19 *described in paragraph (1) over time, together with*  
20 *any recommendations the Commission determines ap-*  
21 *propriate.*

1 **SEC. 3. ENSURING FAIR ASSESSMENT OF PHARMACY PER-**  
2 **FORMANCE AND QUALITY UNDER MEDICARE**  
3 **PART D.**

4 (a) *STANDARDIZED PHARMACY PERFORMANCE MEAS-*  
5 *URES.—Section 1860D–2 of the Social Security Act (42*  
6 *U.S.C. 1395w–102) is amended by adding at the end the*  
7 *following new subsection:*

8 “(f) *APPLICATION OF STANDARDIZED PHARMACY PER-*  
9 *FORMANCE MEASURES.—*

10 “(1) *MEASURES.—For plan years beginning on*  
11 *or after January 1, 2025, a PDP sponsor offering a*  
12 *prescription drug plan and an MA organization offer-*  
13 *ing an MA–PD plan shall, for purposes of incentive*  
14 *payments, price concessions, or any fees or other re-*  
15 *muneration paid or charged to a pharmacy based on*  
16 *performance measures, only use measures that are—*

17 “(A) *established or adopted by the Secretary*  
18 *under paragraph (2) and included on the list de-*  
19 *scribed in subparagraph (B) of such paragraph;*  
20 *and*

21 “(B) *relevant to the performance of such*  
22 *pharmacy based on the type of pharmacy (in-*  
23 *cluding retail, mail order, specialty, long term*  
24 *care, and home infusion or other types of phar-*  
25 *macies), drugs dispensed by such pharmacy, and*

1           *pharmacy services used to dispense and manage*  
2           *drugs by such pharmacy.*

3           “(2) *STANDARDIZED PHARMACY PERFORMANCE*  
4           *MEASURES.—*

5                   “(A) *MEASURES.—*

6                           “(i) *IN GENERAL .—Notwithstanding*  
7                           *any other provision of law, the Secretary*  
8                           *shall establish (or adopt pursuant to clause*  
9                           *(iii)) standardized pharmacy performance*  
10                           *measures that may be used by a PDP spon-*  
11                           *sor offering a prescription drug plan and*  
12                           *an MA organization offering an MA-PD*  
13                           *plan for the purpose of determining incen-*  
14                           *tive payments, price concessions, or fees or*  
15                           *other remuneration described in paragraph*  
16                           *(1).*

17                           “(ii) *REQUIREMENTS.—The measures*  
18                           *under clause (i) shall focus on pharmacy*  
19                           *performance and quality of care based on*  
20                           *the type of pharmacy, as determined by the*  
21                           *Secretary. Such measures shall be evidence-*  
22                           *based, feasible, appropriate and reasonable.*

23                           “(iii) *ADOPTION OF MEASURE.—In*  
24                           *lieu of establishing some or all of the meas-*  
25                           *ures under this paragraph, the Secretary*

1           *may adopt measures that are endorsed by*  
2           *one or more multi-stakeholder consensus or-*  
3           *ganizations (such as the Pharmacy Quality*  
4           *Alliance), that has participation from phar-*  
5           *macies (including retail and specialty phar-*  
6           *macies not owned or affiliated with a plan,*  
7           *pharmacy benefit manager, or other phar-*  
8           *macy), health plans, pharmacy benefit*  
9           *managers, and the Centers for Medicare &*  
10           *Medicaid Services. Any measure adopted*  
11           *under this clause shall be deemed to meet*  
12           *the requirements under clause (ii).*

13           “(B) *MAINTENANCE OF LIST.*—

14                   “(i) *IN GENERAL.*—*The Secretary shall*  
15                   *maintain, and publish on a publicly avail-*  
16                   *able internet website, a list of measures es-*  
17                   *tablished or adopted under this paragraph.*  
18                   *Such list shall initially be published no*  
19                   *later than June 1, 2024.*

20                   “(ii) *UPDATE.*—*The Secretary shall*  
21                   *periodically evaluate measures, and how*  
22                   *measures are applied by type of pharmacy*  
23                   *and update the measures on the list under*  
24                   *clause (i) so that such measures meet the re-*  
25                   *quirements under subparagraph (A)(ii).*

1           “(3) *NONAPPLICATION OF PAPERWORK REDUC-*  
 2           *TION ACT.*—Chapter 35 of title 44, United States  
 3           Code, shall not apply to any data collection under-  
 4           taken by the Secretary under this subsection.”.

5           (b) *FUNDING.*—In addition to amounts otherwise  
 6 available, there is appropriated to the Centers for Medicare  
 7 & Medicaid Services Program Management Account, out of  
 8 any money in the Treasury not otherwise appropriated,  
 9 \$4,000,000 for fiscal year 2025, to remain available until  
 10 expended, to carry out the amendment made by subsection  
 11 (a).

12 **SEC. 4. PROMOTING TRANSPARENCY FOR PHARMACIES**  
 13 **UNDER MEDICARE PART D.**

14           (a) *TRANSPARENCY FOR PHARMACIES.*—Section  
 15 1860D–2(f) of the Social Security Act (42 U.S.C. 1395w–  
 16 102(f)), as added by section 3, is amended by adding at  
 17 the end the following new paragraph:

18           “(4) *TRANSPARENCY FOR PHARMACIES.*—

19                   “(A) *IN GENERAL.*—For plan years begin-  
 20                   ning on or after January 1, 2025, a PDP spon-  
 21                   sor offering a prescription drug plan and an MA  
 22                   organization offering an MA–PD plan, with re-  
 23                   spect to payment made by such PDP sponsor or  
 24                   such MA organization to a pharmacy for a cov-  
 25                   ered part D drug dispensed by such pharmacy

