

118TH CONGRESS  
1ST SESSION

# S. 2973

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

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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,*

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

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

6       (b) TABLE OF CONTENTS.—The table of contents of  
7       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.

**1 SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MAN-**  
**2 AGERS WITH RESPECT TO PRESCRIPTION**  
**3 DRUG PLANS AND MA-PD PLANS.**

**4 (a) IN GENERAL.—**

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

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

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

1 on behalf of such sponsor has a written agreement  
2 with the PDP sponsor under which the pharmacy  
3 benefit manager agrees to meet the following re-  
4 quirements:

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

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

15 “(ii) INCENTIVE PAYMENTS.—For the  
16 purposes of this subsection, an incentive  
17 payment paid by a PDP sponsor to a phar-  
18 macy benefit manager that is performing  
19 services on behalf of such sponsor shall be  
20 deemed a ‘bona fide service fee’ if such  
21 payment is a flat dollar amount, is con-  
22 sistent with fair market value, and is re-  
23 lated to services actually performed by the  
24 pharmacy benefit manager or affiliate of  
25 such pharmacy benefit manager in connec-

tion with the utilization of covered part D drugs.

“(iii) CLARIFICATION ON REBATES AND DISCOUNTS USED TO LOWER COSTS FOR COVERED PART D DRUGS.—Rebates, discounts, and other price concessions received from manufacturers, even if such price concessions are calculated as a percentage of a drug’s price, shall not be considered a violation of the requirements of clause (i) if they are fully passed through to a PDP sponsor and exclusively used to lower costs for prescription drugs under this part, including in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.

“(iv) EVALUATION OF REMUNERATION ARRANGEMENTS.—Remuneration arrangements between pharmacy benefit managers or affiliates of such pharmacy benefit managers, as applicable, and other entities involved in the dispensing or utilization of covered part D drugs (including PDP sponsors, manufacturers, pharmacies, and

other entities as determined appropriate by the Secretary) shall be subject to review by the Secretary and the Office of the Inspector General of the Department of Health and Human Services. The Secretary, in consultation with the Office of the Inspector General, shall evaluate whether remuneration under such arrangements is consistent with fair market value through reviews and assessments of such remuneration, as determined appropriate.

“(B) TRANSPARENCY REGARDING GUARANTEES AND COST PERFORMANCE EVALUATIONS.—The pharmacy benefit manager shall—

“(i) define, interpret, and apply, in a fully transparent and consistent manner for purposes of calculating or otherwise evaluating pharmacy benefit manager performance against pricing guarantees or similar cost performance measurements related to rebates, discounts, price concessions, or net costs, terms such as—

“(I) ‘generic drug’, in a manner consistent with the definition of the term under section 423.4 of title 42,

1 Code of Federal Regulations, or a suc-  
2 cessor regulation;

3 “(II) ‘brand name drug’, in a  
4 manner consistent with the definition  
5 of the term under section 423.4 of  
6 title 42, Code of Federal Regulations,  
7 or a successor regulation;

8 “(III) ‘specialty drug’;

9 “(IV) ‘rebate’; and

10 “(V) ‘discount’;

11 “(ii) identify any drugs, claims, or  
12 price concessions excluded from any pric-  
13 ing guarantee or other cost performance  
14 calculation or evaluation in a clear and  
15 consistent manner; and

16 “(iii) where a pricing guarantee or  
17 other cost performance measure is based  
18 on a pricing benchmark other than the  
19 wholesale acquisition cost (as defined in  
20 section 1847A(c)(6)(B)) of a drug, cal-  
21 culate and provide a wholesale acquisition  
22 cost-based equivalent to the pricing guar-  
23 antee or other cost performance measure  
24 in the written agreement.

25 “(C) PROVISION OF INFORMATION.—

“(i) IN GENERAL.—Not later than July 1 of each year, beginning in 2026, the pharmacy benefit manager shall submit to the PDP sponsor, and to the Secretary, a report, in accordance with this subparagraph, and shall make such report available to such sponsor at no cost to such sponsor in a format specified by the Secretary under paragraph (4). Each such report shall include, with respect to such PDP sponsor and each plan offered by such sponsor, the following information with respect to the previous plan year:

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

“(aa) the brand name, generic or non-proprietary name, and National Drug Code;

“(bb) the number of plan enrollees for whom the drug was dispensed, the total number of prescription claims for the drug (including original prescriptions and refills, counted as separate

1 claims), and the total number of  
2 dosage units of the drug dis-  
3 pensed;

4 “(cc) the number of pre-  
5 scription claims described in item  
6 (bb) by each type of dispensing  
7 channel through which the drug  
8 was dispensed, including retail,  
9 mail order, specialty pharmacy,  
10 long term care pharmacy, home  
11 infusion pharmacy, or other types  
12 of pharmacies or providers;

13 “(dd) the average wholesale  
14 acquisition cost, listed as cost per  
15 day’s supply, cost per dosage  
16 unit, and cost per typical course  
17 of treatment (as applicable);

18 “(ee) the average wholesale  
19 price for the drug, listed as cost  
20 per day’s supply, cost per dosage  
21 unit, and cost per typical course  
22 of treatment (as applicable);

23 “(ff) the total out-of-pocket  
24 spending by plan enrollees on  
25 such drug after application of



1 any benefits under the plan, in-  
2 cluding plan enrollee spending  
3 through copayments, coinsurance,  
4 and deductibles;

5 “(gg) total rebates paid by  
6 the manufacturer on the drug as  
7 reported under the Detailed DIR  
8 Report (or any successor report)  
9 submitted by such sponsor to the  
10 Centers for Medicare & Medicaid  
11 Services;

12 “(hh) all other direct or in-  
13 direct remuneration on the drug  
14 as reported under the Detailed  
15 DIR Report (or any successor re-  
16 port) submitted by such sponsor  
17 to the Centers for Medicare &  
18 Medicaid Services;

19 “(ii) the average pharmacy  
20 reimbursement amount paid by  
21 the plan for the drug in the ag-  
22 gregate and disaggregated by dis-  
23 pensing channel identified in item  
24 (cc);

1 “(jj) the average National  
2 Average Drug Acquisition Cost  
3 (NADAC) for retail community  
4 pharmacies; and

5 “(kk) total manufacturer-de-  
6 rived revenue, inclusive of bona  
7 fide service fees, retained by the  
8 pharmacy benefit manager and  
9 any affiliate of such pharmacy  
10 benefit manager attributable to  
11 the drug.

