118th CONGRESS 1st Session

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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.

## IN THE SENATE OF THE UNITED STATES

\_\_\_\_\_ introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

## 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. 14. GNO 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

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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-

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tion with the utilization of covered part D drugs.

"(iii) 3 CLARIFICATION ON REBATES 4 AND DISCOUNTS USED TO LOWER COSTS 5 FOR COVERED PART D DRUGS.—Rebates, 6 discounts, and other price concessions re-7 ceived from manufacturers, even if such 8 price concessions are calculated as a per-9 centage of a drug's price, shall not be con-10 sidered a violation of the requirements of 11 clause (i) if they are fully passed through 12 to a PDP sponsor and exclusively used to 13 lower costs for prescription drugs under 14 this part, including in cases where a PDP 15 sponsor is acting as a pharmacy benefit 16 manager on behalf of a prescription drug 17 plan offered by such PDP sponsor.

18 "(iv) EVALUATION OF REMUNERATION 19 ARRANGEMENTS.—Remuneration arrange-20 ments between pharmacy benefit managers 21 or affiliates of such pharmacy benefit man-22 agers, as applicable, and other entities in-23 volved in the dispensing or utilization of 24 covered part D drugs (including PDP 25 sponsors, manufacturers, pharmacies, and

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1	other entities as determined appropriate by
2	the Secretary) shall be subject to review by
3	the Secretary and the Office of the Inspec-
4	tor General of the Department of Health
5	and Human Services. The Secretary, in
6	consultation with the Office of the Inspec-
7	tor General, shall evaluate whether remu-
8	neration under such arrangements is con-
9	sistent with fair market value through re-
10	views and assessments of such remunera-
11	tion, as determined appropriate.
12	"(B) TRANSPARENCY REGARDING GUARAN-
13	TEES AND COST PERFORMANCE EVALUA-
14	TIONS.—The pharmacy benefit manager shall—
15	"(i) define, interpret, and apply, in a
16	fully transparent and consistent manner
17	for purposes of calculating or otherwise
18	evaluating pharmacy benefit manager per-
19	formance against pricing guarantees or
20	similar cost performance measurements re-
21	lated to rebates, discounts, price conces-
22	sions, or net costs, terms such as—
23	"(I) 'generic drug', in a manner
24	consistent with the definition of the
25	term under section 423.4 of title 42,

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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.—

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1	"(i) IN GENERAL.—Not later than
2	July 1 of each year, beginning in 2026, the
3	pharmacy benefit manager shall submit to
4	the PDP sponsor, and to the Secretary, a
5	report, in accordance with this subpara-
6	graph, and shall make such report avail-
7	able to such sponsor at no cost to such
8	sponsor in a format specified by the Sec-
9	retary under paragraph (4). Each such re-
10	port shall include, with respect to such
11	PDP sponsor and each plan offered by
12	such sponsor, the following information
13	with respect to the previous plan year:
14	"(I) A list of all drugs covered by
15	the plan that were dispensed includ-
16	ing, with respect to each such drug—
17	"(aa) the brand name, ge-
18	neric or non-proprietary name,
19	and National Drug Code;
20	"(bb) the number of plan
21	enrollees for whom the drug was
22	dispensed, the total number of
23	prescription claims for the drug
24	(including original prescriptions
25	and refills, counted as separate

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claims), and the total number of dosage units of the drug dispensed;

"(cc) the number of pre-4 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

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1 any benefits under the plan, in-2 cluding plan enrollee spending 3 through copayments, coinsurance, 4 and deductibles; "(gg) total rebates paid by 5 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; "(hh) all other direct or in-12 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 &

19"(ii) the average pharmacy20reimbursement amount paid by21the plan for the drug in the ag-22gregate and disaggregated by dis-23pensing channel identified in item24(cc);

Medicaid Services;

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 1 2 of treatment, per 30-day supply, 3 and per 90-day supply for each 4 drug dispensed by pharmacies 5 that are not an affiliate of the 6 pharmacy benefit manager and 7 that are included in the phar-8 macy network of such plan. 9 "(ee) The interquartile 10 range of the total combined costs 11 paid by the plan and plan enroll-12 ees, per dosage unit, per course 13 of treatment, per 30-day supply, 14 and per 90-day supply for each 15 drug dispensed by pharmacies 16 that are an affiliate of the phar-17 macy benefit manager and that 18 are included in the pharmacy 19 network of such plan.