1           *during a plan year, shall promptly furnish,*  
2           *upon paying a claim for a covered part D drug*  
3           *from a pharmacy, to such pharmacy information*  
4           *related to such claim, such as the Network Reim-*  
5           *bursement ID, fees, pharmacy price concessions,*  
6           *discounts, incentives, or any other forms of re-*  
7           *muneration that affect payment and pricing of*  
8           *the claim.*

9           “(B) *STANDARDIZED FORMAT.—The PDP*  
10          *sponsor and the MA organization shall furnish*  
11          *the information described in subparagraph (A)*  
12          *in a standardized format (as specified by the*  
13          *Secretary) that includes all fields needed to price*  
14          *the claim for a covered part D drug dispensed by*  
15          *such pharmacy.*

16          “(C) *AVAILABILITY OF INFORMATION TO*  
17          *THE SECRETARY.—A PDP sponsor offering a*  
18          *prescription drug plan or an MA organization*  
19          *offering an MA-PD plan shall make the informa-*  
20          *tion described in subparagraph (A) available to*  
21          *the Secretary upon request.*

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



1       of the State or entity, is based on a transparent pre-  
2       scription drug pass-through pricing model under  
3       which—

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

6               “(i) is limited to—

7                       “(I) ingredient cost; and

8                       “(II) a professional dispensing fee  
9       that is not less than the professional  
10      dispensing fee that the State plan or  
11      waiver would pay if the plan or waiv-  
12      er was making the payment directly;

13               “(ii) is passed through in its entirety  
14      by the entity or PBM to the pharmacy or  
15      provider that dispenses the drug (and shall  
16      not be reduced or denied retroactively under  
17      post-adjudication processes); and

18               “(iii) is made in a manner that is con-  
19      sistent with sections 447.502, 447.512,  
20      447.514, and 447.518 of title 42, Code of  
21      Federal Regulations (or any successor regu-  
22      lation) as if such requirements applied di-  
23      rectly to the entity or the PBM, except that  
24      any payment by the entity or the PBM for  
25      the ingredient cost of such drug purchased

1           *by a covered entity (as defined in subsection*  
2           *(a)(5)(B)) may exceed the actual acquisi-*  
3           *tion cost (as defined in 447.502 of title 42,*  
4           *Code of Federal Regulations, or any suc-*  
5           *cessor regulation) for such drug if—*

6                     *“(I) such drug was subject to an*  
7                     *agreement under section 340B of the*  
8                     *Public Health Service Act;*

9                     *“(II) such payment for the ingre-*  
10                    *redient cost of such drug does not exceed*  
11                    *the maximum payment that would*  
12                    *have been made by the entity or the*  
13                    *PBM for the ingredient cost of such*  
14                    *drug if such drug had not been pur-*  
15                    *chased by such covered entity; and*

16                    *“(III) such covered entity reports*  
17                    *to the Secretary (in a form and man-*  
18                    *ner specified by the Secretary), on an*  
19                    *annual basis and with respect to pay-*  
20                    *ments for the ingredient costs of such*  
21                    *drugs so purchased by such covered en-*  
22                    *tity that are in excess of the actual ac-*  
23                    *quisition costs for such drugs, the ag-*  
24                    *gregate amount of such excess;*

1           “(B) payment to the entity or the PBM (as  
2           applicable) for administrative services performed  
3           by the entity or PBM is limited to the fair mar-  
4           ket value of such services;

5           “(C) the entity or the PBM (as applicable)  
6           shall make available to the State, and the Sec-  
7           retary upon request, all costs and payments re-  
8           lated to covered outpatient drugs and accom-  
9           panying administrative services incurred, re-  
10          ceived, or made by the entity or the PBM, in-  
11          cluding ingredient costs, professional dispensing  
12          fees, administrative fees, post-sale and post-in-  
13          voice fees, discounts, or related adjustments such  
14          as direct and indirect remuneration fees, and  
15          any and all other remuneration; and

16          “(D) any form of spread pricing whereby  
17          any amount charged or claimed by the entity or  
18          the PBM (as applicable) that exceeds the amount  
19          paid to the pharmacies or providers on behalf of  
20          the State or entity, including any post-sale or  
21          post-invoice fees, discounts, or related adjust-  
22          ments such as direct and indirect remuneration  
23          fees or assessments (after allowing for an admin-  
24          istrative fee as described in subparagraph (B)) is

1           *not allowable for purposes of claiming Federal*  
2           *matching payments under this title.”.*

3           **(b) DEFINITION OF PHARMACY BENEFIT MANAGER.—**  
4           *Section 1927(k) of the Social Security Act (42 U.S.C.*  
5           *1396r–8(k)) is amended by adding at the end the following*  
6           *new paragraph:*

7           **“(12) PHARMACY BENEFIT MANAGER.—***The term*  
8           *‘pharmacy benefit manager’ means any person or en-*  
9           *tity that, either directly or through an intermediary,*  
10           *acts as a price negotiator or group purchaser on be-*  
11           *half of a State, managed care entity or other specified*  
12           *entity (as such terms are defined in section*  
13           *1903(m)(9)(D)), or manages the prescription drug*  
14           *benefits provided by such State, managed care entity,*  
15           *or other specified entity, including the processing and*  
16           *payment of claims for prescription drugs, the per-*  
17           *formance of drug utilization review, the processing of*  
18           *drug prior authorization requests, the managing of*  
19           *appeals or grievances related to the prescription drug*  
20           *benefits, contracting with pharmacies, controlling the*  
21           *cost of covered outpatient drugs, or the provision of*  
22           *services related thereto. Such term includes any per-*  
23           *son or entity that carries out 1 or more of the activi-*  
24           *ties described in the preceding sentence, irrespective of*

1       *whether such person or entity calls itself a ‘pharmacy*  
 2       *benefit manager’.*”.