12 “(II) In the case of a pharmacy  
13 benefit manager that has an affiliate  
14 that is a retail, mail order, or spe-  
15 cialty pharmacy, with respect to drugs  
16 covered by such plan that were dis-  
17 pensed, the following information:

18 “(aa) The percentage of  
19 total prescriptions that were dis-  
20 pensed by pharmacies that are an  
21 affiliate of the pharmacy benefit  
22 manager for each drug.

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

ees, per dosage unit, per course  
of treatment, per 30-day supply,  
and per 90-day supply for each  
drug dispensed by pharmacies  
that are not an affiliate of the  
pharmacy benefit manager and  
that are included in the phar-  
macy network of such plan.

“(cc) The interquartile  
range of the total combined costs  
paid by the plan and plan enroll-  
ees, per dosage unit, per course  
of treatment, per 30-day supply,  
and per 90-day supply for each  
drug dispensed by pharmacies  
that are an affiliate of the phar-  
macy benefit manager and that  
are included in the pharmacy  
network of such plan.

“(dd) The lowest total com-  
bined cost paid by the plan and  
plan enrollees, per dosage unit,  
per course of treatment, per 30-  
day supply, and per 90-day sup-  
ply, for each drug that is avail-

1 able from any pharmacy included  
2 in the pharmacy network of such  
3 plan.

4 “(ee) The difference between  
5 the average acquisition cost of  
6 the affiliate, such as a pharmacy  
7 or other entity that acquires pre-  
8 scription drugs, that initially ac-  
9 quires the drug and the amount  
10 reported under subclause (I)(jj)  
11 for each drug.

12 “(ff) A list of covered part  
13 D drugs subject to an agreement  
14 with a covered entity under sec-  
15 tion 340B of the Public Health  
16 Service Act for which the phar-  
17 macy benefit manager or an affil-  
18 iate of the pharmacy benefit  
19 manager had a contract or other  
20 arrangement with such a covered  
21 entity in the service area of such  
22 plan.

23 “(III) Where a drug approved  
24 under section 505(c) of the Federal  
25 Food, Drug, and Cosmetic Act (re-

1           ferred to in this subclause as the ‘list-  
2           ed drug’) is covered by the plan, the  
3           following information:

4                   “(aa) A list of currently  
5                   marketed generic drugs approved  
6                   under section 505(j) of the Fed-  
7                   eral Food, Drug, and Cosmetic  
8                   Act pursuant to an application  
9                   that references such listed drug  
10                  that are not covered by the plan,  
11                  are covered on the same for-  
12                  mulary tier or a formulary tier  
13                  typically associated with higher  
14                  cost-sharing than the listed drug,  
15                  or are subject to utilization man-  
16                  agement that the listed drug is  
17                  not subject to.

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

22                  “(cc) Where a generic drug  
23                  listed under item (aa) is on a for-  
24                  mulary tier typically associated  
25                  with higher cost-sharing than the

1 listed drug, the estimated aver-  
2 age cost-sharing that a bene-  
3 ficiary would have paid for a 30-  
4 day supply of each of the generic  
5 drugs described in item (aa), had  
6 the plan provided coverage for  
7 such drugs on the same for-  
8 mulary tier as the listed drug.

9 “(dd) A written justification  
10 for providing more favorable cov-  
11 erage of the listed drug than the  
12 generic drugs described in item  
13 (aa).

14 “(ee) The number of cur-  
15 rently marketed generic drugs  
16 approved under section 505(j) of  
17 the Federal Food, Drug, and  
18 Cosmetic Act pursuant to an ap-  
19 plication that references such  
20 listed drug.

21 “(IV) Where a reference product  
22 (as defined in section 351(i) of the  
23 Public Health Service Act) is covered  
24 by the plan, the following information:

1           “(aa) A list of currently  
2 marketed biosimilar biological  
3 products licensed under section  
4 351(k) of the Public Health  
5 Service Act pursuant to an appli-  
6 cation that refers to such ref-  
7 erence product that are not cov-  
8 ered by the plan, are covered on  
9 the same formulary tier or a for-  
10 mulary tier typically associated  
11 with higher cost-sharing than the  
12 reference product, or are subject  
13 to utilization management that  
14 the reference product is not sub-  
15 ject to.

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

20           “(cc) Where a biosimilar bi-  
21 ological product listed under item  
22 (aa) is on a formulary tier typi-  
23 cally associated with higher cost-  
24 sharing than the listed drug, the  
25 estimated average cost-sharing

1 that a beneficiary would have  
2 paid for a 30-day supply of each  
3 of the biosimilar biological prod-  
4 ucts described in item (aa), had  
5 the plan provided coverage for  
6 such products on the same for-  
7 mulary tier as the reference prod-  
8 uct.

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

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

21 “(V) Total gross spending on  
22 covered part D drugs by the plan, not  
23 net of rebates, fees, discounts, or  
24 other direct or indirect remuneration.



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

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

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

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

1 other services offered to PDP spon-  
 2 sors related to pharmacy benefit man-  
 3 agement services.

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

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

11 “(ii) WRITTEN EXPLANATION OF CON-  
 12 TRACTS OR AGREEMENTS WITH DRUG  
 13 MANUFACTURERS.—

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

1 manufacturer directly or indirectly  
 2 contingent upon coverage, formulary  
 3 placement, or utilization management  
 4 conditions on any other prescription  
 5 drugs, submit to the PDP sponsor a  
 6 written explanation of such contract  
 7 or agreement.

8 “(II) REQUIREMENTS.—A writ-  
 9 ten explanation under subclause (I)  
 10 shall—

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

21 “(bb) be certified by the  
 22 Chief Executive Officer, Chief Fi-  
 23 nancial Officer, or General Coun-  
 24 sel of such pharmacy benefit  
 25 manager, affiliate of such phar-

1 macy benefit manager, or an in-  
2 dividual delegated with the au-  
3 thority to sign on behalf of one of  
4 these officers, who reports di-  
5 rectly to the officer.

6 “(D) AUDIT RIGHTS.—

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

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

20 “(iii) PROVISION OF INFORMATION.—  
21 The pharmacy benefit manager shall make  
22 available to such auditor all records, data,  
23 contracts, and other information necessary  
24 to confirm the accuracy of information  
25 provided under subparagraph (C), subject

1 to reasonable restrictions on how such in-  
2 formation must be reported to prevent re-  
3 disclosure of such information.