20 "(dd) The lowest total com21 bined cost paid by the plan and
22 plan enrollees, per dosage unit,
23 per course of treatment, per 3024 day supply, and per 90-day sup25 ply, for each drug that is avail-

1able from any pharmacy included2in the pharmacy network of such3plan.

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

"(ff) A list of covered part 12 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-

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- 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 tier13 typically associated with higher
- 14 cost-sharing than the listed drug,
- 15or are subject to utilization man-16agement 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 for24 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).
	(aa). "(ee) The number of cur-
13	
13 14	"(ee) The number of cur-
13 14 15	"(ee) The number of cur- rently marketed generic drugs
13 14 15 16	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of
13 14 15 16 17	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> </ol>	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an ap-
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> </ol>	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an ap- plication that references such
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> </ol>	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an ap- plication that references such listed drug.
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an ap- plication that references such listed drug. "(IV) Where a reference product
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	"(ee) The number of cur- rently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an ap- plication that references such listed drug. "(IV) Where a reference product (as defined in section 351(i) of the

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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

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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.

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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

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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-

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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,

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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).

"(B) BONA FIDE SERVICE FEE.—The term 16 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

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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-

1	ment of claims for prescription drugs, the per-
2	formance of drug utilization review, the proc-
3	essing of drug prior authorization requests, the
4	adjudication of appeals or grievances related to
5	the prescription drug benefit, contracting with
6	network pharmacies, controlling the cost of cov-
7	ered part D drugs, or the provision of related
8	services. Such term includes any person or enti-
9	ty that carries out one or more of the activities
10	described in the preceding sentence, irrespective
11	of whether such person or entity calls itself a
12	'pharmacy benefit manager'.".
13	(2) MA–PD plans.—Section $1857(f)(3)$ of the
14	Social Security Act (42 U.S.C. $1395w-27(f)(3)$ ) is
15	amended by adding at the end the following new
16	subparagraph:
17	"(F) REQUIREMENTS RELATING TO PHAR-
18	MACY BENEFIT MANAGERS.—For plan years be-
19	ginning on or after January 1, 2026, section
20	1860D–12(h).".
21	(3) FUNDING.—
22	(A) Secretary.—In addition to amounts
23	otherwise available, there is appropriated to the
24	Centers for Medicare & Medicaid Services Pro-
25	gram Management Account, out of any money

in the Treasury not otherwise appropriated,
 \$20,000,000 for fiscal year 2026, to remain
 available until expended, to carry out the
 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.—

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

(A) Federal statutory and regulatory reporting requirements for health plans and pharmacy benefit managers related to prescription
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

pharmacy benefit managers described in paragraph
 (1).
 (c) MEDPAC REPORTS ON AGREEMENTS WITH

4 PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE5 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 re9 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 sub15 mitted;

16 (B) an analysis of any differences in agree17 ments and their effects on plan enrollee out-of18 pocket spending and average pharmacy reim19 bursement, and any other impacts; and

20 (C) any recommendations the Commission21 determines appropriate.

(2) Not later than March 31, 2029, a report describing any changes with respect to the information
described in paragraph (1) over time, together with

any recommendations the Commission determines
 appropriate.

## 3 SEC. 3. ENSURING FAIR ASSESSMENT OF PHARMACY PER4 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 Pharmacy11 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 Sec21 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 such25 pharmacy based on the type of pharmacy (in-

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1	cluding retail, mail order, specialty, long term
2	care, and home infusion or other types of phar-
3	macies), drugs dispensed by such pharmacy,
4	and pharmacy services used to dispense and
5	manage drugs by such pharmacy.
6	"(2) Standardized pharmacy performance
7	MEASURES.—
8	"(A) Measures.—
9	"(i) IN GENERAL Notwithstanding
10	any other provision of law, the Secretary
11	shall establish (or adopt pursuant to clause
12	(iii)) standardized pharmacy performance
13	measures that may be used by a PDP
14	sponsor offering a prescription drug plan
15	and an MA organization offering an MA-
16	PD plan for the purpose of determining in-
17	centive payments, price concessions, or fees
18	or other remuneration described in para-
19	graph (1).
20	"(ii) Requirements.—The measures
21	under clause (i) shall focus on pharmacy
22	performance and quality of care based on
23	the type of pharmacy, as determined by
24	the Secretary. Such measures shall be evi-

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dence-based, feasible, appropriate and reasonable.

