

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 7623
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 “Telehealth Moderniza-
3 tion Act of 2024”.

**4 TITLE I—PRESERVING PA-
5 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—

13 (1) in paragraph (2)(B)(iii), by striking “end-
14 ing December 31, 2024” and inserting “ending De-
15 cember 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”.

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

6 (c) EXTENDING TELEHEALTH SERVICES FOR FED-
7 ERALLY QUALIFIED HEALTH CENTERS AND RURAL
8 HEALTH CLINICS.—Section 1834(m)(8) of the Social Se-
9 curity Act (42 U.S.C. 1395m(m)(8)) is amended—

10 (1) in subparagraph (A), by striking “ending on
11 December 31, 2024” and inserting “ending on De-
12 cember 31, 2026”;

13 (2) in subparagraph (B)—

14 (A) in the subparagraph heading, by in-
15 serting “BEFORE 2025” after “RULE”;

16 (B) in clause (i), by striking “during the
17 periods for which subparagraph (A) applies”
18 and inserting “before January 1, 2025”; and

19 (C) in clause (ii), by inserting “furnished
20 to an eligible telehealth individual before Janu-
21 ary 1, 2025” after “telehealth services”; and

22 (3) by adding at the end the following new sub-
23 paragraph:

24 “(C) PAYMENT RULE FOR 2025 AND SUB-
25 SEQUENT YEARS.—

1 “(i) IN GENERAL.—A telehealth serv-
2 ice furnished to an eligible telehealth indi-
3 vidual by a Federally qualified health cen-
4 ter or rural health clinic on or after Janu-
5 ary 1, 2025, shall be deemed to be so fur-
6 nished to such individual as an outpatient
7 of such center or clinic (as applicable) for
8 purposes of paragraphs (1) and (3), re-
9 spectively, of section 1861(aa), and pay-
10 able as a Federally qualified health center
11 service or rural health clinic service (as ap-
12 plicable) under the prospective payment
13 system established under section 1834(o)
14 or the payment methodology established
15 under section 1833(a)(3), respectively.

16 “(ii) TREATMENT OF COSTS.—Costs
17 associated with the delivery of telehealth
18 services by a Federally qualified health
19 center or rural health clinic on or after
20 January 1, 2025, shall be considered allow-
21 able costs for purposes of the prospective
22 payment system established under section
23 1834(o) and any payment methodology de-
24 veloped under section 1833(a)(3), as appli-
25 cable.”.

1 (d) DELAYING THE IN-PERSON REQUIREMENTS
2 UNDER MEDICARE FOR MENTAL HEALTH SERVICES
3 FURNISHED THROUGH TELEHEALTH AND TELE-
4 COMMUNICATIONS TECHNOLOGY.—

5 (1) DELAY IN REQUIREMENTS FOR MENTAL
6 HEALTH SERVICES FURNISHED THROUGH TELE-
7 HEALTH.—Section 1834(m)(7)(B)(i) of the Social
8 Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is
9 amended, in the matter preceding subclause (I), by
10 striking “on or after” and all that follows through
11 “described in section 1135(g)(1)(B))” and inserting
12 “on or after January 1, 2027”.

13 (2) MENTAL HEALTH VISITS FURNISHED BY
14 RURAL HEALTH CLINICS.—Section 1834(y)(2) of the
15 Social Security Act (42 U.S.C. 1395m(y)(2)) is
16 amended by striking “January 1, 2025” and all that
17 follows through the period at the end and inserting
18 “January 1, 2027.”.

19 (3) MENTAL HEALTH VISITS FURNISHED BY
20 FEDERALLY QUALIFIED HEALTH CENTERS.—Section
21 1834(o)(4)(B) of the Social Security Act (42 U.S.C.
22 1395m(o)(4)(B)) is amended by striking “January
23 1, 2025” and all that follows through the period at
24 the end and inserting “January 1, 2027.”.

1 (e) ALLOWING FOR THE FURNISHING OF AUDIO-
2 ONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of
3 the Social Security Act (42 U.S.C. 1395m(m)(9)) is
4 amended by striking “ending on December 31, 2024” and
5 inserting “ending on December 31, 2026”.