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

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

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

22 “(i) disgorge to a PDP sponsor (or, in  
23 a case where the PDP sponsor is an affil-  
24 iate of such pharmacy benefit manager, to  
25 the Secretary) any payment, remuneration,

1 or other amount received by the pharmacy  
2 benefit manager or an affiliate of such  
3 pharmacy benefit manager in violation of  
4 subparagraph (A) or the written agreement  
5 entered into with such sponsor under this  
6 part with respect to a prescription drug  
7 plan;

8 “(ii) reimburse the PDP sponsor for  
9 any civil money penalty imposed on the  
10 PDP sponsor as a result of the failure of  
11 the pharmacy benefit manager to meet the  
12 requirements of this paragraph that are  
13 applicable to the pharmacy benefit man-  
14 ager under the agreement; and

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

19 “(2) CERTIFICATION OF COMPLIANCE.—Each  
20 PDP sponsor shall furnish to the Secretary (in a  
21 time and manner specified by the Secretary) an an-  
22 nual certification of compliance with this subsection,  
23 as well as such information as the Secretary deter-  
24 mines necessary to carry out this subsection.

1           “(3) RULE OF CONSTRUCTION.—Nothing in  
2           this subsection shall be construed as prohibiting pay-  
3           ments related to reimbursement for ingredient costs  
4           to any entity that acquires prescription drugs, such  
5           as a pharmacy or wholesaler.

6           “(4) STANDARD FORMATS.—Not later than  
7           June 1, 2025, the Secretary shall specify standard,  
8           machine-readable formats for pharmacy benefit  
9           managers to submit annual reports required under  
10          paragraph (1)(C)(i).

11          “(5) CONFIDENTIALITY.—

12                 “(A) IN GENERAL.—Information disclosed  
13                 by a pharmacy benefit manager or PDP spon-  
14                 sor under this subsection that is not otherwise  
15                 publicly available or available for purchase shall  
16                 not be disclosed by the Secretary or a PDP  
17                 sponsor receiving the information, except that  
18                 the Secretary may disclose the information for  
19                 the following purposes:

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

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

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

4           “(iv) To permit the Executive Direc-  
5           tor of the Medicare Payment Advisory  
6           Commission to review the information pro-  
7           vided.

8           “(v) To the Attorney General for the  
9           purposes of conducting oversight and en-  
10          forcement under this title.

11          “(vi) To the Inspector General of the  
12          Department of Health and Human Serv-  
13          ices in accordance with its authorities  
14          under the Inspector General Act of 1978  
15          (section 406 of title 5, United States  
16          Code), and other applicable statutes.

17          “(B) RESTRICTION ON USE OF INFORMA-  
18          TION.—The Secretary, the Comptroller General,  
19          the Director of the Congressional Budget Of-  
20          fice, and the Executive Director of the Medicare  
21          Payment Advisory Commission shall not report  
22          on or disclose information disclosed pursuant to  
23          subparagraph (A) to the public in a manner  
24          that would identify a specific pharmacy benefit  
25          manager, affiliate, manufacturer or wholesaler,



1 PDP sponsor, or plan, or contract prices, re-  
2 bates, discounts, or other remuneration for spe-  
3 cific drugs in a manner that may allow the  
4 identification of specific contracting parties.

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

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

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

1 and shall not be directly or indirectly based on,  
2 or contingent upon—

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

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

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

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

18 “(C) PHARMACY BENEFIT MANAGER.—The  
19 term ‘pharmacy benefit manager’ means any  
20 person or entity that, either directly or through  
21 an intermediary, acts as a price negotiator or  
22 group purchaser on behalf of a PDP sponsor or  
23 prescription drug plan, or manages the pre-  
24 scription drug benefits provided by such spon-  
25 sor or plan, including the processing and pay-

ment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered part D drugs, or the provision of related services. Such term includes any person or entity that carries out one or more of the activities described in the preceding sentence, irrespective of whether such person or entity calls itself a ‘pharmacy benefit manager’.”.

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

“(F) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2026, section 1860D–12(h).”.

(3) FUNDING.—

(A) SECRETARY.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money

1 in the Treasury not otherwise appropriated,  
2 \$20,000,000 for fiscal year 2026, to remain  
3 available until expended, to carry out the  
4 amendments made by this subsection.

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

13 (b) GAO STUDY AND REPORT ON CERTAIN REPORT-  
14 ING REQUIREMENTS.—

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

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

1           (B) Selected States' statutory and regu-  
 2           latory reporting requirements for health plans  
 3           and pharmacy benefit managers related to pre-  
 4           scription drug costs and prices.

5           (C) The extent to which the statutory and  
 6           regulatory reporting requirements identified in  
 7           subparagraphs (A) and (B) overlap and con-  
 8           flict.

9           (D) The resources required by health plans  
 10          and pharmacy benefit managers to comply with  
 11          the reporting requirements described in sub-  
 12          paragraphs (A) and (B).

13          (E) Other items determined appropriate by  
 14          the Comptroller General.

15          (2) REPORT.—Not later than 2 years after the  
 16          date on which information is first required to be re-  
 17          ported under section 1860D–12(h)(1)(C) of the So-  
 18          cial Security Act, as added by subsection (a)(1), the  
 19          Comptroller General shall submit to Congress a re-  
 20          port containing the results of the study conducted  
 21          under paragraph (1), together with recommenda-  
 22          tions for legislation and administrative actions that  
 23          would streamline and reduce the burden associated  
 24          with the reporting requirements for health plans and

1 pharmacy benefit managers described in paragraph  
2 (1).

3 (c) MEDPAC REPORTS ON AGREEMENTS WITH  
4 PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE-  
5 SCRIPTION DRUG PLANS AND MA–PD PLANS.—The  
6 Medicare Payment Advisory Commission shall submit to  
7 Congress the following reports:

8 (1) Not later than March 31, 2027, a report re-  
9 garding agreements with pharmacy benefit managers  
10 with respect to prescription drug plans and MA–PD  
11 plans. Such report shall include—

12 (A) a description of trends and patterns,  
13 including relevant averages, totals, and other  
14 figures for each of the types of information sub-  
15 mitted;

16 (B) an analysis of any differences in agree-  
17 ments and their effects on plan enrollee out-of-  
18 pocket spending and average pharmacy reim-  
19 bursement, and any other impacts; and

20 (C) any recommendations the Commission  
21 determines appropriate.

22 (2) Not later than March 31, 2029, a report de-  
23 scribing any changes with respect to the information  
24 described in paragraph (1) over time, together with

1       any recommendations the Commission determines  
2       appropriate.