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

5           (1) *in paragraph (2)(A)(xiii)—*

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

8               (B) *by inserting before the period at the end*  
 9               *the following: “, and (IV) if the entity, or a*  
 10               *pharmacy benefit manager acting on behalf of*  
 11               *the entity under a contract or other arrangement*  
 12               *between the entity and the pharmacy benefit*  
 13               *manager, performs any of the activities described*  
 14               *in section 1927(k)(12), such activities shall com-*  
 15               *ply with the requirements of section 1927(e)(6)”;*  
 16               *and*

17               (C) *by moving the left margin 2 ems to the*  
 18               *left; and*

19           (2) *by adding at the end the following new para-*  
 20           *graph:*

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

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

3       (d) *EFFECTIVE DATE.*—*The amendments made by this*  
 4 *section apply to contracts between States and managed care*  
 5 *entities, other specified entities, or pharmacy benefit man-*  
 6 *agers that have an effective date beginning on or after the*  
 7 *date that is 18 months after the date of enactment of this*  
 8 *Act.*

9 **SEC. 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES**  
 10 **UNDER MEDICAID.**

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

13               (1) *by striking “and” after the semicolon at the*  
 14 *end of paragraph (1)(A)(i) and all that precedes it*  
 15 *through “(1)” and inserting the following:*

16               “(1) *DETERMINING PHARMACY ACTUAL ACQUISSI-*  
 17 *TION COSTS.*—*The Secretary shall conduct a survey of*  
 18 *retail community pharmacy drug prices to determine*  
 19 *the national average drug acquisition cost as follows:*

20                       “(A) *USE OF VENDOR.*—*The Secretary may*  
 21 *contract services for—*

22                               “(i) *with respect to retail community*  
 23 *pharmacies, the determination of retail sur-*  
 24 *vey prices of the national average drug ac-*  
 25 *quisition cost for covered outpatient drugs*

1           that represent a nationwide average of con-  
2           sumer purchase prices for such drugs, net of  
3           all discounts and rebates (to the extent any  
4           information with respect to such discounts  
5           and rebates is available) based on a month-  
6           ly survey of such pharmacies; and”;

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

9           “(F) SURVEY REPORTING.—In order to  
10          meet the requirement of section 1902(a)(54), a  
11          State shall require that any retail community  
12          pharmacy in the State that receives any pay-  
13          ment, reimbursement, administrative fee, dis-  
14          count, or rebate related to the dispensing of cov-  
15          ered outpatient drugs to individuals receiving  
16          benefits under this title, regardless of whether  
17          such payment, reimbursement, administrative  
18          fee, discount, or rebate is received from the State  
19          or a managed care entity or other specified enti-  
20          ty (as such terms are defined in section  
21          1903(m)(9)(D)) directly or from a pharmacy  
22          benefit manager or another entity that has a  
23          contract with the State or a managed care entity  
24          or other specified entity (as so defined), shall re-

1           *spond to surveys of retail prices conducted under*  
2           *this paragraph.*

3           “(G) *SURVEY INFORMATION.*—*Information*  
4           *on national drug acquisition prices obtained*  
5           *under this paragraph shall be made publicly*  
6           *available and shall include at least the following:*

7                   “(i) *The monthly response rate to the*  
8                   *survey including a list of pharmacies not in*  
9                   *compliance with subparagraph (F).*

10                   “(ii) *The sampling frame and number*  
11                   *of pharmacies sampled monthly.*

12                   “(iii) *Information on price concessions*  
13                   *to the pharmacy, including discounts, re-*  
14                   *bates, and other price concessions, to the ex-*  
15                   *tent that such information may be publicly*  
16                   *released and has been collected by the Sec-*  
17                   *retary as part of the survey.*

18           “(H) *PENALTIES.*—*The Secretary may en-*  
19           *force non-compliance with this paragraph by a*  
20           *pharmacy through the establishment of penalties*  
21           *or the suspension of payments under this title, in*  
22           *full or in part, until compliance with this para-*  
23           *graph has been completed.”;*

24           (3) *in paragraph (2)—*

1           (A) in subparagraph (A), by inserting “,  
2           including payment rates under Medicaid man-  
3           aged care entities or other specified entities (as  
4           such terms are defined in section  
5           1903(m)(9)(D)),” after “under this title”; and

6           (B) in subparagraph (B), by inserting “and  
7           the basis for such dispensing fees” before the  
8           semicolon; and

9           (4) in paragraph (4), by inserting “, and  
10          \$5,000,000 for fiscal year 2024 and each fiscal year  
11          thereafter,” after “2010”.

12          (b) *EFFECTIVE DATE.*—*The amendments made by this*  
13 *section take effect on the first day of the first quarter that*  
14 *begins on or after the date that is 18 months after the date*  
15 *of enactment of this Act.*

16 **SEC. 7. OIG STUDY AND REPORT ON DRUG PRICE MARK-UPS**  
17 **IN MEDICARE PART D.**

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

21          “(e) *OIG STUDY AND REPORT ON DRUG PRICE MARK-*  
22 *UPS UNDER THIS PART.*—

23                 “(1) *STUDY.*—*The Inspector General of the De-*  
24 *partment of Health and Human Services (in this sub-*  
25 *section referred to as the ‘Inspector General’) shall*

1        *conduct a study on the impact of related party trans-*  
2        *actions within select vertically integrated entities on*  
3        *the negotiated price (as defined in section 1860D-*  
4        *2(d)(1)(B)) paid by part D plan sponsors for covered*  
5        *part D drugs. Such study may include an analysis*  
6        *of the following:*