"(iii) Adoption of measure.—In 3 lieu of establishing some or all of the 4 5 measures under this paragraph, the Sec-6 retary may adopt measures that are en-7 dorsed by one or more multi-stakeholder 8 consensus organizations (such as the Phar-9 macy Quality Alliance), that has participa-10 tion from pharmacies (including retail and 11 specialty pharmacies not owned or affili-12 ated with a plan, pharmacy benefit man-13 ager, or other pharmacy), health plans, 14 pharmacy benefit managers, and the Cen-15 ters for Medicare & Medicaid Services. Any 16 measure adopted under this clause shall be 17 deemed to meet the requirements under 18 clause (ii).

19 "(B) MAINTENANCE OF LIST.—

20 "(i) IN GENERAL.—The Secretary
21 shall maintain, and publish on a publicly
22 available internet website, a list of meas23 ures established or adopted under this
24 paragraph. Such list shall initially be pub25 lished no later than June 1, 2024.

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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.—

35

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. "(B) STANDARDIZED FORMAT.—The PDP 16 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-

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

pensed by such pharmacy.

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

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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

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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;
13 14	fair market value of such services; "(C) the entity or the PBM (as applicable)
14	"(C) the entity or the PBM (as applicable)
14 15	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec-
14 15 16	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re-
14 15 16 17	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re- lated to covered outpatient drugs and accom-
14 15 16 17 18	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re- lated to covered outpatient drugs and accom- panying administrative services incurred, re-
14 15 16 17 18 19	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re- lated to covered outpatient drugs and accom- panying administrative services incurred, re- ceived, or made by the entity or the PBM, in-
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> </ol>	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re- lated to covered outpatient drugs and accom- panying administrative services incurred, re- ceived, or made by the entity or the PBM, in- cluding ingredient costs, professional dispensing
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re- lated to covered outpatient drugs and accom- panying administrative services incurred, re- ceived, or made by the entity or the PBM, in- cluding ingredient costs, professional dispensing fees, administrative fees, post-sale and post-in-
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	"(C) the entity or the PBM (as applicable) shall make available to the State, and the Sec- retary upon request, all costs and payments re- lated to covered outpatient drugs and accom- panying administrative services incurred, re- ceived, or made by the entity or the PBM, in- cluding ingredient costs, professional dispensing fees, administrative fees, post-sale and post-in- voice fees, discounts, or related adjustments

1 "(D) any form of spread pricing whereby 2 any amount charged or claimed by the entity or 3 PBM (as applicable) that exceeds the 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.".

(b) DEFINITION OF PHARMACY BENEFIT MAN14 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 $\rm KEL23812~41L$ 

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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)"; and

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

3 (2) by adding at the end the following new4 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 Se21 curity Act (42 U.S.C. 1396r-8(f)) is amended—

(1) by striking "and" after the semicolon at the
end of paragraph (1)(A)(i) and all that precedes it
through "(1)" and inserting the following:

	10
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-

	11
1	count, or rebate related to the dispensing of
2	covered outpatient drugs to individuals receiv-
3	ing benefits under this title, regardless of
4	whether such payment, reimbursement, admin-
5	istrative fee, discount, or rebate is received
6	from the State or a managed care entity or
7	other specified entity (as such terms are defined
8	in section $1903(m)(9)(D)$ ) directly or from a
9	pharmacy benefit manager or another entity
10	that has a contract with the State or a man-
11	aged care entity or other specified entity (as so
12	defined), shall respond to surveys of retail
13	prices conducted under this paragraph.
14	"(G) SURVEY INFORMATION.—Information
15	on national drug acquisition prices obtained
16	under this paragraph shall be made publicly
17	available and shall include at least the fol-
18	lowing:
19	"(i) The monthly response rate to the
20	survey including a list of pharmacies not in
21	compliance with subparagraph (F).
22	"(ii) The sampling frame and number
23	of pharmacies sampled monthly.
24	"(iii) Information on price concessions
25	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

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

## 3 SEC. 7. OIG STUDY AND REPORT ON DRUG PRICE MARK4 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 PRICE9 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:

"(A) Acquisition costs by the affiliate within such vertically integrated entities that initially acquires the prescription drug for a sample of covered part D drugs, including at least
5 generic drugs, brand drugs, specialty brand
drugs, and specialty generic drugs.