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

6       (a)   STANDARDIZED PHARMACY PERFORMANCE  
7 MEASURES.—Section 1860D–2 of the Social Security Act  
8 (42 U.S.C. 1395w–102) is amended by adding at the end  
9 the following new subsection:

10       “(f) APPLICATION OF STANDARDIZED PHARMACY  
11 PERFORMANCE MEASURES.—

12               “(1) MEASURES.—For plan years beginning on  
13 or after January 1, 2025, a PDP sponsor offering  
14 a prescription drug plan and an MA organization of-  
15 fering an MA–PD plan shall, for purposes of incen-  
16 tive payments, price concessions, or any fees or  
17 other remuneration paid or charged to a pharmacy  
18 based on performance measures, only use measures  
19 that are—

20               “(A) established or adopted by the Sec-  
21 retary under paragraph (2) and included on the  
22 list described in subparagraph (B) of such  
23 paragraph; and

24               “(B) relevant to the performance of such  
25 pharmacy based on the type of pharmacy (in-

cluding retail, mail order, specialty, long term  
 care, and home infusion or other types of phar-  
 macies), drugs dispensed by such pharmacy,  
 and pharmacy services used to dispense and  
 manage drugs by such pharmacy.

“(2) STANDARDIZED PHARMACY PERFORMANCE  
 MEASURES.—

“(A) MEASURES.—

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

“(ii) REQUIREMENTS.—The measures  
 under clause (i) shall focus on pharmacy  
 performance and quality of care based on  
 the type of pharmacy, as determined by  
 the Secretary. Such measures shall be evi-



dence-based, feasible, appropriate and reasonable.

“(iii) ADOPTION OF MEASURE.—In lieu of establishing some or all of the measures under this paragraph, the Secretary may adopt measures that are endorsed by one or more multi-stakeholder consensus organizations (such as the Pharmacy Quality Alliance), that has participation from pharmacies (including retail and specialty pharmacies not owned or affiliated with a plan, pharmacy benefit manager, or other pharmacy), health plans, pharmacy benefit managers, and the Centers for Medicare & Medicaid Services. Any measure adopted under this clause shall be deemed to meet the requirements under clause (ii).

“(B) MAINTENANCE OF LIST.—

“(i) IN GENERAL.—The Secretary shall maintain, and publish on a publicly available internet website, a list of measures established or adopted under this paragraph. Such list shall initially be published no later than June 1, 2024.

1                   “(ii) UPDATE.—The Secretary shall  
 2                   periodically evaluate measures, and how  
 3                   measures are applied by type of pharmacy  
 4                   and update the measures on the list under  
 5                   clause (i) so that such measures meet the  
 6                   requirements under subparagraph (A)(ii).

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

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

18   **SEC. 4. PROMOTING TRANSPARENCY FOR PHARMACIES**  
 19                   **UNDER MEDICARE PART D.**

20                  (a) TRANSPARENCY FOR PHARMACIES.—Section  
 21                  1860D–2(f) of the Social Security Act (42 U.S.C. 1395w–  
 22                  102(f)), as added by section 3, is amended by adding at  
 23                  the end the following new paragraph:

24                   “(4) TRANSPARENCY FOR PHARMACIES.—

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

16          “(B) STANDARDIZED FORMAT.—The PDP  
17          sponsor and the MA organization shall furnish  
18          the information described in subparagraph (A)  
19          in a standardized format (as specified by the  
20          Secretary) that includes all fields needed to  
21          price the claim for a covered part D drug dis-  
22          pensed by such pharmacy.

23          “(C) AVAILABILITY OF INFORMATION TO  
24          THE SECRETARY.—A PDP sponsor offering a  
25          prescription drug plan or an MA organization

1 offering an MA–PD plan shall make the infor-  
 2 mation described in subparagraph (A) available  
 3 to the Secretary upon request.

4 “(D) IMPLEMENTATION.—Notwithstanding  
 5 any other provision of law, the Secretary shall  
 6 implement this paragraph by program instruc-  
 7 tion or otherwise.”.

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

15 **SEC. 5. PREVENTING THE USE OF ABUSIVE SPREAD PRIC-**  
 16 **ING IN MEDICAID.**

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

20 “(6) TRANSPARENT PRESCRIPTION DRUG PASS-  
 21 THROUGH PRICING REQUIRED.—A contract between  
 22 the State and a pharmacy benefit manager (referred  
 23 to in this paragraph as a ‘PBM’), or a contract be-  
 24 tween the State and a managed care entity or other  
 25 specified entity (as such terms are defined in section

1       1903(m)(9)(D) and collectively referred to in this  
 2       paragraph as the ‘entity’) that includes provisions  
 3       making the entity responsible for coverage of covered  
 4       outpatient drugs dispensed to individuals enrolled  
 5       with the entity, shall require that payment for such  
 6       drugs and related administrative services (as appli-  
 7       cable), including payments made by a PBM on be-  
 8       half of the State or entity, is based on a transparent  
 9       prescription drug pass-through pricing model under  
 10      which—

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

13                      “(i) is limited to—

14                              “(I) ingredient cost; and

15                              “(II) a professional dispensing  
 16                              fee that is not less than the profes-  
 17                              sional dispensing fee that the State  
 18                              plan or waiver would pay if the plan  
 19                              or waiver was making the payment di-  
 20                              rectly;

21                      “(ii) is passed through in its entirety  
 22                      by the entity or PBM to the pharmacy or  
 23                      provider that dispenses the drug (and shall  
 24                      not be reduced or denied retroactively  
 25                      under post-adjudication processes); and

1 “(iii) is made in a manner that is con-  
2 sistent with sections 447.502, 447.512,  
3 447.514, and 447.518 of title 42, Code of  
4 Federal Regulations (or any successor reg-  
5 ulation) as if such requirements applied di-  
6 rectly to the entity or the PBM, except  
7 that any payment by the entity or the  
8 PBM for the ingredient cost of such drug  
9 purchased by a covered entity (as defined  
10 in subsection (a)(5)(B)) may exceed the  
11 actual acquisition cost (as defined in  
12 447.502 of title 42, Code of Federal Regu-  
13 lations, or any successor regulation) for  
14 such drug if—

15 “(I) such drug was subject to an  
16 agreement under section 340B of the  
17 Public Health Service Act;