6 (f) REQUIRING MODIFIERS FOR TELEHEALTH SERV-
7 ICES IN CERTAIN INSTANCES.—Section 1834(m) of the
8 Social Security Act (42 U.S.C. 1395m(m)) is amended by
9 adding at the end the following new paragraph:

10 “(10) REQUIRED USE OF MODIFIERS IN CER-
11 TAIN INSTANCES.—Not later than January 1, 2026,
12 the Secretary shall establish requirements to include
13 a code or modifier, as determined appropriate by the
14 Secretary, in the case of—

15 “(A) claims for telehealth services under
16 this subsection that are provided through a tele-
17 health virtual platform; and

18 “(B) claims for telehealth services under
19 this subsection that are billed incident to a phy-
20 sician’s or practitioner’s professional service.”.

21 (g) PROGRAM INSTRUCTION AUTHORITY.—The Sec-
22 retary of Health and Human Services may implement the
23 amendments made by this section through program in-
24 struction or otherwise.

1 **SEC. 102. EXTENDING ACUTE HOSPITAL CARE AT HOME**
2 **WAIVER FLEXIBILITIES.**

3 Section 1866G of the Social Security Act (42 U.S.C.
4 1395cc-7) is amended—

5 (1) in subsection (a)(1), by striking “2024” and
6 inserting “2029”; and

7 (2) in subsection (b)—

8 (A) in the header, by striking “STUDY AND
9 REPORT” and inserting “STUDIES AND RE-
10 PORTS”;

11 (B) in paragraph (1)—

12 (i) in the matter preceding subpara-
13 graph (A), by striking “The Secretary”
14 and inserting “Not later than September
15 30, 2024, and again not later than Sep-
16 tember 30, 2028, the Secretary”;

17 (ii) in clause (iv), by striking “and” at
18 the end;

19 (iii) in clause (v), by striking the pe-
20 riod at the end and inserting “; and”;

21 (iv) by adding at the end the following
22 new clause:

23 “(vi) in the case of the second study
24 conducted under this paragraph, the qual-
25 ity of care, outcomes, costs, quantity and
26 intensity of services, and other relevant

1 metrics between individuals who entered
2 into the Acute Hospital Care at Home ini-
3 tiative directly from an emergency depart-
4 ment compared with individuals who en-
5 tered into the Acute Hospital Care at
6 Home initiative directly from an existing
7 inpatient stay in a hospital.”; and

8 (C) in paragraph (2)—

9 (i) in the header, by striking “RE-
10 PORT” and inserting “REPORTS”; and

11 (ii) by inserting “and again not later
12 than September 30, 2028,” after “2024,”;
13 and

14 (iii) by striking “on the study con-
15 ducted under paragraph (1).” and insert-
16 ing the following: “on—

17 “(A) with respect to the first report sub-
18 mitted under this paragraph, the first study
19 conducted under paragraph (1); and

20 “(B) with respect to the second report sub-
21 mitted under this paragraph, the second study
22 conducted under paragraph (1).”.

1 **SEC. 103. ENHANCING CERTAIN PROGRAM INTEGRITY RE-**
2 **QUIREMENTS FOR DME UNDER MEDICARE.**

3 (a) DURABLE MEDICAL EQUIPMENT.—Section
4 1834(a) of the Social Security Act (42 U.S.C. 1395m(a))
5 is amended by adding at the end the following new para-
6 graph:

7 “(23) MASTER LIST INCLUSION AND CLAIM RE-
8 VIEW FOR CERTAIN ITEMS.—

9 “(A) MASTER LIST INCLUSION.—Begin-
10 ning January 1, 2027, for purposes of the Mas-
11 ter List described in section 414.234(b) of title
12 42, Code of Federal Regulations (or any suc-
13 cessor regulation), an item for which payment
14 may be made under this subsection shall be
15 treated as having aberrant billing patterns (as
16 such term is used for purposes of such section)
17 if the Secretary determines that, without ex-
18 planatory contributing factors (such as fur-
19 nishing emergent care services), a substantial
20 number of claims for such items under this sub-
21 section are from an ordering physician or prac-
22 titioner with whom the individual involved does
23 not have a prior relationship, as determined on
24 the basis of claims.

