Amendment in the Nature of a Substitute to H.R. 5385 Offered by M .

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the "Medicare PBM Ac-3 countability Act".

4 SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MAN5 AGERS WITH RESPECT TO PRESCRIPTION 6 DRUG PLANS AND MA-PD PLANS.

7 (a) PRESCRIPTION DRUG PLANS.—Section 1860D8 12 of the Social Security Act (42 U.S.C. 1395w-112) is
9 amended by adding at the end the following new sub10 section:

11 "(h) REQUIREMENTS ON PHARMACY BENEFIT MAN12 AGERS.—For plan years beginning on or after January 1,
13 2027:

14 "(1) AGREEMENTS WITH PHARMACY BENEFIT
15 MANAGERS.—Each contract entered into with a
16 PDP sponsor under this part with respect to a pre17 scription drug plan offered by such sponsor shall
18 provide that any pharmacy benefit manager acting

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

"(A) TRANSPARENCY REGARDING GUARAN-5 6 AND COST PERFORMANCE TEES EVALUA-7 TIONS.—The pharmacy benefit manager shall— 8 "(i) define, interpret, and apply, in a 9 fully transparent and consistent manner 10 for purposes of calculating or otherwise 11 evaluating pharmacy benefit manager per-12 formance against pricing guarantees or similar cost performance measurements re-13 14 lated to rebates, discounts, price conces-15 sions, or net costs, terms such as— 16 "(I) 'generic drug', in a manner 17 consistent with the definition of the

- 18 term under section 423.4 of title 42,
- 19 Code of Federal Regulations, or a suc-
- 20 cessor regulation;

21 "(II) 'brand name drug', in a
22 manner consistent with the definition
23 of the term under section 423.4 of
24 title 42, Code of Federal Regulations,
25 or a successor regulation;

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1	"(III) 'specialty drug';
2	"(IV) 'rebate'; and
3	"(V) 'discount';
4	"(ii) identify any drugs, claims, or
5	price concessions excluded from any pric-
6	ing guarantee or other cost performance
7	calculation or evaluation in a clear and
8	consistent manner; and
9	"(iii) where a pricing guarantee or
10	other cost performance measure is based
11	on a pricing benchmark other than the
12	wholesale acquisition cost (as defined in
13	section $1847A(c)(6)(B)$) of a drug, cal-
14	culate and provide a wholesale acquisition
15	cost-based equivalent to the pricing guar-
16	antee or other cost performance measure
17	in the written agreement.
18	"(B) Provision of information.—
19	"(i) IN GENERAL.—Not later than
20	July 1 of each year, beginning in 2027, the
21	pharmacy benefit manager shall submit to
22	the PDP sponsor, and to the Secretary, a
23	report, in accordance with this subpara-
24	graph, and shall make such report avail-
25	able to such sponsor at no cost to such

1	sponsor in a format specified by the Sec-
2	retary under paragraph (4). Each such re-
3	port shall include, with respect to such
4	PDP sponsor and each plan offered by
5	such sponsor, the following information
6	with respect to the previous plan year:
7	"(I) A list of all drugs covered by
8	the plan that were dispensed includ-
9	ing, with respect to each such drug—
10	"(aa) the brand name, ge-
11	neric or non-proprietary name,
12	and National Drug Code;
13	"(bb) the number of plan
14	enrollees for whom the drug was
15	dispensed, the total number of
16	prescription claims for the drug
17	(including original prescriptions
18	and refills, counted as separate
19	claims), and the total number of
20	dosage units of the drug dis-
21	pensed;
22	"(cc) the number of pre-
23	scription claims described in item
24	(bb) by each type of dispensing
25	channel through which the drug

