AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. _____

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 "Preserving Telehealth,3 Hospital, and Ambulance Access Act".

4 TITLE I—PRESERVING PA5 TIENTS' ACCESS TO CARE IN 6 THE HOME

7 SEC. 101. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILI-

8

TIES.

9 (a) REMOVING GEOGRAPHIC REQUIREMENTS AND
10 EXPANDING ORIGINATING SITES FOR TELEHEALTH
11 SERVICES.—Section 1834(m) of the Social Security Act
12 (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (2)(B)(iii), by striking "ending December 31, 2024" and inserting "ending December 31, 2026"; and

16 (2) in paragraph (4)(C)(iii), by striking "ending
17 on December 31, 2024" and inserting "ending on
18 December 31, 2026".

 $\mathbf{2}$

(b) EXPANDING PRACTITIONERS ELIGIBLE TO FUR NISH TELEHEALTH SERVICES.—Section 1834(m)(4)(E)
 of the Social Security Act (42 U.S.C. 1395m(m)(4)(E))
 is amended by striking "ending on December 31, 2024"
 and inserting "ending on December 31, 2026".

6 (c) EXTENDING TELEHEALTH SERVICES FOR FED7 ERALLY QUALIFIED HEALTH CENTERS AND RURAL
8 HEALTH CLINICS.—Section 1834(m)(8)(A) of the Social
9 Security Act (42 U.S.C. 1395m(m)(8)(A)) is amended by
10 striking "ending on December 31, 2024" and inserting
11 "ending on December 31, 2026".

12 (d) DELAYING THE IN-PERSON REQUIREMENTS
13 UNDER MEDICARE FOR MENTAL HEALTH SERVICES
14 FURNISHED THROUGH TELEHEALTH AND TELE15 COMMUNICATIONS TECHNOLOGY.—

16 (1) DELAY IN REQUIREMENTS FOR MENTAL 17 HEALTH SERVICES FURNISHED THROUGH TELE-18 HEALTH.—Section 1834(m)(7)(B)(i) of the Social 19 Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is 20 amended, in the matter preceding subclause (I), by striking "on or after" and all that follows through 21 22 "described in section 1135(g)(1)(B)" and inserting "on or after January 1, 2027". 23

24 (2) MENTAL HEALTH VISITS FURNISHED BY
25 RURAL HEALTH CLINICS.—Section 1834(y)(2) of the

Social Security Act (42 U.S.C. 1395m(y)(2)) is
 amended by striking "January 1, 2025" and all that
 follows through the period at the end and inserting
 "January 1, 2027.".

5 (3) MENTAL HEALTH VISITS FURNISHED BY
6 FEDERALLY QUALIFIED HEALTH CENTERS.—Section
7 1834(o)(4)(B) of the Social Security Act (42 U.S.C.
8 1395m(o)(4)(B)) is amended by striking "January
9 1, 2025" and all that follows through the period at
10 the end and inserting "January 1, 2027.".

(e) ALLOWING FOR THE FURNISHING OF AUDIOONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of
the Social Security Act (42 U.S.C. 1395m(m)(9)) is
amended by striking "ending on December 31, 2024" and
inserting "ending on December 31, 2026".

(f) EXTENDING USE OF TELEHEALTH TO CONDUCT
FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION
OF ELIGIBILITY FOR HOSPICE CARE.—Section
1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C.
1395f(a)(7)(D)(i)(II)) is amended—

(1) by striking "ending on December 31, 2024"
and inserting "ending on December 31, 2026"; and
(2) by inserting ", except that this subclause
shall not apply in the case of such an encounter with
an individual occurring on or after January 1, 2025,

1 if such individual is located in an area that is sub-2 ject to a moratorium on the enrollment of hospice programs under this title pursuant to section 3 4 1866(j)(7), if such individual is receiving hospice 5 care from a provider that is subject to enhanced 6 oversight under this title pursuant to section 7 1866(i)(3), or if such encounter is performed by a 8 hospice physician or nurse practitioner who is not 9 enrolled under section 1866(j) and is not an opt-out 10 physician or practitioner (as defined in section 11 1802(b)(6)(D))" before the semicolon.

(g) PROGRAM INSTRUCTION AUTHORITY.—The Secretary of Health and Human Services may implement the
amendments made by this section through program instruction or otherwise.

16 SEC. 102. GUIDANCE ON FURNISHING SERVICES VIA TELE17 HEALTH TO INDIVIDUALS WITH LIMITED 18 ENGLISH PROFICIENCY.

(a) IN GENERAL.—Not later than 1 year after the
date of the enactment of this section, the Secretary of
Health and Human Services, in consultation with 1 or
more entities from each of the categories described in
paragraphs (1) through (7) of subsection (b), shall issue
and disseminate, or update and revise as applicable, guid-

ance for the entities described in such subsection on the
 following:

3 (1) Best practices on facilitating and inte4 grating use of interpreters during a telemedicine ap5 pointment.

6 (2) Best practices on providing accessible in-7 structions on how to access telecommunications sys-8 tems (as such term is used for purposes of section 9 1834(m) of the Social Security Act (42 U.S.C. 10 1395m(m)) for individuals with limited English pro-11 ficiency.

12 (3) Best practices on improving access to dig13 ital patient portals for individuals with limited
14 English proficiency.

(4) Best practices on integrating the use of
video platforms that enable multi-person video calls
furnished via a telecommunications system for purposes of providing interpretation during a telemedicine appointment for an individual with limited
English proficiency.

(5) Best practices for providing patient materials, communications, and instructions in multiple
languages, including text message appointment reminders and prescription information.

1	(b) ENTITIES DESCRIBED.—For purposes of sub-
2	section (a), an entity described in this subsection is an
3	entity in 1 or more of the following categories:
4	(1) Health information technology service pro-
5	viders, including—
6	(A) electronic medical record companies;
7	(B) remote patient monitoring companies;
8	and
9	(C) telehealth or mobile health vendors and
10	companies.
11	(2) Health care providers, including—
12	(A) physicians; and
13	(B) hospitals.
14	(3) Health insurers.
15	(4) Language service companies.
16	(5) Interpreter or translator professional asso-
17	ciations.
18	(6) Health and language services quality certifi-
19	cation organizations.
20	(7) Patient and consumer advocates, including
21	such advocates that work with individuals with lim-
22	ited English proficiency.

1SEC. 103. ESTABLISHMENT OF MODIFIER FOR RECERTIFI-2CATIONS OF HOSPICE CARE ELIGIBILITY3CONDUCTED THROUGH TELEHEALTH.