25 “(B) CLAIM REVIEW.—With respect to
26 items furnished on or after January 1, 2027

1 that are included on the Master List pursuant
2 to subparagraph (A), if such an item is not sub-
3 ject to a determination of coverage in advance
4 pursuant to paragraph (15)(C), the Secretary
5 may conduct prepayment review of claims for
6 payment for such item.”.

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

17 (1) which, if any, clinical diagnostic laboratory
18 tests are identified as being at high risk of fraudu-
19 lent claims, and an analysis of the factors that con-
20 tribute to such risk;

21 (2) with respect to a clinical diagnostic labora-
22 tory test identified under paragraph (1) as being at
23 high risk of fraudulent claims—

24 (A) the amount payable under such section
25 1834A with respect to such test;

1 (B) the number of such tests furnished to
2 individuals enrolled under part B of title XVIII
3 of the Social Security Act (42 U.S.C. 1395j et
4 seq.);

5 (C) whether an order for such a test was
6 more likely to come from a provider with whom
7 the individual involved did not have a prior re-
8 lationship, as determined on the basis of prior
9 payment experience; and

10 (D) the frequency with which a claim for
11 payment under such section 1834A included the
12 payment modifier identified by code 59 or 91;
13 and

14 (3) suggested strategies for reducing the num-
15 ber of fraudulent claims made with respect to tests
16 so identified as being at high risk, including—

17 (A) an analysis of whether the Centers for
18 Medicare & Medicaid Services can detect aber-
19 rant billing patterns with respect to such tests
20 in a timely manner;

21 (B) any strategies for identifying and mon-
22 itoring the providers who are outliers with re-
23 spect to the number of such tests that such pro-
24 viders order; and

1 (C) targeted education efforts to mitigate
2 improper billing for such tests.

3 **TITLE II—OFFSETS**

4 **SEC. 201. REVISING PHASE-IN OF MEDICARE CLINICAL LAB-**
5 **ORATORY TEST PAYMENT CHANGES.**

6 (a) REVISED PHASE-IN OF REDUCTIONS FROM PRI-
7 VATE PAYOR RATE IMPLEMENTATION.—Section
8 1834A(b)(3) of the Social Security Act (42 U.S.C.
9 1395m–1(b)(3)) is amended—

10 (1) in subparagraph (A), by striking “2027”
11 and inserting “2028”; and

12 (2) in subparagraph (B)—

13 (A) in clause (ii), by striking “2024” and
14 inserting “2025”; and

15 (B) in clause (iii), by striking “2025
16 through 2027” and inserting “2026 through
17 2028”.

18 (b) REVISED REPORTING PERIOD FOR REPORTING
19 OF PRIVATE SECTOR PAYMENT RATES FOR ESTABLISH-
20 MENT OF MEDICARE PAYMENT RATES.—Section
21 1834A(a)(1)(B) of the Social Security Act (42 U.S.C.
22 1395m–1(a)(1)(B)) is amended—

23 (1) in clause (i), by striking “2024” and insert-
24 ing “2025”; and

1 (2) in clause (ii), by striking “2025” each place
2 it appears and inserting “2026”.

3 (c) IMPLEMENTATION.—The Secretary of Health and
4 Human Services may implement the amendments made by
5 this section by program instruction or otherwise.