1	was dispensed, including retail,
2	mail order, specialty pharmacy,
3	long term care pharmacy, home
4	infusion pharmacy, or other types
5	of pharmacies or providers;
6	"(dd) the average wholesale
7	acquisition cost, listed as cost per
8	day's supply, cost per dosage
9	unit, and cost per typical course
10	of treatment (as applicable);
11	"(ee) the average wholesale
12	price for the drug, listed as cost
13	per day's supply, cost per dosage
14	unit, and cost per typical course
15	of treatment (as applicable);
16	"(ff) the total out-of-pocket
17	spending by plan enrollees on
18	such drug after application of
19	any benefits under the plan, in-
20	cluding plan enrollee spending
21	through copayments, coinsurance,
22	and deductibles;
23	"(gg) total rebates paid by
24	the manufacturer on the drug as
25	reported under the Detailed DIR

1	Report (or any successor report)
2	submitted by such sponsor to the
3	Centers for Medicare & Medicaid
4	Services;
5	"(hh) all other direct or in-
6	direct remuneration on the drug
7	as reported under the Detailed
8	DIR Report (or any successor re-
9	port) submitted by such sponsor
10	to the Centers for Medicare &
11	Medicaid Services;
12	"(ii) the average pharmacy
13	reimbursement amount paid by
14	the plan for the drug in the ag-
15	gregate and disaggregated by dis-
16	pensing channel identified in item
17	(cc);
18	"(jj) the average National
19	Average Drug Acquisition Cost
20	(NADAC) for retail community
21	pharmacies; and
22	"(kk) total manufacturer-de-
23	rived revenue, inclusive of bona
24	fide service fees, retained by the
25	pharmacy benefit manager and

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1	any affiliate of such pharmacy
2	benefit manager attributable to
3	the drug.
4	"(II) In the case of a pharmacy
5	benefit manager that has an affiliate
6	that is a retail, mail order, or spe-
7	cialty pharmacy, with respect to drugs
8	covered by such plan that were dis-
9	pensed, the following information:
10	"(aa) The percentage of
11	total prescriptions that were dis-
12	pensed by pharmacies that are an
13	affiliate of the pharmacy benefit
14	manager for each drug.
15	"(bb) The interquartile
16	range of the total combined costs
17	paid by the plan and plan enroll-
18	ees, per dosage unit, per course
19	of treatment, per 30-day supply,
20	and per 90-day supply for each
21	drug dispensed by pharmacies
22	that are not an affiliate of the
23	pharmacy benefit manager and
24	that are included in the phar-
25	macy network of such plan.

1	"(cc) The interquartile
2	range of the total combined costs
3	paid by the plan and plan enroll-
4	ees, per dosage unit, per course
5	of treatment, per 30-day supply,
6	and per 90-day supply for each
7	drug dispensed by pharmacies
8	that are an affiliate of the phar-
9	macy benefit manager and that
10	are included in the pharmacy
11	network of such plan.
12	"(dd) The lowest total com-
13	bined cost paid by the plan and
14	plan enrollees, per dosage unit,
15	per course of treatment, per 30-
16	day supply, and per 90-day sup-
17	ply, for each drug that is avail-
18	able from any pharmacy included
19	in the pharmacy network of such
20	plan.
21	"(ee) The difference between
22	the average acquisition cost of
23	the affiliate, such as a pharmacy
24	or other entity that acquires pre-
25	scription drugs, that initially ac-

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quires the drug and the amount reported under subclause (I)(jj) for each drug.

"(ff) A list of covered part 4 5 D drugs subject to an agreement 6 with a covered entity under sec-7 tion 340B of the Public Health 8 Service Act for which the phar-9 macy benefit manager or an affil-10 iate of the pharmacy benefit 11 manager had a contract or other 12 arrangement with such a covered 13 entity in the service area of such 14 plan.