4 Section 1814(a)(7)(D)(i)(II) of the Social Security 5 Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by section 101(f), is further amended by inserting ", provided 6 7 that, in the case of such an encounter occurring on or after the date that is 2 years after the date of the enact-8 9 ment of the 'Preserving Telehealth, Hospital, and Ambulance Access Act', such physician or nurse practitioner in-10 11 cludes in any claim for such encounter one or more modifiers or codes specified by the Secretary to indicate that 12 such encounter was furnished through telehealth" after 13 14 "as determined appropriate by the Secretary".

15 SEC. 104. EXTENDING ACUTE HOSPITAL CARE AT HOME 16 WAIVER FLEXIBILITIES.

17 Section 1866G of the Social Security Act (42 U.S.C.
18 1395cc-7) is amended—

- 19 (1) in subsection (a)(1), by striking "2024" and
- $20 \qquad \text{inserting "2029"; and} \\$
- 21 (2) in subsection (b)—

(A) in the header, by striking "STUDY AND
REPORT" and inserting "STUDIES AND REPORTS";

25 (B) in paragraph (1)—

1	(i) in the matter preceding subpara-
2	graph (A), by striking "The Secretary"
3	and inserting "Not later than September
4	30, 2024, and again not later than Sep-
5	tember 30, 2028, the Secretary';
6	(ii) in clause (vi), by striking "and" at
7	the end;
8	(iii) in clause (vii), by striking the pe-
9	riod and inserting "; and"; and
10	(iv) by adding at the end the following
11	new clause:
12	"(viii) in the case of the second study
13	conducted under this paragraph, the qual-
14	ity of care, outcomes, costs, quantity and
15	intensity of services, and other relevant
16	metrics between individuals who entered
17	into the Acute Hospital Care at Home ini-
18	tiative directly from an emergency depart-
19	ment compared with individuals who en-
20	tered into the Acute Hospital Care at
21	Home initiative directly from an existing
22	inpatient stay in a hospital."; and
23	(C) in paragraph (2)—
24	(i) in the header, by striking "RE-
25	PORT" and inserting "REPORTS"; and

1	(ii) by inserting "and again not later
2	than September 30, 2028," after "2024,";
3	and
4	(iii) by striking "on the study con-
5	ducted under paragraph (1)." and insert-
6	ing the following: "on—
7	"(A) with respect to the first report sub-
8	mitted under this paragraph, the first study
9	conducted under paragraph (1); and
10	"(B) with respect to the second report sub-
11	mitted under this paragraph, the second study
12	conducted under paragraph (1).".
13	SEC. 105. REPORT ON WEARABLE MEDICAL DEVICES.
14	Not later than 18 months after the date of the enact-
15	ment of this Act, the Comptroller General of the United
16	States shall conduct a technology assessment of, and sub-
17	mit to Congress a report on, the capabilities and limita-
18	tions of wearable medical devices used to support clinical
19	decision-making. Such report shall include a description
20	of—
21	(1) the potential for such devices to accurately
22	prescribe treatments;
23	(2) an examination of the benefits and chal-
24	lenges of artificial intelligence to augment such ca-
25	pabilities; and

1 (3) policy options to enhance the benefits and 2 mitigate potential challenges of developing or using 3 such devices.

4 SEC. 106. ENHANCING CERTAIN PROGRAM INTEGRITY RE-5

QUIREMENTS FOR DME UNDER MEDICARE.

6 MEDICAL EQUIPMENT.—Section (a) DURABLE 7 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) 8 is amended by adding at the end the following new para-9 graph:

10 "(23) MASTER LIST INCLUSION AND CLAIM RE-11 VIEW FOR CERTAIN ITEMS.—

12 "(A) MASTER LIST INCLUSION.—Begin-13 ning January 1, 2027, for purposes of the Mas-14 ter List described in section 414.234(b) of title 15 42, Code of Federal Regulations (or any suc-16 cessor regulation), an item for which payment 17 may be made under this subsection shall be 18 treated as having aberrant billing patterns (as 19 such term is used for purposes of such section) 20 if the Secretary determines that, without ex-21 planatory contributing factors (such as fur-22 nishing emergent care services), a substantial 23 number of claims for such items under this sub-24 section are from an ordering physician or prac-25 titioner with whom the individual involved does

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not have a prior relationship, as determined on the basis of claims.

"(B) CLAIM REVIEW.—With respect to 3 4 items furnished on or after January 1, 2027 that are included on the Master List pursuant 5 6 to subparagraph (A), if such an item is not subject to a determination of coverage in advance 7 8 pursuant to paragraph (15)(C), the Secretary 9 may conduct prepayment review of claims for 10 payment for such item.".

11 (b) Report on Identifying Clinical Diagnostic LABORATORY TESTS AT HIGH RISK FOR FRAUD AND EF-12 FECTIVE MITIGATION MEASURES.—Not later than Janu-13 ary 1, 2026, the Inspector General of the Department of 14 15 Health and Human Services shall submit to Congress a report assessing fraudulent claims for clinical diagnostic 16 laboratory tests for which payment may be made under 17 section 1834A of the Social Security Act (42 U.S.C. 18 19 1395m–1) and effective tools for reducing such fraudulent 20claims. The report shall include—

(1) which, if any, clinical diagnostic laboratory
tests are identified as being at high risk of fraudulent claims, and an analysis of the factors that contribute to such risk;

1	(2) with respect to a clinical diagnostic labora-
2	tory test identified under subparagraph (A) as being
3	at high risk of fraudulent claims—
4	(A) the amount payable under such section
5	1834A with respect to such test;
6	(B) the number of such tests furnished to
7	individuals enrolled under part B of title XVIII
8	of the Social Security Act (42 U.S.C. 1395j et
9	seq.);
10	(C) whether an order for such a test was
11	more likely to come from a provider with whom
12	the individual involved did not have a prior re-
13	lationship, as determined on the basis of prior
14	payment experience; and
15	(D) the frequency with which a claim for
16	payment under such section 1834A included the
17	payment modifier identified by code 59 or 91;
18	and
19	(3) suggested strategies for reducing the num-
20	ber of fraudulent claims made with respect to tests
21	so identified as being at high risk, including—
22	(A) an analysis of whether the Centers for
23	Medicare & Medicaid Services can detect aber-
24	rant billing patterns with respect to such tests
25	in a timely manner;