6 **SEC. 202. ARRANGEMENTS WITH PHARMACY BENEFIT MAN-**
7 **AGERS WITH RESPECT TO PRESCRIPTION**
8 **DRUG PLANS AND MA-PD PLANS.**

9 (a) PRESCRIPTION DRUG PLANS.—Section 1860D–
10 12 of the Social Security Act (42 U.S.C. 1395w–112) is
11 amended by adding at the end the following new sub-
12 section:

13 “(h) REQUIREMENTS ON PHARMACY BENEFIT MAN-
14 AGERS.—For plan years beginning on or after January 1,
15 2027:

16 “(1) AGREEMENTS WITH PHARMACY BENEFIT
17 MANAGERS.—Each contract entered into with a
18 PDP sponsor under this part with respect to a pre-
19 scription drug plan offered by such sponsor shall
20 provide that any pharmacy benefit manager acting
21 on behalf of such sponsor has a written agreement
22 with the PDP sponsor under which the pharmacy
23 benefit manager agrees to meet the following re-
24 quirements:

1 “(A) TRANSPARENCY REGARDING GUARAN-
2 TEES AND COST PERFORMANCE EVALUA-
3 TIONS.—The pharmacy benefit manager shall—

4 “(i) define, interpret, and apply, in a
5 fully transparent and consistent manner
6 for purposes of calculating or otherwise
7 evaluating pharmacy benefit manager per-
8 formance against pricing guarantees or
9 similar cost performance measurements re-
10 lated to rebates, discounts, price conces-
11 sions, or net costs, terms such as—

12 “(I) ‘generic drug’, in a manner
13 consistent with the definition of the
14 term under section 423.4 of title 42,
15 Code of Federal Regulations, or a suc-
16 cessor regulation;

17 “(II) ‘brand name drug’, in a
18 manner consistent with the definition
19 of the term under section 423.4 of
20 title 42, Code of Federal Regulations,
21 or a successor regulation;

22 “(III) ‘specialty drug’;

23 “(IV) ‘rebate’; and

24 “(V) ‘discount’;

1 “(ii) identify any drugs, claims, or
2 price concessions excluded from any pric-
3 ing guarantee or other cost performance
4 calculation or evaluation in a clear and
5 consistent manner; and

6 “(iii) where a pricing guarantee or
7 other cost performance measure is based
8 on a pricing benchmark other than the
9 wholesale acquisition cost (as defined in
10 section 1847A(e)(6)(B)) of a drug, cal-
11 culate and provide a wholesale acquisition
12 cost-based equivalent to the pricing guar-
13 antee or other cost performance measure
14 in the written agreement.

15 “(B) PROVISION OF INFORMATION.—

16 “(i) IN GENERAL.—Not later than
17 July 1 of each year, beginning in 2027, the
18 pharmacy benefit manager shall submit to
19 the PDP sponsor, and to the Secretary, a
20 report, in accordance with this subpara-
21 graph, and shall make such report avail-
22 able to such sponsor at no cost to such
23 sponsor in a format specified by the Sec-
24 retary under paragraph (4). Each such re-
25 port shall include, with respect to such

1 PDP sponsor and each plan offered by
2 such sponsor, the following information
3 with respect to the previous plan year:

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

7 “(aa) the brand name, ge-
8 neric or non-proprietary name,
9 and National Drug Code;

10 “(bb) the number of plan
11 enrollees for whom the drug was
12 dispensed, the total number of
13 prescription claims for the drug
14 (including original prescriptions
15 and refills, counted as separate
16 claims), and the total number of
17 dosage units of the drug dis-
18 pensed;

19 “(cc) the number of pre-
20 scription claims described in item
21 (bb) by each type of dispensing
22 channel through which the drug
23 was dispensed, including retail,
24 mail order, specialty pharmacy,
25 long term care pharmacy, home

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

1 Centers for Medicare & Medicaid
2 Services;

3 “(hh) all other direct or in-
4 direct remuneration on the drug
5 as reported under the Detailed
6 DIR Report (or any successor re-
7 port) submitted by such sponsor
8 to the Centers for Medicare &
9 Medicaid Services;

10 “(ii) the average pharmacy
11 reimbursement amount paid by
12 the plan for the drug in the ag-
13 gregate and disaggregated by dis-
14 pensing channel identified in item
15 (cc);

16 “(jj) the average National
17 Average Drug Acquisition Cost
18 (NADAC) for retail community
19 pharmacies; and

20 “(kk) total manufacturer-de-
21 rived revenue, inclusive of bona
22 fide service fees, retained by the
23 pharmacy benefit manager and
24 any affiliate of such pharmacy

1 benefit manager attributable to
2 the drug.