7                *“(A) Acquisition costs by the affiliate with-*  
8                *in such vertically integrated entities that ini-*  
9                *tially acquires the prescription drug for a sam-*  
10               *ple of covered part D drugs, including at least*  
11               *5 generic drugs, brand drugs, specialty brand*  
12               *drugs, and specialty generic drugs.*

13               *“(B) The methodologies and negotiation*  
14               *processes used to calculate transfer prices or*  
15               *other transactions between related parties with*  
16               *respect to such covered part D drugs.*

17               *“(C) The impact of the transactions de-*  
18               *scribed in subparagraph (B) on the negotiated*  
19               *price, net of direct and indirect remuneration,*  
20               *for such covered part D drugs.*

21               *“(D) The margin captured by different af-*  
22               *filiates within such vertically integrated entities*  
23               *through the transactions described in subpara-*  
24               *graph (B).*

1           “(E) *An assessment of the impact of the*  
2           *transactions described in subparagraph (B) on*  
3           *costs to individuals enrolled in a prescription*  
4           *drug plan or an MA–PD plan and program*  
5           *spending on prescription drugs under this part.*

6           “(F) *Other issues determined to be relevant*  
7           *and appropriate by the Inspector General.*

8           “(2) *REPORT.—Not later than 3 years after the*  
9           *date of enactment of this subsection, the Inspector*  
10          *General shall submit to the Committee on Finance of*  
11          *the Senate and the Committee on Energy and Com-*  
12          *merce and the Committee on Ways and Means of the*  
13          *House of Representatives a report containing the re-*  
14          *sults of the study conducted under paragraph (1), to-*  
15          *gether with recommendations for such legislation and*  
16          *administrative action as the Inspector General deter-*  
17          *mines appropriate.*

18          “(3) *FUNDING.—In addition to amounts other-*  
19          *wise available, there is appropriated to the Inspector*  
20          *General, out of any money in the Treasury not other-*  
21          *wise appropriated, \$5,200,000 for fiscal year 2024, to*  
22          *remain available until expended, to carry out this*  
23          *subsection.”.*

1 **SEC. 8. RESOLVING P&T COMMITTEE CONFLICTS OF INTER-**  
 2 **EST.**

3 *Section 1860D–4(b)(3)(A)(ii)(I) of the Social Security*  
 4 *Act (42 U.S.C. 1395w–104(b)(3)(A)(ii)(I)) is amended by*  
 5 *inserting the following before the semicolon: “(and, for 2025*  
 6 *and each subsequent year, any pharmacy benefit manager*  
 7 *acting under contract with such sponsor offering such*  
 8 *plan)”.*

9 **SEC. 9. ENHANCING PBM TRANSPARENCY REQUIREMENTS.**

10 *(a) IN GENERAL.—Section 1150A of the Social Secu-*  
 11 *rity Act (42 U.S.C. 1320b–23) is amended—*

12 *(1) by striking subsection (a) and inserting the*  
 13 *following:*

14 *“(a) PROVISION OF INFORMATION.—*

15 *“(1) IN GENERAL.—The following entities shall*  
 16 *provide the information described in subsection (b) to*  
 17 *the Secretary and, in the case of an entity described*  
 18 *in subparagraph (B) or an affiliate of such entity de-*  
 19 *scribed in subparagraph (C), to the health benefits*  
 20 *plan with which the entity is under contract, at such*  
 21 *times, and in such form and manner, as the Sec-*  
 22 *retary shall specify:*

23 *“(A) A health benefits plan.*

24 *“(B) Any entity that provides pharmacy*  
 25 *benefits management services on behalf of a*  
 26 *health benefits plan (in this section referred to as*

1 a ‘PBM’) that manages prescription drug cov-  
2 erage under a contract with—

3 “(i) a PDP sponsor of a prescription  
4 drug plan or an MA organization offering  
5 an MA–PD plan under part D of title  
6 XVIII; or

7 “(ii) a qualified health benefits plan  
8 offered through an exchange established by a  
9 State under section 1311 of the Patient Pro-  
10 tection and Affordable Care Act.

11 “(C) Any affiliate of an entity described in  
12 subparagraph (B) that acts as a price negotiator  
13 or group purchaser on behalf of such PBM, PDP  
14 sponsor, MA organization, or qualified health  
15 benefits plan.

16 “(2) AFFILIATE DEFINED.—In this section, the  
17 term ‘affiliate’ means any entity that is owned by,  
18 controlled by, or related under a common ownership  
19 structure with a PBM (including an entity owned or  
20 controlled by the PDP sponsor of a prescription drug  
21 plan, MA organization offering an MA–PD plan, or  
22 qualified health benefits plan for which such entity is  
23 acting as a price negotiator or group purchaser).”;

24 (2) in subsection (b)—

1           (A) in paragraph (2), by inserting “and  
2           percentage” after “and the aggregate amount”;  
3           and

4           (B) by adding at the end the following new  
5           paragraph:

6           “(4) The amount (in the aggregate and  
7           disaggregated by type) of all fees the PBM or an affil-  
8           iate of the PBM receives from all pharmaceutical  
9           manufacturers in connection with patient utilization  
10          under the plan, and the amount and percentage (in  
11          the aggregate and disaggregated by type) of such fees  
12          that are passed through to the plan sponsor or  
13          issuer.”; and

14          (3) by adding at the end the following new sub-  
15          section:

16          “(e) ANNUAL REPORT.—The Secretary shall make  
17          publicly available on the Internet website of the Centers for  
18          Medicare & Medicaid Services an annual report that sum-  
19          marizes the trends observed with respect to data reported  
20          under subsection (b).”.