1	(B) any strategies for identifying and mon-
2	itoring the providers who are outliers with re-
3	spect to the number of such tests that such pro-
4	viders order; and
5	(C) targeted education efforts to mitigate
6	improper billing for such tests.
7	TITLE II—SUSTAINING ACCESS
8	TO HOSPITAL AND EMER-
9	GENCY SERVICES
10	SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL
11	PAYMENT ADJUSTMENT FOR CERTAIN LOW-
12	VOLUME HOSPITALS.
13	(a) IN GENERAL.—Section 1886(d)(12) of the Social
14	Security Act (42 U.S.C. 1395ww(d)(12)) is amended—
15	(1) in subparagraph (B), by striking "during
16	the portion of fiscal year 2025 beginning on January
17	1, 2025, and ending on September 30, 2025, and";
18	(2) in subparagraph (C)(i)—
19	(A) in the matter preceding subclause
20	(I)—
21	(i) by striking "or portion of a fiscal
22	year''; and
23	(ii) by striking "2024 and the portion
24	of fiscal year 2025 beginning on October 1,

1	2024, and ending on December 31, 2024"
2	and inserting "2025";
3	(B) in subclause (III), by striking "2024
4	and the portion of fiscal year 2025 beginning
5	on October 1, 2024, and ending on December
6	31, 2024" and inserting "2025"; and
7	(C) in subclause (IV), by striking "the por-
8	tion of fiscal year 2025 beginning on January
9	1, 2025, and ending on September 30, 2025,
10	and"; and
11	(3) in subparagraph (D)—
12	(A) in the matter preceding clause (i), by
13	striking "2024 or during the portion of fiscal
14	year 2025 beginning on October 1, 2024, and
15	ending on December 31, 2024" and inserting
16	"2025"; and
17	(B) in clause (ii), by striking "2024 and
18	the portion of fiscal year 2025 beginning on Oc-
19	tober 1, 2024, and ending on December 31,
20	2024" and inserting "2025".
21	(b) IMPLEMENTATION.—Notwithstanding any other
22	provision of law, the Secretary of Health and Human
23	Services may implement the provisions of, including the
24	amendments made by, this section by program instruction
25	or otherwise.

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1	SEC. 202. EXTENSION OF THE MEDICARE-DEPENDENT HOS-
2	PITAL PROGRAM.
3	(a) IN GENERAL.—Section $1886(d)(5)(G)$ of the So-
4	cial Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amend-
5	ed—
6	(1) in clause (i), by striking "January 1, 2025"
7	and inserting "October 1, 2025"; and
8	(2) in clause (ii)(II), by striking "January 1,
9	2025" and inserting "October 1, 2025".
10	(b) Conforming Amendments.—
11	(1) EXTENSION OF TARGET AMOUNT.—Section
12	1886(b)(3)(D) of the Social Security Act (42 U.S.C.
13	1395ww(b)(3)(D)) is amended—
14	(A) in the matter preceding clause (i), by
15	striking "January 1, 2025" and inserting "Oc-
16	tober 1, 2025"; and
17	(B) in clause (iv), by striking "2024 and
18	the portion of fiscal year 2025 beginning on Oc-
19	tober 1, 2024, and ending on December 31,
20	2024" and inserting "2025".
21	(2) Permitting hospitals to decline re-
22	CLASSIFICATION.—Section 13501(e)(2) of the Omni-
23	bus Budget Reconciliation Act of 1993 (42 U.S.C.
24	1395ww note) is amended by striking "2024, or the
25	portion of fiscal year 2025 beginning on October 1,

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16 2024, and ending on December 31, 2024" and inserting "2025". SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBU-LANCE SERVICES. (a) IN GENERAL.—Section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)) is amended— (1) in paragraph (12)(A), by striking "January 1, 2025" and inserting "October 1, 2025"; and (2) in paragraph (13), by striking "January 1, 2025" in each place it appears and inserting "October 1, 2025" in each such place. (b) PROGRAM INSTRUCTION AUTHORITY.---Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, including amendments made by, this section through program instruction or otherwise. TITLE III—OFFSETS

18 SEC. 301. REVISING PHASE-IN OF MEDICARE CLINICAL LAB-

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ORATORY TEST PAYMENT CHANGES.

20 (a) REVISED PHASE-IN OF REDUCTIONS FROM PRI21 VATE PAYOR RATE IMPLEMENTATION.—Section
22 1834A(b)(3) of the Social Security Act (42 U.S.C.
23 1395m-1(b)(3)) is amended—

24 (1) in subparagraph (A), by striking "2027"
25 and inserting "2028"; and

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1	(2) in subparagraph (B)—
2	(A) in clause (ii), by striking "2024" and
3	inserting "2025"; and
4	(B) in clause (iii), by striking "2025
5	through 2027 " and inserting "2026 through
6	2028".
7	(b) Revised Reporting Period for Reporting
8	OF PRIVATE SECTOR PAYMENT RATES FOR ESTABLISH-
9	MENT OF MEDICARE PAYMENT RATES.—Section
10	1834A(a)(1)(B) of the Social Security Act (42 U.S.C.
11	1395m–1(a)(1)(B)) is amended—
12	(1) in clause (i), by striking "2024" and insert-
13	ing "2025"; and
14	(2) in clause (ii), by striking "2025" each place
15	it appears and inserting "2026".
16	(c) IMPLEMENTATION.—The Secretary of Health and
17	Human Services may implement the amendments made by
18	this section by program instruction or otherwise.
19	SEC. 302. ARRANGEMENTS WITH PHARMACY BENEFIT MAN-
20	AGERS WITH RESPECT TO PRESCRIPTION
21	DRUG PLANS AND MA-PD PLANS.
22	(a) IN GENERAL.—
23	(1) PRESCRIPTION DRUG PLANS.—Section
24	1860D–12 of the Social Security Act (42 U.S.C.

1395w-112) is amended by adding at the end the
 following new subsection:

3 "(h) REQUIREMENTS RELATING TO PHARMACY BEN4 EFIT MANAGERS.—For plan years beginning on or after
5 January 1, 2027:

6 "(1) AGREEMENTS WITH PHARMACY BENEFIT 7 MANAGERS.—Each contract entered into with a 8 PDP sponsor under this part with respect to a pre-9 scription drug plan offered by such sponsor shall 10 provide that any pharmacy benefit manager acting 11 on behalf of such sponsor has a written agreement 12 with the PDP sponsor under which the pharmacy 13 benefit manager, and any affiliates of such phar-14 macy benefit manager, as applicable, agree to meet 15 the following requirements:

16 "(A) NO INCOME OTHER THAN BONA FIDE
17 SERVICE FEES.—

18 "(i) IN GENERAL.—The pharmacy
19 benefit manager and any affiliate of such
20 pharmacy benefit manager shall not derive
21 any remuneration with respect to any serv22 ices provided on behalf of any entity or in23 dividual, in connection with the utilization
24 of covered part D drugs, from any such en-

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tity or individual other than bona fide service fees, subject to clauses (ii) and (iii).