	11
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-

13 Section 1860D-4(b)(3)(A)(i)(1) of the Social Secu14 rity Act (42 U.S.C. 1395w-104(b)(3)(A)(ii)(I)) is amend15 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 Secu21 rity Act (42 U.S.C. 1320b–23) is amended—

(1) by striking subsection (a) and inserting thefollowing:

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

(3) by adding at the end the following new sub 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.

(c) IMPLEMENTATION.—Notwithstanding any other
provision of law, the Secretary may implement the amendments made by this section by program instruction or otherwise.

(d) NON-APPLICATION OF THE PAPERWORK REDUC16 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.

(a) IN GENERAL.—Section 1860D-4(b) of the Social
Security Act (42 U.S.C. 1395w-104(b)) is amended by
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  $\mathbf{OF}$ 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.—

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

16 (2) NON-APPLICATION OF THE PAPERWORK RE17 DUCTION ACT.—Chapter 35 of title 44, United
18 States Code (commonly referred to as the "Paper19 work Reduction Act of 1995"), shall not apply to the
20 implementation of the amendment made by sub21 section (a).

1	SEC. 11. STRENGTHENING PHARMACY ACCESS FOR SEN-
2	IORS.
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-

1	ginning with plan year 2026), each PDP
2	sponsor offering a prescription drug plan
3	shall submit to the Secretary, at a time
4	and in a manner specified by the Sec-
5	retary, with respect to each prescription
6	drug plan offered by the sponsor during
7	such plan year—
8	"(I) a list of all covered part D
9	drugs that the PDP sponsor des-
10	ignated as a limited access drug;
11	"(II) for each covered part D
12	drug included in the list described in
13	subclause (I), a written rationale for
14	why such drug meets the definition of
15	a limited access drug;
16	"(III) a summary of the require-
17	ments imposed on network pharmacies
18	(including all accreditation require-
19	ments, if any) to ensure appropriate
20	handling and dispensing of each cov-
21	ered part D drug included in the list
22	described in subclause (I);
23	"(IV) the percentages of each
24	covered part D drug included in the
25	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-

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1	tion drug plan, or pharmacy benefit
2	manager, or any proprietary pricing
3	information); and
4	"(III) any other information de-
5	termined appropriate by the Sec-
6	retary.
7	"(v) Limited access drug de-
8	FINED.—In this subparagraph, the term
9	'limited access drug' means a covered part
10	D drug that meets at least one of the fol-
11	lowing:
12	"(I) The Food and Drug Admin-
13	istration has restricted distribution of
14	such covered part D drug to certain
15	facilities or physicians.
16	"(II) The dispensing of such cov-
17	ered part D drug requires extraor-
18	dinary special handling, provider co-
19	ordination, or patient education that
20	cannot be met by a network phar-
21	macy.".
22	"(vii) Implementation.—Notwith-
23	standing any other provision of law, the
24	Secretary shall implement this subpara-
25	graph by program instruction or otherwise.

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59

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 by adding at the end the following new subsection: 11 12 "(f) BENEFICIARY-FOCUSED LISTENING SESSIONS 13 TO IMPROVE PRESCRIPTION DRUG PLAN TRANSPARENCY, 14 ACCESS, AND CHOICE.— "(1) IN GENERAL.—Not later than December 15 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);

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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.".	

## 1SEC. 14. GAO STUDY ON PRICE-RELATED COMPENSATION2ACROSS 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 amend5 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 study shall summarize information from Federal 15 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 of a prescription drug's price, between inter-23 24 mediaries in the prescription drug supply chain, 25 including-

26 "(i) pharmacy benefit managers;

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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