15 "(III) Where a drug approved
16 under section 505(c) of the Federal
17 Food, Drug, and Cosmetic Act (re18 ferred to in this subclause as the 'list19 ed drug') is covered by the plan, the
20 following information:
21 "(aa) A list of currently

21 "(aa) A list of currently
22 marketed generic drugs approved
23 under section 505(j) of the Fed24 eral Food, Drug, and Cosmetic
25 Act pursuant to an application

1	that references such listed drug
2	that are not covered by the plan,
3	are covered on the same for-
4	mulary tier or a formulary tier
5	typically associated with higher
6	cost-sharing than the listed drug,
7	or are subject to utilization man-
8	agement that the listed drug is
9	not subject to.
10	"(bb) The estimated average
11	beneficiary cost-sharing under
12	the plan for a 30-day supply of
13	the listed drug.
14	"(cc) Where a generic drug
15	listed under item (aa) is on a for-
16	mulary tier typically associated
17	with higher cost-sharing than the
18	listed drug, the estimated aver-
19	age cost-sharing that a bene-
20	ficiary would have paid for a 30-
21	day supply of each of the generic
22	drugs described in item (aa), had
23	the plan provided coverage for
24	such drugs on the same for-
25	mulary tier as the listed drug.

1	"(dd) A written justification
2	for providing more favorable cov-
3	erage of the listed drug than the
4	generic drugs described in item
5	(aa).
6	"(ee) The number of cur-
7	rently marketed generic drugs
8	approved under section 505(j) of
9	the Federal Food, Drug, and
10	Cosmetic Act pursuant to an ap-
11	plication that references such
12	listed drug.
13	"(IV) Where a reference product
14	(as defined in section 351(i) of the
15	Public Health Service Act) is covered
16	by the plan, the following information:
17	"(aa) A list of currently
18	marketed biosimilar biological
19	products licensed under section
20	351(k) of the Public Health
21	Service Act pursuant to an appli-
22	cation that refers to such ref-
23	erence product that are not cov-
24	ered by the plan, are covered on
25	the same formulary tier or a for-

1	mulary tier typically associated
2	with higher cost-sharing than the
3	reference product, or are subject
4	to utilization management that
5	the reference product is not sub-
6	ject to.
7	"(bb) The estimated average
8	beneficiary cost-sharing under
9	the plan for a 30-day supply of
10	the reference product.
11	"(cc) Where a biosimilar bi-
12	ological product listed under item
13	(aa) is on a formulary tier typi-
14	cally associated with higher cost-
15	sharing than the listed drug, the
16	estimated average cost-sharing
17	that a beneficiary would have
18	paid for a 30-day supply of each
19	of the biosimilar biological prod-
20	ucts described in item (aa), had
21	the plan provided coverage for
22	such products on the same for-
23	mulary tier as the reference prod-
24	uct.

1	"(dd) A written justification
2	for providing more favorable cov-
3	erage of the reference product
4	than the biosimilar biological
5	product described in item (aa).
6	"(ee) The number of cur-
7	rently marketed biosimilar bio-
8	logical products licensed under
9	section 351(k) of the Public
10	Health Service Act, pursuant to
11	an application that refers to such
12	reference product.
13	"(V) Total gross spending on
14	covered part D drugs by the plan, not
15	net of rebates, fees, discounts, or
16	other direct or indirect remuneration.
17	"(VI) The total amount retained
18	by the pharmacy benefit manager or
19	an affiliate of such pharmacy benefit
20	manager in revenue related to utiliza-
21	tion of prescription drugs under that
22	plan, inclusive of bona fide service
23	fees.
24	"(VII) The total spending on cov-

ered part D drugs net of rebates, fees,

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

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

11 "(IX) A list of all brokers, con-12 sultants, advisors, and auditors that 13 receive compensation from the phar-14 macy benefit manager or an affiliate 15 of such pharmacy benefit manager for consulting, 16 referrals, auditing, or 17 other services offered to PDP spon-18 sors related to pharmacy benefit man-19 agement services. 20 "(X) A list of all affiliates of the

20 (X) A list of an anniates of the pharmacy benefit manager.