"(ii) INCENTIVE PAYMENTS.—For the 3 4 purposes of this subsection, an incentive payment paid by a PDP sponsor to a phar-5 6 macy benefit manager that is performing 7 services on behalf of such sponsor shall be 8 deemed a 'bona fide service fee'(even if 9 such payment does not otherwise meet the definition of such term under paragraph 10 11 (7)(B) if such payment is a flat dollar 12 amount, is consistent with fair market 13 value (as specified by the Secretary), is re-14 lated to services actually performed by the 15 pharmacy benefit manager or affiliate of 16 such pharmacy benefit manager, on behalf 17 of the entity making such payment, in con-18 nection with the utilization of covered part 19 D drugs, and meets additional require-20 ments, if any, as determined appropriate 21 by the Secretary.

22 "(iii) CLARIFICATION ON REBATES
23 AND DISCOUNTS USED TO LOWER COSTS
24 FOR COVERED PART D DRUGS.—Rebates,
25 discounts, and other price concessions re-

1 ceived by a pharmacy benefit manager or 2 an affiliate of a pharmacy benefit manager from manufacturers, even if such price 3 4 concessions are calculated as a percentage of a drug's price, shall not be considered a 5 6 violation of the requirements of clause (i) 7 if they are fully passed through to a PDP 8 sponsor and are compliant with all regu-9 latory and subregulatory requirements related to direct and indirect remuneration 10 11 for manufacturer rebates under this part, 12 including in cases where a PDP sponsor is 13 acting as a pharmacy benefit manager on 14 behalf of a prescription drug plan offered 15 by such PDP sponsor. "(iv) EVALUATION OF REMUNERATION 16 17 ARRANGEMENTS.—Components of subsets 18 of remuneration arrangements (such as 19 fees or other forms of compensation paid 20 to or retained by the pharmacy benefit 21 manager or affiliate of such pharmacy ben-22 efit manager), as determined appropriate 23 by the Secretary, between pharmacy ben-24 efit managers or affiliates of such phar-

macy benefit managers, as applicable, and

1 other entities involved in the dispensing or 2 utilization of covered part D drugs (including PDP sponsors, manufacturers, phar-3 4 macies, and other entities as determined appropriate by the Secretary) shall be sub-5 6 ject to review by the Secretary, in con-7 sultation with the Office of the Inspector 8 General of the Department of Health and 9 Human Services, as determined appropriate by the Secretary. The Secretary, in 10 11 consultation with the Office of the Inspec-12 tor General, shall review whether remu-13 neration under such arrangements is con-14 sistent with fair market value (as specified 15 by the Secretary) through reviews and as-16 sessments of such remuneration, as deter-17 mined appropriate. 18 "(v) DISGORGEMENT.—The pharmacy 19 benefit manager shall disgorge any remu-20 neration paid to such pharmacy benefit 21 manager or an affiliate of such pharmacy 22 benefit manager in violation of this sub-23 paragraph to the PDP sponsor. 24 "(vi) Additional requirements.—

1	"(I) enter into a written agree-
2	ment with any affiliate of such phar-
3	macy benefit manager, under which
4	the affiliate shall identify and disgorge
5	any remuneration described in clause
6	(v) to the pharmacy benefit manager;
7	and
8	"(II) attest, subject to any re-
9	quirements determined appropriate by
10	the Secretary, that the pharmacy ben-
11	efit manager has entered into a writ-
12	ten agreement described in subclause
13	(I) with any relevant affiliate of the
14	pharmacy benefit manager.
15	"(B) TRANSPARENCY REGARDING GUARAN-
16	TEES AND COST PERFORMANCE EVALUA-
17	TIONS.—The pharmacy benefit manager shall—
18	"(i) define, interpret, and apply, in a
19	fully transparent and consistent manner
20	for purposes of calculating or otherwise
21	evaluating pharmacy benefit manager per-
22	formance against pricing guarantees or
23	similar cost performance measurements re-
24	lated to rebates, discounts, price conces-
25	sions, or net costs, terms such as—

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1	"(I) 'generic drug', in a manner
2	consistent with the definition of the
3	term under section 423.4 of title 42,
4	Code of Federal Regulations, or a suc-
5	cessor regulation;
6	"(II) 'brand name drug', in a
7	manner consistent with the definition
8	of the term under section 423.4 of
9	title 42, Code of Federal Regulations,
10	or a successor regulation;
11	"(III) 'specialty drug';
12	"(IV) 'rebate'; and
13	"(V) 'discount';
14	"(ii) identify any drugs, claims, or
15	price concessions excluded from any pric-
16	ing guarantee or other cost performance
17	calculation or evaluation in a clear and
18	consistent manner; and
19	"(iii) where a pricing guarantee or
20	other cost performance measure is based
21	on a pricing benchmark other than the
22	wholesale acquisition cost (as defined in
23	section $1847A(c)(6)(B)$) of a drug, cal-
24	culate and provide a wholesale acquisition
25	cost-based equivalent to the pricing guar-

1	antee or other cost performance measure
2	in the written agreement.
3	"(C) Provision of information.—
4	"(i) IN GENERAL.—Not later than
5	July 1 of each year, beginning in 2027, the
6	pharmacy benefit manager shall submit to
7	the PDP sponsor, and to the Secretary, a
8	report, in accordance with this subpara-
9	graph, and shall make such report avail-
10	able to such sponsor at no cost to such
11	sponsor in a format specified by the Sec-
12	retary under paragraph (5). Each such re-
13	port shall include, with respect to such
14	PDP sponsor and each plan offered by
15	such sponsor, the following information
16	with respect to the previous plan year:
17	"(I) A list of all drugs covered by
18	the plan that were dispensed includ-
19	ing, with respect to each such drug—
20	"(aa) the brand name, ge-
21	neric or non-proprietary name,
22	and National Drug Code;
23	"(bb) the number of plan
24	enrollees for whom the drug was
25	dispensed, the total number of

1 prescription claims for the drug 2 (including original prescriptions 3 and refills, counted as separate 4 claims), and the total number of 5 dosage units of the drug dis-6 pensed; "(cc) the number of pre-7 8 scription claims described in item 9 (bb) by each type of dispensing 10 channel through which the drug

11 was dispensed, including retail,12 mail order, specialty pharmacy,

13 long term care pharmacy, home14 infusion pharmacy, or other types

of pharmacies or providers;

"(dd) the average wholesale acquisition cost, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

"(ee) the average wholesale price for the drug, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