18 “(II) such payment for the ingre-  
19 dient cost of such drug does not ex-  
20 ceed the maximum payment that  
21 would have been made by the entity or  
22 the PBM for the ingredient cost of  
23 such drug if such drug had not been  
24 purchased by such covered entity; and

1                   “(III) such covered entity reports  
2                   to the Secretary (in a form and man-  
3                   ner specified by the Secretary), on an  
4                   annual basis and with respect to pay-  
5                   ments for the ingredient costs of such  
6                   drugs so purchased by such covered  
7                   entity that are in excess of the actual  
8                   acquisition costs for such drugs, the  
9                   aggregate amount of such excess;

10                  “(B) payment to the entity or the PBM  
11                  (as applicable) for administrative services per-  
12                  formed by the entity or PBM is limited to the  
13                  fair market value of such services;

14                  “(C) the entity or the PBM (as applicable)  
15                  shall make available to the State, and the Sec-  
16                  retary upon request, all costs and payments re-  
17                  lated to covered outpatient drugs and accom-  
18                  panying administrative services incurred, re-  
19                  ceived, or made by the entity or the PBM, in-  
20                  cluding ingredient costs, professional dispensing  
21                  fees, administrative fees, post-sale and post-in-  
22                  voice fees, discounts, or related adjustments  
23                  such as direct and indirect remuneration fees,  
24                  and any and all other remuneration; and

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

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

17               “(12) PHARMACY BENEFIT MANAGER.—The  
 18          term ‘pharmacy benefit manager’ means any person  
 19          or entity that, either directly or through an inter-  
 20          mediary, acts as a price negotiator or group pur-  
 21          chaser on behalf of a State, managed care entity or  
 22          other specified entity (as such terms are defined in  
 23          section 1903(m)(9)(D)), or manages the prescription  
 24          drug benefits provided by such State, managed care  
 25          entity, or other specified entity, including the proc-



1       essing and payment of claims for prescription drugs,  
 2       the performance of drug utilization review, the proc-  
 3       essing of drug prior authorization requests, the man-  
 4       aging of appeals or grievances related to the pre-  
 5       scription drug benefits, contracting with pharmacies,  
 6       controlling the cost of covered outpatient drugs, or  
 7       the provision of services related thereto. Such term  
 8       includes any person or entity that carries out 1 or  
 9       more of the activities described in the preceding sen-  
 10      tence, irrespective of whether such person or entity  
 11      calls itself a ‘pharmacy benefit manager’.”.

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

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

15                   (A) by striking “and (III)” and inserting  
 16                   “(III)”;

17                   (B) by inserting before the period at the  
 18                   end the following: “, and (IV) if the entity, or  
 19                   a pharmacy benefit manager acting on behalf of  
 20                   the entity under a contract or other arrange-  
 21                   ment between the entity and the pharmacy ben-  
 22                   efit manager, performs any of the activities de-  
 23                   scribed in section 1927(k)(12), such activities  
 24                   shall comply with the requirements of section  
 25                   1927(e)(6)”;

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

3 (2) by adding at the end the following new  
 4 paragraph:

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

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

18 **SEC. 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES**

19 **UNDER MEDICAID.**

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

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

1           “(1) DETERMINING PHARMACY ACTUAL ACQUI-  
 2           SITION COSTS.—The Secretary shall conduct a sur-  
 3           vey of retail community pharmacy drug prices to de-  
 4           termine the national average drug acquisition cost as  
 5           follows:

6                   “(A) USE OF VENDOR.—The Secretary  
 7           may contract services for—

8                           “(i) with respect to retail community  
 9                           pharmacies, the determination of retail  
 10                          survey prices of the national average drug  
 11                          acquisition cost for covered outpatient  
 12                          drugs that represent a nationwide average  
 13                          of consumer purchase prices for such  
 14                          drugs, net of all discounts and rebates (to  
 15                          the extent any information with respect to  
 16                          such discounts and rebates is available)  
 17                          based on a monthly survey of such phar-  
 18                          macies; and”;

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

21                   “(F) SURVEY REPORTING.—In order to  
 22                   meet the requirement of section 1902(a)(54), a  
 23                   State shall require that any retail community  
 24                   pharmacy in the State that receives any pay-  
 25                   ment, reimbursement, administrative fee, dis-

count, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, or rebate is received from the State or a managed care entity or other specified entity (as such terms are defined in section 1903(m)(9)(D)) directly or from a pharmacy benefit manager or another entity that has a contract with the State or a managed care entity or other specified entity (as so defined), shall respond to surveys of retail prices conducted under this paragraph.

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

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

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

“(iii) Information on price concessions to the pharmacy, including discounts, re-

1           bates, and other price concessions, to the  
 2           extent that such information may be pub-  
 3           licly released and has been collected by the  
 4           Secretary as part of the survey.

5           “(H) PENALTIES.—The Secretary may en-  
 6           force non-compliance with this paragraph by a  
 7           pharmacy through the establishment of pen-  
 8           alties or the suspension of payments under this  
 9           title, in full or in part, until compliance with  
 10          this paragraph has been completed.”;

11          (3) in paragraph (2)—

12           (A) in subparagraph (A), by inserting “,  
 13           including payment rates under Medicaid man-  
 14           aged care entities or other specified entities (as  
 15           such terms are defined in section  
 16           1903(m)(9)(D)),” after “under this title”; and

17           (B) in subparagraph (B), by inserting  
 18           “and the basis for such dispensing fees” before  
 19           the semicolon; and

20          (4) in paragraph (4), by inserting “, and  
 21          \$5,000,000 for fiscal year 2024 and each fiscal year  
 22          thereafter,” after “2010”.

23          (b) EFFECTIVE DATE.—The amendments made by  
 24          this section take effect on the first day of the first quarter

1 that begins on or after the date that is 18 months after  
 2 the date of enactment of this Act.

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

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

8 “(e) OIG STUDY AND REPORT ON DRUG PRICE  
 9 MARK-UPS UNDER THIS PART.—

10 “(1) STUDY.—The Inspector General of the De-  
 11 partment of Health and Human Services (in this  
 12 subsection referred to as the ‘Inspector General’)  
 13 shall conduct a study on the impact of related party  
 14 transactions within select vertically integrated enti-  
 15 ties on the negotiated price (as defined in section  
 16 1860D–2(d)(1)(B)) paid by part D plan sponsors  
 17 for covered part D drugs. Such study may include  
 18 an analysis of the following:

19 “(A) Acquisition costs by the affiliate with-  
 20 in such vertically integrated entities that ini-  
 21 tially acquires the prescription drug for a sam-  
 22 ple of covered part D drugs, including at least  
 23 5 generic drugs, brand drugs, specialty brand  
 24 drugs, and specialty generic drugs.