21          (b) EFFECTIVE DATE.—The amendments made by this  
22          section shall apply to plan or contract years beginning on  
23          or after January 1, 2027.

24          (c) IMPLEMENTATION.—Notwithstanding any other  
25          provision of law, the Secretary may implement the amend-

1 *ments made by this section by program instruction or other-*  
 2 *wise.*

3 *(d) NON-APPLICATION OF THE PAPERWORK REDUC-*  
 4 *TION ACT.—Chapter 35 of title 44, United States Code*  
 5 *(commonly referred to as the “Paperwork Reduction Act of*  
 6 *1995”), shall not apply to the implementation of the*  
 7 *amendments made by this section.*

8 **SEC. 10. FACILITATING MIDYEAR FORMULARY CHANGES**  
 9 **FOR BIOSIMILARS.**

10 *(a) IN GENERAL.—Section 1860D–4(b) of the Social*  
 11 *Security Act (42 U.S.C. 1395w–104(b)) is amended by add-*  
 12 *ing at the end the following new paragraph:*

13 *“(5) MID-YEAR CHANGES IN FORMULARIES PER-*  
 14 *MITTED FOR CERTAIN BIOSIMILAR BIOLOGICAL PROD-*  
 15 *UCTS AND THE REFERENCE PRODUCT OF SUCH*  
 16 *BIOSIMILARS.—If a PDP sponsor of a prescription*  
 17 *drug plan uses a formulary (including the use of*  
 18 *tiered cost-sharing), the following shall apply:*

19 *“(A) IN GENERAL.—For plan year 2025,*  
 20 *and subsequent plan years, in the case of a cov-*  
 21 *ered part D drug that is the reference biological*  
 22 *product (as defined in section 351(i) of the Pub-*  
 23 *lic Health Service Act) with respect to a bio-*  
 24 *similar biological product (defined as a biologi-*  
 25 *cal product licensed under section 351(k) of such*

1           *Act), the PDP sponsor may, with respect to a*  
2           *formulary, at any time after the first 60 days of*  
3           *the plan year, subject to paragraph (3)(E),*  
4           *change the preferred or tiered cost-sharing status*  
5           *of such reference biological product if such PDP*  
6           *sponsor adds, before or at the same time, to such*  
7           *formulary such biosimilar biological product at*  
8           *the same or a higher preferred status, or to the*  
9           *same or lower cost-sharing tier, as that of such*  
10          *reference biological product immediately prior to*  
11          *such change.*

12           “(B) *REQUEST FOR APPROVAL OF*  
13          *CHANGE.—Prior to making a change described*  
14          *in subparagraph (A), the PDP sponsor shall sub-*  
15          *mit to the Secretary a request to make such*  
16          *change. If the Secretary approves the request or*  
17          *has not provided a decision to the PDP sponsor*  
18          *regarding such request within 30 days of receiv-*  
19          *ing such request, such PDP sponsor may make*  
20          *such change.”.*

21          **(b) ADMINISTRATION.—**

22           **(1) IMPLEMENTATION.—***Notwithstanding any*  
23          *other provision of law, the Secretary of Health and*  
24          *Human Services may implement the amendment*

1       *made by subsection (a) by program instruction or*  
 2       *otherwise.*

3               (2) *NON-APPLICATION OF THE PAPERWORK RE-*  
 4       *DUCTION ACT.—Chapter 35 of title 44, United States*  
 5       *Code (commonly referred to as the “Paperwork Re-*  
 6       *duction Act of 1995”), shall not apply to the imple-*  
 7       *mentation of the amendment made by subsection (a).*

8       **SEC. 11. STRENGTHENING PHARMACY ACCESS FOR SEN-**  
 9               **IORS.**

10       *Section 1860D–4(b)(1) of the Social Security Act (42*  
 11       *U.S.C. 1395w–104(b)(1)) is amended by adding at the end*  
 12       *the following new subparagraph:*

13               “(F) *LIMITED ACCESS DRUGS.—*

14                       “(i) *LIMITATION ON RESTRICTIONS OR*  
 15       *LIMITS ON ACCESS.—For each plan year*  
 16       *(beginning with plan year 2026), a PDP*  
 17       *sponsor offering a prescription drug plan—*

18                               “(I) *may not restrict or limit ac-*  
 19       *cess to any covered part D drug to a*  
 20       *subset of their network pharmacies,*  
 21       *other than with respect to a limited ac-*  
 22       *cess drug, as defined in clause (v); and*

23                               “(II) *shall document the rationale*  
 24       *for why a covered part D drug meets*  
 25       *the definition of a limited access drug*

1            *under clause (v), if such plan restricts*  
2            *or limits access to a limited access*  
3            *drug to a subset of network phar-*  
4            *macies.*

5            *“(ii) ANNUAL SUBMISSION OF INFOR-*  
6            *MATION TO THE SECRETARY ON LIMITED*  
7            *ACCESS DRUGS.—For each plan year (be-*  
8            *ginning with plan year 2026), each PDP*  
9            *sponsor offering a prescription drug plan*  
10           *shall submit to the Secretary, at a time and*  
11           *in a manner specified by the Secretary,*  
12           *with respect to each prescription drug plan*  
13           *offered by the sponsor during such plan*  
14           *year—*

15           *“(I) a list of all covered part D*  
16           *drugs that the PDP sponsor designated*  
17           *as a limited access drug;*

18           *“(II) for each covered part D drug*  
19           *included in the list described in sub-*  
20           *clause (I), a written rationale for why*  
21           *such drug meets the definition of a*  
22           *limited access drug;*

23           *“(III) a summary of the require-*  
24           *ments imposed on network pharmacies*  
25           *(including all accreditation require-*

1                   ments, if any) to ensure appropriate  
2                   handling and dispensing of each cov-  
3                   ered part D drug included in the list  
4                   described in subclause (I);