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1	"(ff) the total out-of-pocket
2	spending by plan enrollees on
3	such drug after application of
4	any benefits under the plan, in-
5	cluding plan enrollee spending
6	through copayments, coinsurance,
7	and deductibles;
8	"(gg) total rebates paid by
9	the manufacturer on the drug as
10	reported under the Detailed DIR
11	Report (or any successor report)
12	submitted by such sponsor to the
13	Centers for Medicare & Medicaid
14	Services;
15	"(hh) all other direct or in-
16	direct remuneration on the drug
17	as reported under the Detailed
18	DIR Report (or any successor re-
19	port) submitted by such sponsor
20	to the Centers for Medicare &
21	Medicaid Services;
22	"(ii) the average pharmacy
23	reimbursement amount paid by
24	the plan for the drug in the ag-
25	gregate and disaggregated by dis-

	2.
1	pensing channel identified in item
2	(ee);
3	"(jj) the average National
4	Average Drug Acquisition Cost
5	(NADAC); and
6	"(kk) total manufacturer-de-
7	rived revenue, inclusive of bona
8	fide service fees, attributable to
9	the drug and retained by the
10	pharmacy benefit manager and
11	any affiliate of such pharmacy
12	benefit manager.
13	"(II) In the case of a pharmacy
14	benefit manager that has an affiliate
15	that is a retail, mail order, or spe-
16	cialty pharmacy, with respect to drugs
17	covered by such plan that were dis-
18	pensed, the following information:
19	"(aa) The percentage of
20	total prescriptions that were dis-
21	pensed by pharmacies that are an
22	affiliate of the pharmacy benefit
23	manager for each drug.
24	"(bb) The interquartile
25	range of the total combined costs

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

day supply, and per 90-day sup-

1ply, for each drug that is avail-2able from any pharmacy included3in the pharmacy network of such4plan.

"(ee) The difference between 5 6 the average acquisition cost of 7 the affiliate, such as a pharmacy or other entity that acquires pre-8 9 scription drugs, that initially ac-10 quires the drug and the amount 11 reported under subclause (I)(jj) for each drug. 12

"(ff) A list inclusive of the 13 14 brand name, generic or non-pro-15 prietary name, and National 16 Drug Code of covered part D 17 drugs subject to an agreement 18 with a covered entity under sec-19 tion 340B of the Public Health 20 Service Act for which the pharmacy benefit manager or an affil-21 22 iate of the pharmacy benefit 23 manager had a contract or other 24 arrangement with such a covered

entity in the service area of such plan. "(III) Where a drug approved under section 505(c) of the Federal
"(III) Where a drug approved
under section $505(c)$ of the Federal
Food, Drug, and Cosmetic Act (re-
ferred to in this subclause as the 'list-
ed drug') is covered by the plan, the
following information:
"(aa) A list of currently
marketed generic drugs approved
under section 505(j) of the Fed-
eral Food, Drug, and Cosmetic
Act pursuant to an application
that references such listed drug
that are not covered by the plan,
are covered on the same for-
mulary tier or a formulary tier
typically associated with higher
cost-sharing than the listed drug,
or are subject to utilization man-
agement that the listed drug is
not subject to.
"(bb) The estimated average
beneficiary cost-sharing under

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

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

15 "(dd) A written justification
16 for providing more favorable cov17 erage of the listed drug than the
18 generic drugs described in item
19 (aa).

20 "(ee) The number of cur21 rently marketed generic drugs
22 approved under section 505(j) of
23 the Federal Food, Drug, and
24 Cosmetic Act pursuant to an ap-

1	plication that references such
2	listed drug.
3	"(IV) Where a reference product
4	(as defined in section 351(i) of the
5	Public Health Service Act) is covered
6	by the plan, the following information:
7	"(aa) A list of currently
8	marketed biosimilar biological
9	products licensed under section
10	351(k) of the Public Health
11	Service Act pursuant to an appli-
12	cation that refers to such ref-
13	erence product that are not cov-
14	ered by the plan, are covered on
15	the same formulary tier or a for-
16	mulary tier typically associated
17	with higher cost-sharing than the
18	reference product, or are subject
19	to utilization management that
20	the reference product is not sub-
21	ject to.
22	"(bb) The estimated average
23	beneficiary cost-sharing under
24	the plan for a 30-day supply of
25	the reference product.

1	"(cc) Where a biosimilar bi-
2	ological product listed under item
3	(aa) is on a formulary tier typi-
4	cally associated with higher cost-
5	sharing than the listed drug, the
6	estimated average cost-sharing
7	that a beneficiary would have
8	paid for a 30-day supply of each
9	of the biosimilar biological prod-
10	ucts described in item (aa), had
11	the plan provided coverage for
12	such products on the same for-
13	mulary tier as the reference prod-
14	uct.
15	"(dd) A written justification
16	for providing more favorable cov-
17	erage of the reference product
18	than the biosimilar biological
19	product described in item (aa).
20	"(ee) The number of cur-
21	rently marketed biosimilar bio-
22	logical products licensed under
23	section 351(k) of the Public
24	Health Service Act, pursuant to

1	an application that refers to such
2	reference product.

3 "(V) Total gross spending on
4 covered part D drugs by the plan, not
5 net of rebates, fees, discounts, or
6 other direct or indirect remuneration.
7 "(VI) The total amount retained
8 by the pharmacy benefit manager or

9 an affiliate of such pharmacy benefit10 manager in revenue related to utiliza-

11 tion of covered part D drugs under12 that plan, inclusive of bona fide serv-

13 ice fees.

14 "(VII) The total spending on cov-15 ered part D drugs net of rebates, fees,

16 discounts, or other direct and indirect17 remuneration by the plan.

18 "(VIII) An explanation of any 19 benefit design parameters under such 20 plan that encourage plan enrollees to 21 fill prescriptions at pharmacies that 22 are an affiliate of such pharmacy ben-23 efit manager, such as mail and spe-24 cialty home delivery programs, and re-25 tail and mail auto-refill programs.

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"(IX) The following information:
"(aa) A list of all brokers,
consultants, advisors, and audi-
tors that receive compensation
from the pharmacy benefit man-
ager or an affiliate of such phar-
macy benefit manager for refer-
rals, consulting, auditing, or
other services offered to PDP
sponsors related to pharmacy
benefit management services.
"(bb) The amount of com-
pensation provided by such phar-
macy benefit manager or affiliate
to each such broker, consultant,
advisor, and auditor.
"(cc) The methodology for
calculating the amount of com-
pensation provided by such phar-
macy benefit manager or affil-
iate, for each such broker, con-
sultant, advisor, and auditor.
"(X) A list of all affiliates of the
pharmacy benefit manager.