"(XI) A summary document submitted in a standardized template developed by the Secretary that includes

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1	such information described in sub-
2	clauses (I) through (X).
3	"(ii) WRITTEN EXPLANATION OF CON-
4	TRACTS OR AGREEMENTS WITH DRUG
5	MANUFACTURERS.—
6	"(I) IN GENERAL.—The phar-
7	macy benefit manager shall, not later
8	than 30 days after the finalization of
9	any contract or agreement between
10	such pharmacy benefit manager or an
11	affiliate of such pharmacy benefit
12	manager and a drug manufacturer (or
13	subsidiary, agent, or entity affiliated
14	with such drug manufacturer) that
15	makes rebates, discounts, payments,
16	or other financial incentives related to
17	one or more prescription drugs of the
18	manufacturer directly or indirectly
19	contingent upon coverage, formulary
20	placement, or utilization management
21	conditions on any other prescription
22	drugs, submit to the PDP sponsor a
23	written explanation of such contract
24	or agreement.

1 "(II) REQUIREMENTS.—A writ-2 ten explanation under subclause (I) 3 shall—

"(aa) include the manufac-4 5 turer subject to the contract or 6 agreement, all prescription drugs 7 subject to the contract or agree-8 ment and the manufacturers of 9 such drugs, and a high-level de-10 scription of the terms of such 11 contract or agreement and how 12 such terms apply to such drugs; 13 and

14 "(bb) be certified by the 15 Chief Executive Officer, Chief Financial Officer, or General Coun-16 17 sel of such pharmacy benefit 18 manager, affiliate of such phar-19 macy benefit manager, or an in-20 dividual delegated with the au-21 thority to sign on behalf of one of 22 these officers, who reports di-23 rectly to the officer.

"(C) AUDIT RIGHTS.—

1	"(i) IN GENERAL.—Not less than once
2	a year, at the request of the PDP sponsor,
3	the pharmacy benefit manager shall allow
4	for an audit of the pharmacy benefit man-
5	ager to ensure compliance with all terms
6	and conditions under the written agree-
7	ment and the accuracy of information re-
8	ported under subparagraph (C).
9	"(ii) AUDITOR.—The PDP sponsor
10	shall have the right to select an auditor.
11	The pharmacy benefit manager shall not
12	impose any limitations on the selection of
13	such auditor.
14	"(iii) Provision of information.—
15	The pharmacy benefit manager shall make
16	available to such auditor all records, data,
17	contracts, and other information necessary
18	to confirm the accuracy of information
19	provided under subparagraph (C), subject
20	to reasonable restrictions on how such in-
21	formation must be reported to prevent re-
22	disclosure of such information.
23	"(iv) TIMING.—The pharmacy benefit
24	manager must provide information under
25	clause (iii) and other information, data,

1	and records relevant to the audit to such
2	auditor within 6 months of the initiation of
3	the audit and respond to requests for addi-
4	tional information from such auditor with-
5	in 30 days after the request for additional
6	information.
7	"(v) INFORMATION FROM AFFILI-
8	ATES.—The pharmacy benefit manager
9	shall be responsible for providing to such
10	auditor information required to be reported
11	under subparagraph (C) that is owned or
12	held by an affiliate of such pharmacy ben-
13	efit manager.
14	"(D) ENFORCEMENT.—The pharmacy ben-
15	efit manager shall—
16	"(i) disgorge to a PDP sponsor (or, in
17	a case where the PDP sponsor is an affil-
18	iate of such pharmacy benefit manager, to
19	the Secretary) any payment, remuneration,
20	or other amount received by the pharmacy
21	benefit manager or an affiliate of such
22	pharmacy benefit manager in violation of
23	subparagraph (A) or the written agreement
24	entered into with such sponsor under this

part with respect to a prescription drug
 plan;

3 "(ii) reimburse the PDP sponsor for
4 any civil money penalty imposed on the
5 PDP sponsor as a result of the failure of
6 the pharmacy benefit manager to meet the
7 requirements of this paragraph that are
8 applicable to the pharmacy benefit man9 ager under the agreement; and

10 "(iii) be subject to punitive remedies
11 for breach of contract for failure to comply
12 with the requirements applicable under this
13 paragraph.

14 "(2) CERTIFICATION OF COMPLIANCE.—Each
15 PDP sponsor shall furnish to the Secretary (in a
16 time and manner specified by the Secretary) an an17 nual certification of compliance with this subsection,
18 as well as such information as the Secretary deter19 mines necessary to carry out this subsection.