5                   “(IV) the percentages of each cov-  
6                   ered part D drug included in the list  
7                   described in subclause (I) that is dis-  
8                   pensed through retail pharmacies, spe-  
9                   cialty pharmacies, mail order phar-  
10                  macies, or other dispensing channels as  
11                  defined by the PDP sponsor, respec-  
12                  tively;

13                  “(V) the annual percentage of  
14                  each covered part D drug included in  
15                  the list described in subclause (I) that  
16                  is dispensed through a pharmacy that  
17                  is affiliated with the plan or is an af-  
18                  filiate (as defined in section 1860D-  
19                  12(h)(4)(A)) of a pharmacy benefit  
20                  manager acting on behalf of such spon-  
21                  sor or such plan; and

22                  “(VI) any other information de-  
23                  termined appropriate by the Secretary.

24                  “(iii) PHARMACY ACCESS TO LIMITED  
25                  ACCESS DRUG INFORMATION.—For plan

1           *years beginning with plan year 2026, upon*  
2           *the request of a network pharmacy, a PDP*  
3           *sponsor of a prescription drug plan shall*  
4           *provide such pharmacy, not later than 14*  
5           *days after receiving such request, with the*  
6           *information described in subclauses (I),*  
7           *(II), and (III) of clause (ii).*

8           “(iv) *HHS ANNUAL REPORT ON LIM-*  
9           *ITED ACCESS DRUGS.—Not later than De-*  
10          *cember 31, 2028, and annually thereafter,*  
11          *the Secretary shall submit to the Committee*  
12          *on Finance of the Senate, and the Com-*  
13          *mittee on Ways and Means and the Com-*  
14          *mittee on Energy and Commerce of the*  
15          *House of Representatives a report on com-*  
16          *pliance by PDP sponsors with the require-*  
17          *ments under this subparagraph. Each such*  
18          *report shall include—*

19                 “(I) *a description of the patterns,*  
20                 *trends, variations, and rationales for*  
21                 *the designation by PDP sponsors of*  
22                 *certain covered part D drugs as lim-*  
23                 *ited access drugs, and the implications*  
24                 *of such designations on beneficiary ac-*  
25                 *cess to such covered part D drugs;*

1           “(II) a description of the informa-  
2           tion submitted to the Secretary under  
3           clause (ii) (in a manner that does not  
4           disclose the identity of a pharmacy, a  
5           PDP sponsor, a prescription drug  
6           plan, or pharmacy benefit manager, or  
7           any proprietary pricing information);  
8           and

9           “(III) any other information de-  
10          termined appropriate by the Secretary.

11          “(v) *LIMITED ACCESS DRUG DE-*  
12          *FINED.*—In this subparagraph, the term  
13          ‘limited access drug’ means a covered part  
14          D drug that meets at least one of the fol-  
15          lowing:

16               “(I) The Food and Drug Adminis-  
17               tration has restricted distribution of  
18               such covered part D drug to certain fa-  
19               cilities or physicians.

20               “(II) The dispensing of such cov-  
21               ered part D drug requires extraor-  
22               dinary special handling, provider co-  
23               ordination, or patient education that  
24               cannot be met by a network phar-  
25               macy.”.

1                   “(vii) *IMPLEMENTATION.*—*Notwith-*  
 2                   *standing any other provision of law, the*  
 3                   *Secretary shall implement this subpara-*  
 4                   *graph by program instruction or otherwise.*

5                   “(viii) *NONAPPLICATION OF PAPER-*  
 6                   *WORK REDUCTION ACT.*—*Chapter 35 of title*  
 7                   *44, United States Code, shall not apply to*  
 8                   *any data collection undertaken by the Sec-*  
 9                   *retary under this subparagraph.”.*

10 ***SEC. 12. BENEFICIARY-FOCUSED LISTENING SESSIONS TO***  
 11 ***IMPROVE PRESCRIPTION DRUG PLAN TRANS-***  
 12 ***PARENCY, ACCESS, AND CHOICE.***

13                   *Section 1860D–42 of the Social Security Act (42*  
 14 *U.S.C. 1395w–152), as amended by section 7, is amended*  
 15 *by adding at the end the following new subsection:*

16                   “(f) *BENEFICIARY-FOCUSED LISTENING SESSIONS TO*  
 17 *IMPROVE PRESCRIPTION DRUG PLAN TRANSPARENCY, AC-*  
 18 *CESS, AND CHOICE.*—

19                   “(1) *IN GENERAL.*—*Not later than December 31,*  
 20 *2024, the Secretary shall hold at least one beneficiary-*  
 21 *focused listening session to receive input on potential*  
 22 *improvements to the experience with, and trans-*  
 23 *parency of, prescription drug plans under this part,*  
 24 *as described in paragraph (2).*

1           “(2) *BENEFICIARY-FOCUSED LISTENING SES-*  
2           *SIONS.—Any beneficiary-focused listening session held*  
3           *under paragraph (1) shall be open to the public, in-*  
4           *cluding beneficiaries, caregivers of beneficiaries, con-*  
5           *sumer and patient advocacy organizations, health*  
6           *care providers, and other interested parties. Any such*  
7           *listening sessions may include an opportunity for the*  
8           *public to provide input to the Secretary on potential*  
9           *improvements to—*

10                   “(A) *the information made available by*  
11                   *prescription drug plans to individuals;*

12                   “(B) *tools and mechanisms to assist enroll-*  
13                   *ees of prescription drug plans in navigating*  
14                   *plan complaint systems, as well as the efficiency*  
15                   *and effectiveness of such systems;*

16                   “(C) *tools and mechanisms to assist bene-*  
17                   *ficiaries in selecting a prescription drug plan;*