1	"(XI) A summary document sub-
2	mitted in a standardized template de-
3	veloped by the Secretary that includes
4	such information described in sub-
5	clauses (I) through (X).
6	"(ii) Written explanation of con-
7	TRACTS OR AGREEMENTS WITH DRUG
8	MANUFACTURERS.—
9	"(I) IN GENERAL.—The phar-
10	macy benefit manager shall, not later
11	than 30 days after the finalization of
12	any contract or agreement between
13	such pharmacy benefit manager or an
14	affiliate of such pharmacy benefit
15	manager and a drug manufacturer (or
16	subsidiary, agent, or entity affiliated
17	with such drug manufacturer) that
18	makes rebates, discounts, payments,
19	or other financial incentives related to
20	one or more covered part D drugs or
21	other prescription drugs, as applica-
22	ble, of the manufacturer directly or
23	indirectly contingent upon coverage,
24	formulary placement, or utilization
25	management conditions on any other

1	covered part D drugs or other pre-
2	scription drugs, as applicable, submit
3	to the PDP sponsor a written expla-
4	nation of such contract or agreement.
5	"(II) REQUIREMENTS.—A writ-
6	ten explanation under subclause (I)
7	shall—
8	"(aa) include the manufac-
9	turer subject to the contract or
10	agreement, all covered part D
11	drugs and other prescription
12	drugs, as applicable, subject to
13	the contract or agreement and
14	the manufacturers of such drugs,
15	and a high-level description of
16	the terms of such contract or
17	agreement and how such terms
18	apply to such drugs; and
19	"(bb) be certified by the
20	Chief Executive Officer, Chief Fi-
21	nancial Officer, or General Coun-
22	sel of such pharmacy benefit
23	manager, or affiliate of such
24	pharmacy benefit manager, as
25	applicable, or an individual dele-

1	gated with the authority to sign
2	on behalf of one of these officers,
3	who reports directly to the offi-
4	cer.
5	"(III) DEFINITION OF OTHER
6	PRESCRIPTION DRUGS.—For purposes
7	of this clause, the term 'other pre-
8	scription drugs' means prescription
9	drugs covered as supplemental bene-
10	fits under this part or prescription
11	drugs paid outside of this part.
12	"(D) AUDIT RIGHTS.—
13	"(i) IN GENERAL.—Not less than once
14	a year, at the request of the PDP sponsor,
15	the pharmacy benefit manager shall allow
16	for an audit of the pharmacy benefit man-
17	ager to ensure compliance with all terms
18	and conditions under the written agree-
19	ment and the accuracy of information re-
20	ported under subparagraph (C).
21	"(ii) Auditor.—The PDP sponsor
22	shall have the right to select an auditor.
23	The pharmacy benefit manager shall not
24	impose any limitations on the selection of
25	such auditor.

1	"(iii) Provision of information.—
2	The pharmacy benefit manager shall make
3	available to such auditor all records, data,
4	contracts, and other information necessary
5	to confirm the accuracy of information
6	provided under subparagraph (C), subject
7	to reasonable restrictions on how such in-
8	formation must be reported to prevent re-
9	disclosure of such information.
10	"(iv) TIMING.—The pharmacy benefit
11	manager must provide information under
12	clause (iii) and other information, data,
13	and records relevant to the audit to such
14	auditor within 6 months of the initiation of
15	the audit and respond to requests for addi-
16	tional information from such auditor with-
17	in 30 days after the request for additional
18	information.
19	"(v) INFORMATION FROM AFFILI-
20	ATES.—The pharmacy benefit manager
21	shall be responsible for providing to such
22	auditor information required to be reported
23	under subparagraph (C) that is owned or
24	held by an affiliate of such pharmacy ben-
25	efit manager.

1	"(2) Enforcement.—
2	"(A) IN GENERAL.—Each PDP sponsor
3	shall—
4	"(i) disgorge to the Secretary any
5	amounts disgorged to the PDP sponsor by
6	a pharmacy benefit manager under para-
7	graph $(1)(A)(v);$
8	"(ii) require, in a written agreement
9	with any pharmacy benefit manager acting
10	on behalf of such sponsor or affiliate of
11	such pharmacy benefit manager, that such
12	pharmacy benefit manager or affiliate re-
13	imburse the PDP sponsor for any civil
14	money penalty imposed on the PDP spon-
15	sor as a result of the failure of the phar-
16	macy benefit manager or affiliate to meet
17	the requirements of paragraph (1) that are
18	applicable to the pharmacy benefit man-
19	ager or affiliate under the agreement; and
20	"(iii) require, in a written agreement
21	with any such pharmacy benefit manager
22	acting on behalf of such sponsor or affil-
23	iate of such pharmacy benefit manager,
24	that such pharmacy benefit manager or af-
25	filiate be subject to punitive remedies for

1	breach of contract for failure to comply
2	with the requirements applicable under
3	paragraph (1).
4	"(B) REPORTING OF ALLEGED VIOLA-
5	TIONS.—The Secretary shall make available and
6	maintain a mechanism for manufacturers, PDP
7	sponsors, pharmacies, and other entities that
8	have contractual relationships with pharmacy
9	benefit managers or affiliates of such pharmacy
10	benefit managers to report, on a confidential
11	basis, alleged violations of paragraph (1)(A) or
12	subparagraph (C).
13	"(C) ANTI-RETALIATION AND ANTI-COER-
14	CION.—Consistent with applicable Federal or
15	State law, a PDP sponsor shall not—
16	"(i) retaliate against an individual or
17	entity for reporting an alleged violation
18	under subparagraph (B); or

19 "(ii) coerce, intimidate, threaten, or 20 interfere with the ability of an individual 21 or entity to report any such alleged viola-22 tions.

23	"(3) Certification of compliance.—
24	"(A) IN GENERAL.—Each PDP sponsor
25	shall furnish to the Secretary (in a time and

1	manner specified by the Secretary) an annual
2	certification of compliance with this subsection,
3	as well as such information as the Secretary de-
4	termines necessary to carry out this subsection.
5	"(B) IMPLEMENTATION.—Notwithstanding
6	any other provision of law, the Secretary may
7	implement this paragraph by program instruc-
8	tion or otherwise.
9	"(4) RULE OF CONSTRUCTION.—Nothing in
10	this subsection shall be construed as prohibiting pay-
11	ments related to reimbursement for ingredient costs
12	to any entity that acquires prescription drugs, such
13	as a pharmacy or wholesaler.
14	"(5) Standard formats.—
15	"(A) IN GENERAL.—Not later than June
16	1, 2026, the Secretary shall specify standard,
17	machine-readable formats for pharmacy benefit
18	managers to submit annual reports required
19	under paragraph (1)(C)(i).
20	"(B) IMPLEMENTATION.—Notwithstanding
21	any other provision of law, the Secretary may
22	implement this paragraph by program instruc-
23	tion or otherwise.
24	"(6) Confidentiality.—