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64

as entities with common ownership, either full or partial, and subsidiary relationships) and unaffiliated 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 struc14 tures over time and between different market
15 segments, such as under this part and the Med16 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-
13 14	SEC. 15. REPORTS ON INAPPROPRIATE PHARMACY REJEC- TIONS.
14	TIONS.
14 15 16	<b>TIONS.</b> Section 1860D–42 of the Social Security Act (42
14 15 16	TIONS. Section 1860D–42 of the Social Security Act (42 U.S.C. 1395w–152), as amended by section 14, is amend-
14 15 16 17	TIONS. Section 1860D-42 of the Social Security Act (42 U.S.C. 1395w-152), as amended by section 14, is amend- ed by adding at the end the following new subsection:
14 15 16 17 18	TIONS. Section 1860D-42 of the Social Security Act (42 U.S.C. 1395w-152), as amended by section 14, is amend- ed by adding at the end the following new subsection: "(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS
14 15 16 17 18 19	TIONS. Section 1860D-42 of the Social Security Act (42 U.S.C. 1395w-152), as amended by section 14, is amend- ed by adding at the end the following new subsection: "(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS INAPPROPRIATE PHARMACY REJECTIONS AND INAPPRO-
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> </ol>	TIONS. Section 1860D-42 of the Social Security Act (42 U.S.C. 1395w-152), as amended by section 14, is amend- ed by adding at the end the following new subsection: "(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS INAPPROPRIATE PHARMACY REJECTIONS AND INAPPRO- PRIATE COVERAGE DENIALS UNDER MEDICARE PART
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	TIONS. Section 1860D-42 of the Social Security Act (42 U.S.C. 1395w-152), as amended by section 14, is amend- ed by adding at the end the following new subsection: "(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS INAPPROPRIATE PHARMACY REJECTIONS AND INAPPRO- PRIATE COVERAGE DENIALS UNDER MEDICARE PART D.—
<ol> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	TIONS. Section 1860D-42 of the Social Security Act (42 U.S.C. 1395w-152), as amended by section 14, is amend- ed by adding at the end the following new subsection: "(i) BIENNIAL REPORT ON EFFORTS TO ADDRESS INAPPROPRIATE PHARMACY REJECTIONS AND INAPPRO- PRIATE COVERAGE DENIALS UNDER MEDICARE PART D.— "(1) IN GENERAL.—Not later than January 1,

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
14 15	"(i) standards (if any such standards have been adopted) used by the Secretary
15	have been adopted) used by the Secretary
15 16	have been adopted) used by the Secretary for identifying PDP sponsors and MA or-
15 16 17	have been adopted) used by the Secretary for identifying PDP sponsors and MA or- ganizations with relatively high rates of
15 16 17 18	have been adopted) used by the Secretary for identifying PDP sponsors and MA or- ganizations with relatively high rates of such rejections or denials; and
15 16 17 18 19	have been adopted) used by the Secretary for identifying PDP sponsors and MA or- ganizations with relatively high rates of such rejections or denials; and "(ii) notable longitudinal trends or
15 16 17 18 19 20	have been adopted) used by the Secretary for identifying PDP sponsors and MA or- ganizations with relatively high rates of such rejections or denials; and "(ii) notable longitudinal trends or other patterns, as determined appropriate
<ol> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>	have been adopted) used by the Secretary for identifying PDP sponsors and MA or- ganizations with relatively high rates of such rejections or denials; and "(ii) notable longitudinal trends or other patterns, as determined appropriate by the Secretary;
<ol> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	have been adopted) used by the Secretary for identifying PDP sponsors and MA or- ganizations with relatively high rates of such rejections or denials; and "(ii) notable longitudinal trends or other patterns, as determined appropriate by the Secretary; "(C) an overview of corrective actions

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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:	

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68

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

"(1) STUDY.—The Comptroller General of the
United States (in this subsection referred to as the
"Comptroller General") shall conduct a study on factors contributing to shortages of covered part D
drugs across the outpatient prescription drug supply
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;

"(C) patterns, trends, and variations in the
proximate causes and other potential causes of
shortages experienced by covered part D drugs;
"(D) effects of such shortages on beneficiaries enrolled in prescription drug plans
under this part, including with respect to access

under this part, including with respect to access to covered part D drugs and out-of-pocket costs; and

24 "(E) other issues determined appropriate25 by the Comptroller General.

"(2) REPORT.—Not later than 2 years after the
date of enactment of this subsection, the Comptroller General shall submit to Congress a report
containing the results of the study conducted under
paragraph (1), together with recommendations for
such legislation and administrative action as the
Comptroller General determines appropriate.".

# 8 SEC. 17. REPORT ON BIOSIMILAR AND GENERIC ACCESS 9 UNDER MEDICARE PART D.

Section 1860D-42 of the Social Security Act (42
U.S.C. 1395w-152), as amended by section 16, is amended 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

70

gross and net spending effects of policies that in-1 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) U.S.C. 1395iii(b)(1)) is amended by striking "during and 9 after fiscal year 2022, \$180,000,000" and inserting the

following: "during and after— 11

12	"(A) fiscal year 2022, \$180,000,000; and
13	"(B) fiscal year 2028, \$1,947,000,000".