1           “(B) The methodologies and negotiation  
2           processes used to calculate transfer prices or  
3           other transactions between related parties with  
4           respect to such covered part D drugs.

5           “(C) The impact of the transactions de-  
6           scribed in subparagraph (B) on the negotiated  
7           price, net of direct and indirect remuneration,  
8           for such covered part D drugs.

9           “(D) The margin captured by different af-  
10          filiates within such vertically integrated entities  
11          through the transactions described in subpara-  
12          graph (B).

13          “(E) An assessment of the impact of the  
14          transactions described in subparagraph (B) on  
15          costs to individuals enrolled in a prescription  
16          drug plan or an MA–PD plan and program  
17          spending on prescription drugs under this part.

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

20          “(2) REPORT.—Not later than 3 years after the  
21          date of enactment of this subsection, the Inspector  
22          General shall submit to the Committee on Finance  
23          of the Senate and the Committee on Energy and  
24          Commerce and the Committee on Ways and Means  
25          of the House of Representatives a report containing

1 the results of the study conducted under paragraph  
 2 (1), together with recommendations for such legisla-  
 3 tion and administrative action as the Inspector Gen-  
 4 eral determines appropriate.

5 “(3) FUNDING.—In addition to amounts other-  
 6 wise available, there is appropriated to the Inspector  
 7 General, out of any money in the Treasury not oth-  
 8 erwise appropriated, \$5,200,000 for fiscal year  
 9 2024, to remain available until expended, to carry  
 10 out this subsection.”.

11 **SEC. 8. RESOLVING P&T COMMITTEE CONFLICTS OF INTER-**  
 12 **EST.**

13 Section 1860D–4(b)(3)(A)(ii)(I) of the Social Secu-  
 14 rity Act (42 U.S.C. 1395w–104(b)(3)(A)(ii)(I)) is amend-  
 15 ed by inserting the following before the semicolon: “(and,  
 16 for 2025 and each subsequent year, any pharmacy benefit  
 17 manager acting under contract with such sponsor offering  
 18 such plan)”.

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

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

22 (1) by striking subsection (a) and inserting the  
 23 following:

24 “(a) PROVISION OF INFORMATION.—



1           “(1) IN GENERAL.—The following entities shall  
 2       provide the information described in subsection (b)  
 3       to the Secretary and, in the case of an entity de-  
 4       scribed in subparagraph (B) or an affiliate of such  
 5       entity described in subparagraph (C), to the health  
 6       benefits plan with which the entity is under contract,  
 7       at such times, and in such form and manner, as the  
 8       Secretary shall specify:

9           “(A) A health benefits plan.

10          “(B) Any entity that provides pharmacy  
 11       benefits management services on behalf of a  
 12       health benefits plan (in this section referred to  
 13       as a ‘PBM’) that manages prescription drug  
 14       coverage under a contract with—

15               “(i) a PDP sponsor of a prescription  
 16       drug plan or an MA organization offering  
 17       an MA–PD plan under part D of title  
 18       XVIII; or

19               “(ii) a qualified health benefits plan  
 20       offered through an exchange established by  
 21       a State under section 1311 of the Patient  
 22       Protection and Affordable Care Act.

23          “(C) Any affiliate of an entity described in  
 24       subparagraph (B) that acts as a price nego-  
 25       tiator or group purchaser on behalf of such

1 PBM, PDP sponsor, MA organization, or quali-  
 2 fied health benefits plan.

3 “(2) AFFILIATE DEFINED.—In this section, the  
 4 term ‘affiliate’ means any entity that is owned by,  
 5 controlled by, or related under a common ownership  
 6 structure with a PBM (including an entity owned or  
 7 controlled by the PDP sponsor of a prescription  
 8 drug plan, MA organization offering an MA–PD  
 9 plan, or qualified health benefits plan for which such  
 10 entity is acting as a price negotiator or group pur-  
 11 chaser).”;

12 (2) in subsection (b)—

13 (A) in paragraph (2), by inserting “and  
 14 percentage” after “and the aggregate amount”;  
 15 and

16 (B) by adding at the end the following new  
 17 paragraph:

18 “(4) The amount (in the aggregate and  
 19 disaggregated by type) of all fees the PBM or an af-  
 20 filiate of the PBM receives from all pharmaceutical  
 21 manufacturers in connection with patient utilization  
 22 under the plan, and the amount and percentage (in  
 23 the aggregate and disaggregated by type) of such  
 24 fees that are passed through to the plan sponsor or  
 25 issuer.”; and

1           (3) by adding at the end the following new sub-  
2       section:

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

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

11       (c) IMPLEMENTATION.—Notwithstanding any other  
12 provision of law, the Secretary may implement the amend-  
13 ments made by this section by program instruction or oth-  
14 erwise.

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

20 **SEC. 10. FACILITATING MIDYEAR FORMULARY CHANGES**  
21 **FOR BIOSIMILARS.**

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

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

7                   “(A) IN GENERAL.—For plan year 2025,  
8                   and subsequent plan years, in the case of a cov-  
9                   ered part D drug that is the reference biological  
10                  product (as defined in section 351(i) of the  
11                  Public Health Service Act) with respect to a  
12                  biosimilar biological product (defined as a bio-  
13                  logical product licensed under section 351(k) of  
14                  such Act), the PDP sponsor may, with respect  
15                  to a formulary, at any time after the first 60  
16                  days of the plan year, subject to paragraph  
17                  (3)(E), change the preferred or tiered cost-shar-  
18                  ing status of such reference biological product  
19                  if such PDP sponsor adds, before or at the  
20                  same time, to such formulary such biosimilar  
21                  biological product at the same or a higher pre-  
22                  ferred status, or to the same or lower cost-shar-  
23                  ing tier, as that of such reference biological  
24                  product immediately prior to such change.

1           “(B) REQUEST FOR APPROVAL OF  
2           CHANGE.—Prior to making a change described  
3           in subparagraph (A), the PDP sponsor shall  
4           submit to the Secretary a request to make such  
5           change. If the Secretary approves the request  
6           or has not provided a decision to the PDP  
7           sponsor regarding such request within 30 days  
8           of receiving such request, such PDP sponsor  
9           may make such change.”.