18                   “(D) *tools and mechanisms to assist enroll-*  
19                   *ees of prescription drug plans in navigating uti-*  
20                   *lization management requirements of such plans,*  
21                   *such as step therapy and prior authorization;*

22                   “(E) *access to, and effectiveness and utiliza-*  
23                   *tion of, electronic real-time benefit tools (as de-*  
24                   *scribed in section 423.160(b)(7) of title 42, Code*  
25                   *of Federal Regulations, or any successor regula-*

1           tion) and beneficiary real-time benefit tools (as  
 2           described in section 423.128(d)(4) of title 42,  
 3           Code of Federal Regulations, or any successor  
 4           regulation);

5           “(F) formulary management and oversight  
 6           by prescription drug plans; and

7           “(G) other subjects, as determined appro-  
 8           priate by the Secretary.”.

9   **SEC. 13. REPORTING ON ENFORCEMENT AND OVERSIGHT**  
 10                                   **OF PHARMACY ACCESS REQUIREMENTS.**

11           Section 1860D–42 of the Social Security Act (42  
 12   U.S.C. 1395w–152), as amended by section 12, is amended  
 13   by adding at the end the following new subsection:

14           “(g) **BIENNIAL REPORT ON ENFORCEMENT AND OVER-**  
 15   **SIGHT OF PHARMACY ACCESS REQUIREMENTS.**—

16           “(1) **IN GENERAL.**—Not later than 2 years after  
 17           the date of enactment of this subsection, and at least  
 18           once every 2 years thereafter, the Secretary shall pub-  
 19           lish a report on enforcement and oversight actions  
 20           and activities undertaken by the Secretary with re-  
 21           spect to the requirements under section 1860D–  
 22           4(b)(1).

23           “(2) **LIMITATION.**—A report under paragraph  
 24           (1) shall not disclose—

1           “(A) identifiable information about individ-  
 2           uals or entities unless such information is other-  
 3           wise publicly available; or

4           “(B) trade secrets with respect to any enti-  
 5           ties.”.

6 **SEC. 14. GAO STUDY ON PRICE-RELATED COMPENSATION**  
 7           **ACROSS THE SUPPLY CHAIN.**

8           Section 1860D–42 of the Social Security Act (42  
 9 U.S.C. 1395w–152), as amended by section 13, is amended  
 10 by adding at the end the following new subsection:

11           “(h) GAO STUDY AND REPORT ON PRICE-RELATED  
 12 COMPENSATION AND PAYMENT STRUCTURES IN THE PRE-  
 13 SCRIPTIION DRUG 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 describ-  
 17 ing the use of compensation and payment structures  
 18 related to a prescription drug’s price within the retail  
 19 prescription drug supply chain in this part. Such  
 20 study shall summarize information from Federal  
 21 agencies and industry experts, to the extent available,  
 22 with respect to the following:

23           “(A) The type, magnitude, other features  
 24 (such as the pricing benchmarks used), and prev-  
 25 alence of compensation and payment structures

1           *related to a prescription drug’s price, such as*  
2           *calculating fee amounts as a percentage of a pre-*  
3           *scription drug’s price, between intermediaries in*  
4           *the prescription drug supply chain, including—*

5                     *“(i) pharmacy benefit managers;*

6                     *“(ii) part D plan sponsors;*

7                     *“(iii) drug wholesalers;*

8                     *“(iv) pharmacies;*

9                     *“(v) manufacturers;*

10                    *“(vi) pharmacy services administrative*  
11                    *organizations;*

12                    *“(vii) brokers, auditors, consultants,*  
13                    *and other entities that advise part D plan*  
14                    *sponsors about pharmacy benefits or review*  
15                    *part D plan sponsor contracts with phar-*  
16                    *macy benefit managers; and*

17                    *“(viii) other service providers that con-*  
18                    *tract with any of the entities described in*  
19                    *clauses (i) through (vii) that may use price-*  
20                    *related compensation and payment struc-*  
21                    *tures, such as rebate aggregators (or other*  
22                    *entities that negotiate or process price con-*  
23                    *cessions on behalf of pharmacy benefit man-*  
24                    *agers, plan sponsors, or pharmacies).*

1           “(B) *The primary business models and*  
2           *compensation structures for each category of*  
3           *intermediary described in subparagraph (A).*

4           “(C) *Variation in price-related compensa-*  
5           *tion structures between affiliated entities (such*  
6           *as entities with common ownership, either full or*  
7           *partial, and subsidiary relationships) and unaf-*  
8           *filiated entities.*

9           “(D) *Potential conflicts of interest among*  
10           *contracting entities related to the use of prescrip-*  
11           *tion drug price-related compensation structures,*  
12           *such as the potential for fees or other payments*  
13           *set as a percentage of a prescription drug’s price*  
14           *to advantage formulary selection, distribution, or*  
15           *purchasing of prescription drugs with higher*  
16           *prices.*

17           “(E) *Notable differences, if any, in the use*  
18           *and level of price-based compensation structures*  
19           *over time and between different market segments,*  
20           *such as under this part and the Medicaid pro-*  
21           *gram under title XIX.*

22           “(F) *The effects of drug price-related com-*  
23           *penetration structures and alternative compensa-*  
24           *tion structures on Federal health care programs*  
25           *and program beneficiaries, including with re-*



1        *Secretary, in consultation with the Office of the In-*  
2        *pector General of the Department of Health and*  
3        *Human Services, shall post, on a publicly available*  
4        *website, a report related to preventing, identifying, or*  
5        *addressing inappropriate pharmacy rejections (as de-*  
6        *finied in paragraph (2)(B)) and inappropriate cov-*  
7        *erage denials (as defined in paragraph (2)(A)) under*  
8        *this part. Such reports shall include—*