3 “(II) In the case of a pharmacy
4 benefit manager that has an affiliate
5 that is a retail, mail order, or spe-
6 cialty pharmacy, with respect to drugs
7 covered by such plan that were dis-
8 pensed, the following information:

9 “(aa) The percentage of
10 total prescriptions that were dis-
11 pensed by pharmacies that are an
12 affiliate of the pharmacy benefit
13 manager for each drug.

14 “(bb) The interquartile
15 range of the total combined costs
16 paid by the plan and plan enroll-
17 ees, per dosage unit, per course
18 of treatment, per 30-day supply,
19 and per 90-day supply for each
20 drug dispensed by pharmacies
21 that are not an affiliate of the
22 pharmacy benefit manager and
23 that are included in the phar-
24 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-

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

4 “(ff) A list of covered part
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 (re-
18 ferred to in this subclause as the ‘list-
19 ed drug’) is covered by the plan, the
20 following information:

21 “(aa) A list of currently
22 marketed generic drugs approved
23 under section 505(j) of the Fed-
24 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-
25 ered part D drugs net of rebates, fees,

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

3 “(VIII) An explanation of any
4 benefit design parameters under such
5 plan that encourage plan enrollees to
6 fill prescriptions at pharmacies that
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
16 referrals, consulting, 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
21 pharmacy benefit manager.

22 “(XI) A summary document sub-
23 mitted in a standardized template de-
24 veloped by the Secretary that includes

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—

4 “(aa) include the manufac-
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 Fi-
16 nancial Officer, or General Coun-
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.

24 “(C) NO INCOME OTHER THAN BONA FIDE
25 SERVICE FEES.—

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

9 “(ii) INCENTIVE PAYMENTS.—For the
10 purposes of this subparagraph, an incen-
11 tive payment paid by a PDP sponsor to a
12 pharmacy benefit manager that is per-
13 forming services on behalf of such sponsor
14 shall be deemed a ‘bona fide service fee’ if
15 such payment is a flat dollar amount, is
16 consistent with fair market value, and is
17 related to services actually performed by
18 the pharmacy benefit manager or affiliate
19 of such pharmacy benefit manager in con-
20 nection with the utilization of covered part
21 D drugs.

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 from manufacturers, even if such
2 price concessions are calculated as a per-
3 centage of a drug’s price, shall not be con-
4 sidered a violation of the requirements of
5 clause (i) if they are fully passed through
6 to a PDP sponsor and exclusively used to
7 lower costs for prescription drugs under
8 this part, including in cases where a PDP
9 sponsor is acting as a pharmacy benefit
10 manager on behalf of a prescription drug
11 plan offered by such PDP sponsor.

12 “(iv) EVALUATION OF REMUNERATION
13 ARRANGEMENTS.—Remuneration arrange-
14 ments between pharmacy benefit managers
15 or affiliates of such pharmacy benefit man-
16 agers, as applicable, and other entities in-
17 volved in the dispensing or utilization of
18 covered part D drugs (including PDP
19 sponsors, manufacturers, pharmacies, and
20 other entities as determined appropriate by
21 the Secretary) shall be subject to review by
22 the Secretary and the Office of the Inspec-
23 tor General of the Department of Health
24 and Human Services. The Secretary, in
25 consultation with the Office of the Inspec-

1 tor General, shall evaluate whether remuneration under such arrangements is consistent with fair market value through reviews and assessments of such remuneration, as determined appropriate.

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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 manager to ensure compliance with all terms
11 and conditions under the written agreement and the accuracy of information reported under subparagraph (B).