20 "(3) RULE OF CONSTRUCTION.—Nothing in
21 this subsection shall be construed as prohibiting pay22 ments related to reimbursement for ingredient costs
23 to any entity that acquires prescription drugs, such
24 as a pharmacy or wholesaler.

1	"(4) STANDARD FORMATS.—Not later than
2	June 1, 2026, the Secretary shall specify standard,
3	machine-readable formats for pharmacy benefit
4	managers to submit annual reports required under
5	paragraph (1)(C)(i).
6	"(5) Confidentiality.—
7	"(A) IN GENERAL.—Information disclosed
8	by a pharmacy benefit manager or PDP spon-
9	sor under this subsection that is not otherwise
10	publicly available or available for purchase shall
11	not be disclosed by the Secretary or a PDP
12	sponsor receiving the information, except that
13	the Secretary may disclose the information for
14	the following purposes:
15	"(i) As the Secretary determines nec-
16	essary to carry out this part.
17	"(ii) To permit the Comptroller Gen-
18	eral to review the information provided.
19	"(iii) To permit the Director of the
20	Congressional Budget Office to review the
21	information provided.
22	"(iv) To permit the Executive Direc-
23	tor of the Medicare Payment Advisory
24	Commission to review the information pro-
25	vided.

1	"(v) To the Attorney General for the
2	purposes of conducting oversight and en-
3	forcement under this title.
4	"(vi) To the Inspector General of the
5	Department of Health and Human Serv-
6	ices in accordance with its authorities
7	under the Inspector General Act of 1978
8	(section 406 of title 5, United States
9	Code), and other applicable statutes.
10	"(B) RESTRICTION ON USE OF INFORMA-
11	TION.—The Secretary, the Comptroller General,
12	the Director of the Congressional Budget Of-
13	fice, and the Executive Director of the Medicare
14	Payment Advisory Commission shall not report
15	on or disclose information disclosed pursuant to
16	subparagraph (A) to the public in a manner
17	that would identify a specific pharmacy benefit
18	manager, affiliate, manufacturer or wholesaler,
19	PDP sponsor, or plan, or contract prices, re-
20	bates, discounts, or other remuneration for spe-
21	cific drugs in a manner that may allow the
22	identification of specific contracting parties.
23	"(6) Definitions.—For purposes of this sub-
24	section:

"(A) AFFILIATE.—The term 'affiliate' 1 2 means any entity that is owned by, controlled by, or related under a common ownership struc-3 4 ture with a pharmacy benefit manager or PDP 5 sponsor, or that acts as a contractor or agent 6 to such pharmacy benefit manager or PDP sponsor, insofar as such contractor or agent 7 8 performs any of the functions described under 9 subparagraph (C).

10 "(B) BONA FIDE SERVICE FEE.—The term 11 'bona fide service fee' means a fee that is reflec-12 tive of the fair market value for a bona fide, 13 itemized service actually performed on behalf of 14 an entity, that the entity would otherwise per-15 form (or contract for) in the absence of the 16 service arrangement and that are not passed on 17 in whole or in part to a client or customer, 18 whether or not the entity takes title to the 19 drug. Such fee must be a flat dollar amount 20 and shall not be directly or indirectly based on, 21 or contingent upon—

22 "(i) drug price, such as wholesale ac23 quisition cost or drug benchmark price
24 (such as average wholesale price);