24 "(6) CONFIDENTIALITY.—

1	"(A) IN GENERAL.—Information disclosed
2	by a pharmacy benefit manager, an affiliate of
3	a pharmacy benefit manager, a PDP sponsor,
4	or a pharmacy under this subsection that is not
5	otherwise publicly available or available for pur-
6	chase shall not be disclosed by the Secretary or
7	a PDP sponsor receiving the information, ex-
8	cept that the Secretary may disclose the infor-
9	mation for the following purposes:
10	"(i) As the Secretary determines nec-
11	essary to carry out this part.
12	"(ii) To permit the Comptroller Gen-
13	eral to review the information provided.
14	"(iii) To permit the Director of the
15	Congressional Budget Office to review the
16	information provided.
17	"(iv) To permit the Executive Direc-
18	tor of the Medicare Payment Advisory
19	Commission to review the information pro-
20	vided.
21	"(v) To the Attorney General for the
22	purposes of conducting oversight and en-
23	forcement under this title.
24	"(vi) To the Inspector General of the
25	Department of Health and Human Serv-

2under the Inspector General Act of 19783(section 406 of title 5, United States4Code), and other applicable statutes.5"(B) RESTRICTION ON USE OF INFORMA-6TION.—The Secretary, the Comptroller General,7the Director of the Congressional Budget Of-8fice, and the Executive Director of the Medicare9Payment Advisory Commission shall not report10on or disclose information disclosed pursuant to11subparagraph (A) to the public in a manner12that would identify—13"(i) a specific pharmacy benefit man-14ager, affiliate, pharmacy, manufacturer,15wholesaler, PDP sponsor, or plan; or16"(ii) contract prices, rebates, dis-17counts, or other remuneration for specific18drugs in a manner that may allow the19identification of specific contracting parties20or of such specific drugs.21"(A) AFFILIATE.—The term 'affiliate'23"(A) AFFILIATE.—The term 'affiliate'24means any entity that is owned by, controlled25by, or related under a common ownership struc-	1	ices in accordance with its authorities
 Code), and other applicable statutes. "(B) RESTRICTION ON USE OF INFORMA- TION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Of- fice, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify— "(i) a specific pharmacy benefit man- ager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	2	under the Inspector General Act of 1978
 "(B) RESTRICTION ON USE OF INFORMA- TION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Of- fice, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify— "(i) a specific pharmacy benefit man- ager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	3	(section 406 of title 5, United States
 TION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Of- fice, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify— "(i) a specific pharmacy benefit man- ager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	4	Code), and other applicable statutes.
 the Director of the Congressional Budget Of- fice, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify— "(i) a specific pharmacy benefit man- ager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	5	"(B) RESTRICTION ON USE OF INFORMA-
 fice, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify— "(i) a specific pharmacy benefit man- ager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	6	TION.—The Secretary, the Comptroller General,
 Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (A) to the public in a manner that would identify— "(i) a specific pharmacy benefit man- ager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	7	the Director of the Congressional Budget Of-
10on or disclose information disclosed pursuant to11subparagraph (A) to the public in a manner12that would identify—13"(i) a specific pharmacy benefit man-14ager, affiliate, pharmacy, manufacturer,15wholesaler, PDP sponsor, or plan; or16"(ii) contract prices, rebates, dis-17counts, or other remuneration for specific18drugs in a manner that may allow the19identification of specific contracting parties20or of such specific drugs.21"(7) DEFINITIONS.—For purposes of this sub-22section:23"(A) AFFILIATE.—The term 'affiliate'24means any entity that is owned by, controlled	8	fice, and the Executive Director of the Medicare
11subparagraph (A) to the public in a manner12that would identify—13"(i) a specific pharmacy benefit man-14ager, affiliate, pharmacy, manufacturer,15wholesaler, PDP sponsor, or plan; or16"(ii) contract prices, rebates, dis-17counts, or other remuneration for specific18drugs in a manner that may allow the19identification of specific contracting parties20or of such specific drugs.21"(7) DEFINITIONS.—For purposes of this sub-22section:23"(A) AFFILLATE.—The term 'affiliate'24means any entity that is owned by, controlled	9	Payment Advisory Commission shall not report
12that would identify—13"(i) a specific pharmacy benefit man-14ager, affiliate, pharmacy, manufacturer,15wholesaler, PDP sponsor, or plan; or16"(ii) contract prices, rebates, dis-17counts, or other remuneration for specific18drugs in a manner that may allow the19identification of specific contracting parties20or of such specific drugs.21"(7) DEFINITIONS.—For purposes of this sub-22section:23"(A) AFFILIATE.—The term 'affiliate'24means any entity that is owned by, controlled	10	on or disclose information disclosed pursuant to
 "(i) a specific pharmacy benefit manager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(1) DEFINITIONS.—For purposes of this subsection: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	11	subparagraph (A) to the public in a manner
14ager, affiliate, pharmacy, manufacturer,15wholesaler, PDP sponsor, or plan; or16"(ii) contract prices, rebates, dis-17counts, or other remuneration for specific18drugs in a manner that may allow the19identification of specific contracting parties20or of such specific drugs.21"(7) DEFINITIONS.—For purposes of this sub-22section:23"(A) AFFILIATE.—The term 'affiliate'24means any entity that is owned by, controlled	12	that would identify—
 wholesaler, PDP sponsor, or plan; or "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	13	"(i) a specific pharmacy benefit man-
 "(ii) contract prices, rebates, dis- counts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	14	ager, affiliate, pharmacy, manufacturer,
 17 counts, or other remuneration for specific 18 drugs in a manner that may allow the 19 identification of specific contracting parties 20 or of such specific drugs. 21 "(7) DEFINITIONS.—For purposes of this sub- 22 section: 23 "(A) AFFILIATE.—The term 'affiliate' 24 means any entity that is owned by, controlled 	15	wholesaler, PDP sponsor, or plan; or
18drugs in a manner that may allow the19identification of specific contracting parties20or of such specific drugs.21"(7) DEFINITIONS.—For purposes of this sub-22section:23"(A) AFFILIATE.—The term 'affiliate'24means any entity that is owned by, controlled	16	"(ii) contract prices, rebates, dis-
 identification of specific contracting parties or of such specific drugs. "(7) DEFINITIONS.—For purposes of this sub- section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	17	counts, or other remuneration for specific
 20 or of such specific drugs. 21 "(7) DEFINITIONS.—For purposes of this sub- 22 section: 23 "(A) AFFILIATE.—The term 'affiliate' 24 means any entity that is owned by, controlled 	18	drugs in a manner that may allow the
 21 "(7) DEFINITIONS.—For purposes of this sub- 22 section: 23 "(A) AFFILIATE.—The term 'affiliate' 24 means any entity that is owned by, controlled 	19	identification of specific contracting parties
 section: "(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled 	20	or of such specific drugs.
 23 "(A) AFFILIATE.—The term 'affiliate' 24 means any entity that is owned by, controlled 	21	"(7) DEFINITIONS.—For purposes of this sub-
24 means any entity that is owned by, controlled	22	section:
e e e/	23	''(A) AFFILIATE.—The term 'affiliate'
by, or related under a common ownership struc-	24	means any entity that is owned by, controlled
	25	by, or related under a common ownership struc-

ture with a pharmacy benefit manager or PDP
 sponsor, or that acts as a contractor or agent
 to such pharmacy benefit manager or PDP
 sponsor, insofar as such contractor or agent
 performs any of the functions described under
 subparagraph (C).