10       (b) ADMINISTRATION.—

11           (1) IMPLEMENTATION.—Notwithstanding any  
12           other provision of law, the Secretary of Health and  
13           Human Services may implement the amendment  
14           made by subsection (a) by program instruction or  
15           otherwise.

16           (2) NON-APPLICATION OF THE PAPERWORK RE-  
17           DUCTION ACT.—Chapter 35 of title 44, United  
18           States Code (commonly referred to as the “Paper-  
19           work Reduction Act of 1995”), shall not apply to the  
20           implementation of the amendment made by sub-  
21           section (a).

1 **SEC. 11. STRENGTHENING PHARMACY ACCESS FOR SEN-**  
 2 **IORES.**

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

6 “(F) LIMITED ACCESS DRUGS.—

7 “(i) LIMITATION ON RESTRICTIONS OR  
 8 LIMITS ON ACCESS.—For each plan year  
 9 (beginning with plan year 2026), a PDP  
 10 sponsor offering a prescription drug plan—

11 “(I) may not restrict or limit ac-  
 12 cess to any covered part D drug to a  
 13 subset of their network pharmacies,  
 14 other than with respect to a limited  
 15 access drug, as defined in clause (v);  
 16 and

17 “(II) shall document the ration-  
 18 ale for why a covered part D drug  
 19 meets the definition of a limited ac-  
 20 cess drug under clause (v), if such  
 21 plan restricts or limits access to a lim-  
 22 ited access drug to a subset of net-  
 23 work pharmacies.

24 “(ii) ANNUAL SUBMISSION OF INFOR-  
 25 MATION TO THE SECRETARY ON LIMITED  
 26 ACCESS DRUGS.—For each plan year (be-

ginning with plan year 2026), each PDP sponsor offering a prescription drug plan shall submit to the Secretary, at a time and in a manner specified by the Secretary, with respect to each prescription drug plan offered by the sponsor during such plan year—

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

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

“(III) a summary of the requirements imposed on network pharmacies (including all accreditation requirements, if any) to ensure appropriate handling and dispensing of each covered part D drug included in the list described in subclause (I);

“(IV) the percentages of each covered part D drug included in the list described in subclause (I) that is

1 dispensed through retail pharmacies,  
2 specialty pharmacies, mail order phar-  
3 macies, or other dispensing channels  
4 as defined by the PDP sponsor, re-  
5 spectively;

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

15 “(VI) any other information de-  
16 termined appropriate by the Sec-  
17 retary.

18 “(iii) PHARMACY ACCESS TO LIMITED  
19 ACCESS DRUG INFORMATION.—For plan  
20 years beginning with plan year 2026, upon  
21 the request of a network pharmacy, a PDP  
22 sponsor of a prescription drug plan shall  
23 provide such pharmacy, not later than 14  
24 days after receiving such request, with the



1 information described in subclauses (I),  
2 (II), and (III) of clause (ii).

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

14 “(I) a description of the patterns,  
15 trends, variations, and rationales for  
16 the designation by PDP sponsors of  
17 certain covered part D drugs as lim-  
18 ited access drugs, and the implications  
19 of such designations on beneficiary ac-  
20 cess to such covered part D drugs;

21 “(II) a description of the infor-  
22 mation submitted to the Secretary  
23 under clause (ii) (in a manner that  
24 does not disclose the identity of a  
25 pharmacy, a PDP sponsor, a prescrip-

tion drug plan, or pharmacy benefit manager, or any proprietary pricing information); and

“(III) any other information determined appropriate by the Secretary.

“(v) LIMITED ACCESS DRUG DEFINED.—In this subparagraph, the term ‘limited access drug’ means a covered part D drug that meets at least one of the following:

“(I) The Food and Drug Administration has restricted distribution of such covered part D drug to certain facilities or physicians.

“(II) The dispensing of such covered part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.”.

“(vii) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary shall implement this subparagraph by program instruction or otherwise.

1 “(viii) NONAPPLICATION OF PAPER-  
 2 WORK REDUCTION ACT.—Chapter 35 of  
 3 title 44, United States Code, shall not  
 4 apply to any data collection undertaken by  
 5 the Secretary under this subparagraph.”.

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

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

12 “(f) BENEFICIARY-FOCUSED LISTENING SESSIONS  
 13 TO IMPROVE PRESCRIPTION DRUG PLAN TRANS-  
 14 PARENCY, ACCESS, AND CHOICE.—

15 “(1) IN GENERAL.—Not later than December  
 16 31, 2024, the Secretary shall hold at least one bene-  
 17 ficiary-focused listening session to receive input on  
 18 potential improvements to the experience with, and  
 19 transparency of, prescription drug plans under this  
 20 part, as described in paragraph (2).

21 “(2) BENEFICIARY-FOCUSED LISTENING SES-  
 22 SIONS.—Any beneficiary-focused listening session  
 23 held under paragraph (1) shall be open to the public,  
 24 including beneficiaries, caregivers of beneficiaries,  
 25 consumer and patient advocacy organizations, health

1 care providers, and other interested parties. Any  
2 such listening sessions may include an opportunity  
3 for the public to provide input to the Secretary on  
4 potential improvements to—

5 “(A) the information made available by  
6 prescription drug plans to individuals;

7 “(B) tools and mechanisms to assist enroll-  
8 ees of prescription drug plans in navigating  
9 plan complaint systems, as well as the efficiency  
10 and effectiveness of such systems;

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

13 “(D) tools and mechanisms to assist en-  
14 rollees of prescription drug plans in navigating  
15 utilization management requirements of such  
16 plans, such as step therapy and prior authoriza-  
17 tion;

18 “(E) access to, and effectiveness and utili-  
19 zation of, electronic real-time benefit tools (as  
20 described in section 423.160(b)(7) of title 42,  
21 Code of Federal Regulations, or any successor  
22 regulation) and beneficiary real-time benefit  
23 tools (as described in section 423.128(d)(4) of  
24 title 42, Code of Federal Regulations, or any  
25 successor regulation);

1                   “(F) formulary management and oversight  
2                   by prescription drug plans; and

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

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

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

10           “(g) BIENNIAL REPORT ON ENFORCEMENT AND  
11 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

12                   “(1) IN GENERAL.—Not later than 2 years  
13 after the date of enactment of this subsection, and  
14 at least once every 2 years thereafter, the Secretary  
15 shall publish a report on enforcement and oversight  
16 actions and activities undertaken by the Secretary  
17 with respect to the requirements under section  
18 1860D–4(b)(1).