1	"(ii) discounts, rebates, fees, or other
2	direct or indirect remuneration amounts
3	with respect to covered part D drugs dis-
4	pensed to enrollees in a prescription drug
5	plan, except as permitted pursuant to
6	paragraph (1)(A)(ii);
7	"(iii) coverage or formulary placement
8	decisions or the volume or value of any re-
9	ferrals or business generated between the
10	parties to the arrangement; or
11	"(iv) any other amounts or meth-
12	odologies prohibited by the Secretary.
13	"(C) PHARMACY BENEFIT MANAGER.—The
14	term 'pharmacy benefit manager' means any
15	person or entity that, either directly or through
16	an intermediary, acts as a price negotiator or
17	group purchaser on behalf of a PDP sponsor or
18	prescription drug plan, or manages the pre-
19	scription drug benefits provided by such spon-
20	sor or plan, including the processing and pay-
21	ment of claims for prescription drugs, the per-
22	formance of drug utilization review, the proc-
23	essing of drug prior authorization requests, the
24	adjudication of appeals or grievances related to
25	the prescription drug benefit, contracting with

1	network pharmacies, controlling the cost of cov-
2	ered part D drugs, or the provision of related
3	services. Such term includes any person or enti-
4	ty that carries out one or more of the activities
5	described in the preceding sentence, irrespective
6	of whether such person or entity calls itself a
7	'pharmacy benefit manager'.".
8	(b) MA–PD Plans.—Section 1857(f)(3) of the So-
9	cial Security Act (42 U.S.C. 1395w–27(f)(3)) is amended
10	by adding at the end the following new subparagraph:
11	"(F) Requirements relating to phar-
12	MACY BENEFIT MANAGERS.—For plan years be-
13	ginning on or after January 1, 2027, section
14	1860D–12(h).".
15	(c) GAO STUDY AND REPORT ON CERTAIN REPORT-
16	ING REQUIREMENTS.—
17	(1) Study.—The Comptroller General of the
18	United States (in this subsection referred to as the
19	"Comptroller General") shall conduct a study on
20	Federal and State reporting requirements for health
21	plans and pharmacy benefit managers related to the
22	transparency of prescription drug costs and prices.
23	Such study shall include an analysis of the following:
24	(A) Federal statutory and regulatory re-
25	porting requirements for health plans and phar-

1	macy benefit managers related to prescription
2	drug costs and prices.
3	(B) Selected States' statutory and regu-
4	latory reporting requirements for health plans
5	and pharmacy benefit managers related to pre-
6	scription drug costs and prices.
7	(C) The extent to which the statutory and
8	regulatory reporting requirements identified in
9	subparagraphs (A) and (B) overlap and con-
10	flict.
11	(D) The resources required by health plans
12	and pharmacy benefit managers to comply with
13	the reporting requirements described in sub-
14	paragraphs (A) and (B).
15	(E) Other items determined appropriate by
16	the Comptroller General.
17	(2) REPORT.—Not later than 2 years after the
18	date on which information is first required to be re-
19	ported under section $1860D-12(h)(1)(C)$ of the So-
20	cial Security Act, as added by subsection $(a)(1)$, the
21	Comptroller General shall submit to Congress a re-
22	port containing the results of the study conducted
23	under paragraph (1), together with recommenda-
24	tions for legislation and administrative actions that
25	would streamline and reduce the burden associated

with the reporting requirements for health plans and
 pharmacy benefit managers described in paragraph
 (1).

4 (d) MEDPAC REPORTS ON AGREEMENTS WITH
5 PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE6 SCRIPTION DRUG PLANS AND MA-PD PLANS.—The
7 Medicare Payment Advisory Commission shall submit to
8 Congress the following reports:

9 (1) Not later than March 31, 2027, a report re10 garding agreements with pharmacy benefit managers
11 with respect to prescription drug plans and MA-PD
12 plans. Such report shall include—

(A) a description of trends and patterns,
including relevant averages, totals, and other
figures for each of the types of information submitted;

17 (B) an analysis of any differences in agree18 ments and their effects on plan enrollee out-of19 pocket spending and average pharmacy reim20 bursement, and any other impacts; and

21 (C) any recommendations the Commission22 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 (e) FUNDING.—There are appropriated, out of any monies in the Treasury not otherwise 4 obligated, \$55,000,000 for fiscal year 2024, to remain available until 5 expended, to the Secretary of Health and Human Services 6 for purposes of carrying out the amendments made by 7 subsections (a) and (b). 8

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