7 "(B) BONA FIDE SERVICE FEE.—The term 8 'bona fide service fee' means a fee that is reflec-9 tive of the fair market value (as specified by the 10 Secretary) for a bona fide, itemized service ac-11 tually performed on behalf of an entity, that the 12 entity would otherwise perform (or contract for) 13 in the absence of the service arrangement and 14 that is not passed on in whole or in part to a 15 client or customer, whether or not the entity 16 takes title to the drug. Such fee must be a flat 17 dollar amount and shall not be directly or indi-18 rectly based on, or contingent upon—

19 "(i) drug price, such as wholesale ac20 quisition cost or drug benchmark price
21 (such as average wholesale price);

"(ii) the amount of discounts, rebates, fees, or other direct or indirect remuneration with respect to covered part D drugs dispensed to enrollees in a prescription

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1	drug plan, except as permitted pursuant to
2	paragraph (1)(A)(ii);
3	"(iii) coverage or formulary placement
4	decisions or the volume or value of any re-
5	ferrals or business generated between the
6	parties to the arrangement; or
7	"(iv) any other amounts or meth-
8	odologies prohibited by the Secretary.
9	"(C) Pharmacy benefit manager.—The
10	term 'pharmacy benefit manager' means any
11	person or entity that, either directly or through
12	an intermediary, acts as a price negotiator or
13	group purchaser on behalf of a PDP sponsor or
14	prescription drug plan, or manages the pre-
15	scription drug benefits provided by such spon-
16	sor or plan, including the processing and pay-
17	ment of claims for prescription drugs, the per-
18	formance of drug utilization review, the proc-
19	essing of drug prior authorization requests, the
20	adjudication of appeals or grievances related to
21	the prescription drug benefit, contracting with
22	network pharmacies, controlling the cost of cov-
23	ered part D drugs, or the provision of related
24	services. Such term includes any person or enti-
25	ty that carries out one or more of the activities

1	described in the preceding sentence, irrespective
2	of whether such person or entity calls itself a
3	'pharmacy benefit manager'.".
4	(2) MA–PD plans.—Section $1857(f)(3)$ of the
5	Social Security Act (42 U.S.C. 1395w-27(f)(3)) is
6	amended by adding at the end the following new
7	subparagraph:
8	"(F) REQUIREMENTS RELATING TO PHAR-
9	MACY BENEFIT MANAGERS.—For plan years be-
10	ginning on or after January 1, 2027, section
11	1860D–12(h).".
12	(3) Nonapplication of paperwork reduc-
13	TION ACT.—Chapter 35 of title 44, United States
14	Code, shall not apply to the implementation of this
15	subsection.
16	(4) FUNDING.—
17	(A) Secretary.—In addition to amounts
18	otherwise available, there is appropriated to the
19	Centers for Medicare & Medicaid Services Pro-
20	gram Management Account, out of any money
21	in the Treasury not otherwise appropriated,
22	113,000,000 for fiscal year 2025, to remain
23	available until expended, to carry out this sub-
24	

1 (B) OIG.—In addition to amounts other-2 wise available, there is appropriated to the In-3 spector General of the Department of Health and Human Services, out of any money in the 4 5 Treasury not otherwise appropriated, 6 20,000,000 for fiscal year 2025, to remain 7 available until expended, to carry out this sub-8 section. 9 (b) GAO STUDY AND REPORT ON CERTAIN REPORT-10 ING REQUIREMENTS.— 11 (1) STUDY.—The Comptroller General of the 12 United States (in this subsection referred to as the 13 "Comptroller General") shall conduct a study on 14 Federal and State reporting requirements for health 15 plans and pharmacy benefit managers related to the

16 transparency of prescription drug costs and prices.17 Such study shall include an analysis of the following:

18 (A) Federal statutory and regulatory re19 porting requirements for health plans and phar20 macy benefit managers related to prescription
21 drug costs and prices.

(B) Selected States' statutory and regulatory reporting requirements for health plans
and pharmacy benefit managers related to prescription drug costs and prices.

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1 (C) The extent to which the statutory and 2 regulatory reporting requirements identified in 3 subparagraphs (A) and (B) overlap and con-4 flict.

(D) The resources required by health plans and pharmacy benefit managers to comply with the reporting requirements described in subparagraphs (A) and (B).

9 (E) Other items determined appropriate by10 the Comptroller General.

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

23 (c) MEDPAC REPORTS ON AGREEMENTS WITH
24 PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRE25 SCRIPTION DRUG PLANS AND MA-PD PLANS.—The

1	Medicare Payment Advisory Commission shall submit to
2	Congress the following reports:
3	(1) Not later than March 31, 2028, a report re-
4	garding agreements with pharmacy benefit managers
5	with respect to prescription drug plans and MA–PD
6	plans. Such report shall include—
7	(A) a description of trends and patterns,
8	including relevant averages, totals, and other
9	figures for each of the types of information sub-
10	mitted;
11	(B) an analysis of any differences in agree-
12	ments and their effects on plan enrollee out-of-
13	pocket spending and average pharmacy reim-
14	bursement, and any other impacts; and
15	(C) any recommendations the Commission
16	determines appropriate.
17	(2) Not later than March 31, 2030, a report de-
18	scribing any changes with respect to the information
19	described in paragraph (1) over time, together with
20	any recommendations the Commission determines
21	appropriate.

1	SEC. 303. EXTENDING THE ADJUSTMENT TO THE CALCULA-
2	TION OF HOSPICE CAP AMOUNTS UNDER THE
3	MEDICARE PROGRAM.
4	Section $1814(i)(2)(B)$ of the Social Security Act (42)
5	U.S.C. 1395f(i)(2)(B)) is amended—
6	(1) in clause (ii), by striking "2033" and in-
7	serting "2034"; and
8	(2) in clause (iii), by striking "2033" and in-
9	serting "2034".
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