9                *“(A) a description of programs, reviews, or*  
10              *initiatives underway to prevent, identify, or ad-*  
11              *dress such rejections and denials, in accordance*  
12              *with existing authorities;*

13              *“(B) a summary of data collected or other*  
14              *information available with respect to such rejec-*  
15              *tions and denials, including—*

16                      *“(i) standards (if any such standards*  
17                      *have been adopted) used by the Secretary*  
18                      *for identifying PDP sponsors and MA orga-*  
19                      *nizations with relatively high rates of such*  
20                      *rejections or denials; and*

21                      *“(ii) notable longitudinal trends or*  
22                      *other patterns, as determined appropriate*  
23                      *by the Secretary;*

24              *“(C) an overview of corrective actions taken*  
25              *and technical assistance provided by the Sec-*

1           *retary in response to violations of existing re-*  
2           *quirements with respect to such rejections and*  
3           *denials; and*

4           “(D) a description of barriers, if any, pre-

5           *venting the Secretary from taking administrative*  
6           *actions sufficient to identify and address such re-*  
7           *jections and denials.*

8           “(2) *DEFINITIONS.—For purposes of this sub-*  
9           *section:*

10           “(A) *INAPPROPRIATE COVERAGE DENIAL.—*  
11           *The term ‘inappropriate coverage denial’ means*  
12           *a denial of coverage of a covered part D drug*  
13           *claim that violates the requirements of this part.*

14           “(B) *INAPPROPRIATE PHARMACY REJEC-*  
15           *TIONS.—The term ‘inappropriate pharmacy re-*  
16           *jection’ means a rejection of a covered part D*  
17           *drug claim that violates the requirements of this*  
18           *part, such as through the application of utiliza-*  
19           *tion management requirements that the Sec-*  
20           *retary has not approved.”.*

21 **SEC. 16. GAO STUDY ON DRUG SHORTAGES.**

22           *Section 1860D–42 of the Social Security Act (42*  
23           *U.S.C. 1395w–152), as amended by section 15, is amended*  
24           *by adding at the end the following new subsection:*

1       “(j) *GAO STUDY AND REPORT ON DRUG SHORT-*  
2 *AGES.*—

3               “(1) *STUDY.*—*The Comptroller General of the*  
4 *United States (in this subsection referred to as the*  
5 *‘Comptroller General’)* shall conduct a study on fac-  
6 *tors contributing to shortages of covered part D drugs*  
7 *across the outpatient prescription drug supply chain.*  
8 *Such study shall include analysis of—*

9                       “(A) *common features of and trends in cov-*  
10 *ered part D drugs that have experienced at least*  
11 *1 shortage (as defined under section 506C of the*  
12 *Federal Food, Drug, and Cosmetic Act);*

13                       “(B) *patterns, trends, and variations in the*  
14 *duration of shortages experienced by covered part*  
15 *D drugs;*

16                       “(C) *patterns, trends, and variations in the*  
17 *proximate causes and other potential causes of*  
18 *shortages experienced by covered part D drugs;*

19                       “(D) *effects of such shortages on bene-*  
20 *ficiaries enrolled in prescription drug plans*  
21 *under this part, including with respect to access*  
22 *to covered part D drugs and out-of-pocket costs;*  
23 *and*

24                       “(E) *other issues determined appropriate by*  
25 *the Comptroller General.*

1           “(2) *REPORT.*—Not later than 2 years after the  
 2           date of enactment of this subsection, 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   **SEC. 17. REPORT ON BIOSIMILAR AND GENERIC ACCESS**  
 9                                   **UNDER MEDICARE PART D.**

10          Section 1860D–42 of the Social Security Act (42  
 11          U.S.C. 1395w–152), as amended by section 16, is amended  
 12          by adding at the end the following new subsection:

13           “(k) *OIG REPORT ON BIOSIMILAR AND GENERIC AC-*  
 14          *CESS UNDER PART D.*—

15           “(1) *STUDY.*—The Office of the Inspector Gen-  
 16          eral of the Department of Health and Human Serv-  
 17          ices (referred to in this subsection as the ‘Office of the  
 18          Inspector General’) shall conduct a study on bio-  
 19          similar and generic drug access and adoption under  
 20          prescription drug plans offered under this part, in-  
 21          cluding with respect to barriers to increased adoption  
 22          and utilization of lower-priced biosimilar and generic  
 23          utilization, plan features that discourage or encourage  
 24          the utilization of these products, and the gross and

1 *net spending effects of policies that increased adoption*  
2 *of these products under this part.*

3 “(2) *REPORT.*—*Not later than 1 year after the*  
4 *date of enactment of this subsection, the Office of the*  
5 *Inspector General shall publish a report on the study*  
6 *conducted under paragraph (1).”.*

7 **SEC. 18. MEDICARE IMPROVEMENT FUND.**

8 *Section 1898(b)(1) of the Social Security Act (42*  
9 *U.S.C. 1395iii(b)(1)) is amended by striking “during and*  
10 *after fiscal year 2022, \$180,000,000” and inserting the fol-*  
11 *lowing: “during and after—*

12 *“(A) fiscal year 2022, \$180,000,000; and*

13 *“(B) fiscal year 2028, \$1,947,000,000”.*



Calendar No. 266

118<sup>TH</sup> CONGRESS  
1<sup>ST</sup> Session

**S. 2973**

[Report No. 118-122]

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## **A BILL**

To amend titles XVIII and XIX of the Social Security Act to establish requirements relating to pharmacy benefit managers under the Medicare and Medicaid programs, and for other purposes.

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DECEMBER 7, 2023

Reported with an amendment