19                   “(2) LIMITATION.—A report under paragraph  
20 (1) shall not disclose—

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

24                           “(B) trade secrets with respect to any enti-  
25 ties.”.

1 **SEC. 14. GAO STUDY ON PRICE-RELATED COMPENSATION**  
2 **ACROSS THE SUPPLY CHAIN.**

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

6 “(h) GAO STUDY AND REPORT ON PRICE-RELATED  
7 COMPENSATION AND PAYMENT STRUCTURES IN THE  
8 PRESCRIPTION DRUG SUPPLY CHAIN.—

9 “(1) STUDY.—The Comptroller General of the  
10 United States (in this subsection referred to as the  
11 ‘Comptroller General’) shall conduct a study describ-  
12 ing the use of compensation and payment structures  
13 related to a prescription drug’s price within the re-  
14 tail prescription drug supply chain in this part. Such  
15 study shall summarize information from Federal  
16 agencies and industry experts, to the extent avail-  
17 able, with respect to the following:

18 “(A) The type, magnitude, other features  
19 (such as the pricing benchmarks used), and  
20 prevalence of compensation and payment struc-  
21 tures related to a prescription drug’s price,  
22 such as calculating fee amounts as a percentage  
23 of a prescription drug’s price, between inter-  
24 mediaries in the prescription drug supply chain,  
25 including—

26 “(i) pharmacy benefit managers;

1 “(ii) part D plan sponsors;

2 “(iii) drug wholesalers;

3 “(iv) pharmacies;

4 “(v) manufacturers;

5 “(vi) pharmacy services administrative  
6 organizations;

7 “(vii) brokers, auditors, consultants,  
8 and other entities that advise part D plan  
9 sponsors about pharmacy benefits or re-  
10 view part D plan sponsor contracts with  
11 pharmacy benefit managers; and

12 “(viii) other service providers that  
13 contract with any of the entities described  
14 in clauses (i) through (vii) that may use  
15 price-related compensation and payment  
16 structures, such as rebate aggregators (or  
17 other entities that negotiate or process  
18 price concessions on behalf of pharmacy  
19 benefit managers, plan sponsors, or phar-  
20 macies).

21 “(B) The primary business models and  
22 compensation structures for each category of  
23 intermediary described in subparagraph (A).

24 “(C) Variation in price-related compensa-  
25 tion structures between affiliated entities (such

1 as entities with common ownership, either full  
2 or partial, and subsidiary relationships) and un-  
3 affiliated entities.

4 “(D) Potential conflicts of interest among  
5 contracting entities related to the use of pre-  
6 scription drug price-related compensation struc-  
7 tures, such as the potential for fees or other  
8 payments set as a percentage of a prescription  
9 drug’s price to advantage formulary selection,  
10 distribution, or purchasing of prescription drugs  
11 with higher prices.

12 “(E) Notable differences, if any, in the use  
13 and level of price-based compensation struc-  
14 tures over time and between different market  
15 segments, such as under this part and the Med-  
16 icaid program under title XIX.

17 “(F) The effects of drug price-related com-  
18 pensation structures and alternative compensa-  
19 tion structures on Federal health care programs  
20 and program beneficiaries, including with re-  
21 spect to cost-sharing, premiums, Federal out-  
22 lays, biosimilar and generic drug adoption and  
23 utilization, drug shortage risks, and the poten-  
24 tial for fees set as a percentage of a drug’s  
25 price to advantage the formulary selection, dis-



1           tribution, or purchasing of drugs with higher  
2           prices.

3           “(G) Other issues determined to be rel-  
4           evant and appropriate by the Comptroller Gen-  
5           eral.

6           “(2) REPORT.—Not later than 2 years after the  
7           date of enactment of this subsection, the Comp-  
8           troller General shall submit to Congress a report  
9           containing the results of the study conducted under  
10          paragraph (1), together with recommendations for  
11          such legislation and administrative action as the  
12          Comptroller General determines appropriate.”.

13 **SEC. 15. REPORTS ON INAPPROPRIATE PHARMACY REJEC-**  
14 **TIONS.**

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

18          “(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS  
19 INAPPROPRIATE PHARMACY REJECTIONS AND INAPPRO-  
20 PRIATE COVERAGE DENIALS UNDER MEDICARE PART  
21 D.—

22          “(1) IN GENERAL.—Not later than January 1,  
23          2026, and at least once every 4 years thereafter, the  
24          Secretary, in consultation with the Office of the In-  
25          specter General of the Department of Health and

1 Human Services, shall post, on a publicly available  
2 website, a report related to preventing, identifying,  
3 or addressing inappropriate pharmacy rejections (as  
4 defined in paragraph (2)(B)) and inappropriate cov-  
5 erage denials (as defined in paragraph (2)(A)) under  
6 this part. Such reports shall include—

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

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

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

19 “(ii) notable longitudinal trends or  
20 other patterns, as determined appropriate  
21 by the Secretary;

22 “(C) an overview of corrective actions  
23 taken and technical assistance provided by the  
24 Secretary in response to violations of existing

1 requirements with respect to such rejections  
2 and denials; and

3 “(D) a description of barriers, if any, pre-  
4 venting the Secretary from taking administra-  
5 tive actions sufficient to identify and address  
6 such rejections and denials.

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

9 “(A) INAPPROPRIATE COVERAGE DE-  
10 NIAL.—The term ‘inappropriate coverage de-  
11 nial’ means a denial of coverage of a covered  
12 part D drug claim that violates the require-  
13 ments 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  
18 this part, such as through the application of  
19 utilization management requirements that the  
20 Secretary 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 amend-  
24 ed 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  
7 drugs across the outpatient prescription drug supply  
8 chain. Such study shall include analysis of—

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

13               “(B) patterns, trends, and variations in  
14 the duration of shortages experienced by cov-  
15 ered part 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  
23 costs; and

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

1           “(2) REPORT.—Not later than 2 years after the  
 2           date of enactment of this subsection, the Comp-  
 3           troller General shall submit to Congress a report  
 4           containing the results of the study conducted under  
 5           paragraph (1), together with recommendations for  
 6           such legislation and administrative action as the  
 7           Comptroller 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 amend-  
 12   ed 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  
 18               the 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 adop-  
 22               tion and utilization of lower-priced biosimilar and  
 23               generic utilization, plan features that discourage or  
 24               encourage the utilization of these products, and the

1 gross and net spending effects of policies that in-  
2 creased adoption 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  
5 the Inspector General shall publish a report on the  
6 study 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  
11 following: “during and after—

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

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

○