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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 (B), 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 (B) 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), subparagraph (C), or
5 the written agreement entered into with
6 such sponsor under this part with respect
7 to a prescription drug 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, 2026, the Secretary shall specify standard,
8 machine-readable formats for pharmacy benefit
9 managers to submit annual reports required under
10 paragraph (1)(B)(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 (B) to the public in a manner
24 that would identify a specific pharmacy benefit
25 manager, affiliate, manufacturer or wholesaler,

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

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

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

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

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

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

6 “(ii) discounts, rebates, fees, or other
7 direct or indirect remuneration amounts
8 with respect to covered part D drugs dis-
9 pensed to enrollees in a prescription drug
10 plan, except as permitted pursuant to
11 paragraph (1)(C)(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 (b) MA–PD PLANS.—Section 1857(f)(3) of the So-
14 cial Security Act (42 U.S.C. 1395w–27(f)(3)) is amended
15 by adding at the end the following new subparagraph:

16 “(F) REQUIREMENTS RELATING TO PHAR-
17 MACY BENEFIT MANAGERS.—For plan years be-
18 ginning on or after January 1, 2027, section
19 1860D–12(h).”.

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

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

1 plans and pharmacy benefit managers related to the
2 transparency of prescription drug costs and prices.

3 Such study shall include an analysis of the following:

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

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

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

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

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

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

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

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

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

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

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

1 (C) any recommendations the Commission
2 determines appropriate.

3 (2) Not later than March 31, 2029, a report de-
4 scribing any changes with respect to the information
5 described in paragraph (1) over time, together with
6 any recommendations the Commission determines
7 appropriate.

8 (e) FUNDING.—There are appropriated, out of any
9 monies in the Treasury not otherwise obligated,
10 \$55,000,000 for fiscal year 2026, to remain available until
11 expended, to the Secretary of Health and Human Services
12 for purposes of carrying out the amendments made by
13 subsections (a) and (b).

14 **SEC. 203. ENHANCING PBM TRANSPARENCY REQUIRE-**
15 **MENTS.**

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

18 (1) by striking subsection (a) and inserting the
19 following:

20 “(a) PROVISION OF INFORMATION.—

21 “(1) IN GENERAL.—The following entities shall
22 provide the information described in subsection (b)
23 to the Secretary and, in the case of an entity de-
24 scribed in subparagraph (B) or an affiliate of such
25 entity described in subparagraph (C), to the health

1 benefits plan with which the entity is under contract,
2 at such times, and in such form and manner, as the
3 Secretary shall specify:

4 “(A) A health benefits plan.

5 “(B) Any entity that provides pharmacy
6 benefits management services on behalf of a
7 health benefits plan (in this section referred to
8 as a ‘PBM’) that manages prescription drug
9 coverage under a contract with—

10 “(i) a PDP sponsor of a prescription
11 drug plan or an MA organization offering
12 an MA–PD plan under part D of title
13 XVIII; or

14 “(ii) a qualified health benefits plan
15 offered through an exchange established by
16 a State under section 1311 of the Patient
17 Protection and Affordable Care Act.

18 “(C) Any affiliate of an entity described in
19 subparagraph (B) that acts as a price nego-
20 tiator or group purchaser on behalf of such
21 PBM, PDP sponsor, MA organization, or quali-
22 fied health benefits plan.

23 “(2) AFFILIATE DEFINED.—In this section, the
24 term ‘affiliate’ means any entity that is owned by,
25 controlled by, or related under a common ownership

1 structure with a PBM (including an entity owned or
2 controlled by the PDP sponsor of a prescription
3 drug plan, MA organization offering an MA–PD
4 plan, or qualified health benefits plan for which such
5 entity is acting as a price negotiator or group pur-
6 chaser).”;

7 (2) in subsection (b)—

8 (A) in paragraph (2), by inserting “and
9 percentage” after “and the aggregate amount”;
10 and

11 (B) by adding at the end the following new
12 paragraph:

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

21 (3) by adding at the end the following new sub-
22 section:

23 “(e) ANNUAL REPORT.—The Secretary shall make
24 publicly available on the Internet website of the Centers
25 for Medicare & Medicaid Services an annual report that

1 summarizes the trends observed with respect to data re-
2 ported under subsection (b).”.

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

6 (c) IMPLEMENTATION.—Notwithstanding any other
7 provision of law, the Secretary may implement the amend-
8 ments made by this section by program instruction or oth-
9 erwise.

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

