

Union Calendar No. 786

118TH CONGRESS
2D SESSION

H. R. 8261

[Report No. 118-891, Part I]

To amend title XVIII of the Social Security Act to extend certain flexibilities and payment adjustments under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2024

Mr. SCHWEIKERT (for himself and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

DECEMBER 17, 2024

Reported from the Committee on Ways and Means with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

DECEMBER 17, 2024

Referral to the Committee on Energy and Commerce extended for a period ending not later than December 19, 2024

DECEMBER 19, 2024

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on May 7, 2024]

A BILL

To amend title XVIII of the Social Security Act to extend certain flexibilities and payment adjustments under the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Preserving Telehealth,*
5 *Hospital, and Ambulance Access Act”.*

6 **TITLE I—PRESERVING PA-**
7 **TIENTS’ ACCESS TO CARE IN**
8 **THE HOME**

9 **SEC. 101. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILI-**
10 **TIES.**

11 (a) *REMOVING GEOGRAPHIC REQUIREMENTS AND EX-*
12 *PANDING ORIGINATING SITES FOR TELEHEALTH SERV-*
13 *ICES.—Section 1834(m) of the Social Security Act (42*
14 *U.S.C. 1395m(m)) is amended—*

15 (1) *in paragraph (2)(B)(iii), by striking “ending*
16 *December 31, 2024” and inserting “ending December*
17 *31, 2026”; and*

18 (2) *in paragraph (4)(C)(iii), by striking “ending*
19 *on December 31, 2024” and inserting “ending on De-*
20 *cember 31, 2026”.*

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

1 (c) *EXTENDING TELEHEALTH SERVICES FOR FEDER-*
2 *ALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH*
3 *CLINICS.*—Section 1834(m)(8)(A) of the Social Security
4 Act (42 U.S.C. 1395m(m)(8)(A)) is amended by striking
5 “ending on December 31, 2024” and inserting “ending on
6 December 31, 2026”.

7 (d) *DELAYING THE IN-PERSON REQUIREMENTS*
8 *UNDER MEDICARE FOR MENTAL HEALTH SERVICES FUR-*
9 *NISHED THROUGH TELEHEALTH AND TELECOMMUNI-*
10 *CATIONS TECHNOLOGY.*—

11 (1) *DELAY IN REQUIREMENTS FOR MENTAL*
12 *HEALTH SERVICES FURNISHED THROUGH TELE-*
13 *HEALTH.*—Section 1834(m)(7)(B)(i) of the Social Se-
14 *curity Act (42 U.S.C. 1395m(m)(7)(B)(i)) is amend-*
15 *ed, in the matter preceding subclause (I), by striking*
16 *“on or after” and all that follows through “described*
17 *in section 1135(g)(1)(B)” and inserting “on or after*
18 *January 1, 2027”.*

19 (2) *MENTAL HEALTH VISITS FURNISHED BY*
20 *RURAL HEALTH CLINICS.*—Section 1834(y)(2) of the
21 *Social Security Act (42 U.S.C. 1395m(y)(2)) is*
22 *amended by striking “January 1, 2025” and all that*
23 *follows through the period at the end and inserting*
24 *“January 1, 2027.”*

1 (3) *MENTAL HEALTH VISITS FURNISHED BY FED-*
2 *ERALLY QUALIFIED HEALTH CENTERS.*—*Section*
3 *1834(o)(4)(B) of the Social Security Act (42 U.S.C.*
4 *1395m(o)(4)(B)) is amended by striking “January 1,*
5 *2025” and all that follows through the period at the*
6 *end and inserting “January 1, 2027.”.*

7 (e) *ALLOWING FOR THE FURNISHING OF AUDIO-ONLY*
8 *TELEHEALTH SERVICES.*—*Section 1834(m)(9) of the Social*
9 *Security Act (42 U.S.C. 1395m(m)(9)) is amended by strik-*
10 *ing “ending on December 31, 2024” and inserting “ending*
11 *on December 31, 2026”.*

12 (f) *EXTENDING USE OF TELEHEALTH TO CONDUCT*
13 *FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION*
14 *OF ELIGIBILITY FOR HOSPICE CARE.*—*Section*
15 *1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C.*
16 *1395f(a)(7)(D)(i)(II)) is amended—*

17 (1) *by striking “ending on December 31, 2024”*
18 *and inserting “ending on December 31, 2026”; and*
19 (2) *by inserting “; except that this subclause*
20 *shall not apply in the case of such an encounter with*
21 *an individual occurring on or after January 1, 2025,*
22 *if such individual is located in an area that is subject*
23 *to a moratorium on the enrollment of hospice pro-*
24 *grams under this title pursuant to section 1866(j)(7),*
25 *if such individual is receiving hospice care from a*

1 provider that is subject to enhanced oversight under
 2 this title pursuant to section 1866(j)(3), or if such en-
 3 counter is performed by a hospice physician or nurse
 4 practitioner who is not enrolled under section 1866(j)
 5 and is not an opt-out physician or practitioner (as
 6 defined in section 1802(b)(6)(D))” before the semi-
 7 colon.

8 (g) *PROGRAM INSTRUCTION AUTHORITY.*—The Sec-
 9 retary of Health and Human Services may implement the
 10 amendments made by this section through program instruc-
 11 tion or otherwise.

12 **SEC. 102. GUIDANCE ON FURNISHING SERVICES VIA TELE-**
 13 **HEALTH TO INDIVIDUALS WITH LIMITED**
 14 **ENGLISH PROFICIENCY.**

15 (a) *IN GENERAL.*—Not later than 1 year after the date
 16 of the enactment of this section, the Secretary of Health and
 17 Human Services, in consultation with 1 or more entities
 18 from each of the categories described in paragraphs (1)
 19 through (7) of subsection (b), shall issue and disseminate,
 20 or update and revise as applicable, guidance for the entities
 21 described in such subsection on the following:

22 (1) Best practices on facilitating and integrating
 23 use of interpreters during a telemedicine appoint-
 24 ment.

1 (2) *Best practices on providing accessible in-*
2 *structions on how to access telecommunications sys-*
3 *tems (as such term is used for purposes of section*
4 *1834(m) of the Social Security Act (42 U.S.C.*
5 *1395m(m)) for individuals with limited English pro-*
6 *ficiency.*

7 (3) *Best practices on improving access to digital*
8 *patient portals for individuals with limited English*
9 *proficiency.*

10 (4) *Best practices on integrating the use of video*
11 *platforms that enable multi-person video calls fur-*
12 *nished via a telecommunications system for purposes*
13 *of providing interpretation during a telemedicine ap-*
14 *pointment for an individual with limited English*
15 *proficiency.*

16 (5) *Best practices for providing patient mate-*
17 *rials, communications, and instructions in multiple*
18 *languages, including text message appointment re-*
19 *minders and prescription information.*

20 (b) *ENTITIES DESCRIBED.—For purposes of subsection*
21 *(a), an entity described in this subsection is an entity in*
22 *1 or more of the following categories:*

23 (1) *Health information technology service pro-*
24 *viders, including—*

25 (A) *electronic medical record companies;*

1 (B) remote patient monitoring companies;

2 and

3 (C) telehealth or mobile health vendors and

4 companies.

5 (2) Health care providers, including—

6 (A) physicians; and

7 (B) hospitals.

8 (3) Health insurers.

9 (4) Language service companies.

10 (5) Interpreter or translator professional associations.

11 (6) Health and language services quality certification organizations.

12 (7) Patient and consumer advocates, including such advocates that work with individuals with limited English proficiency.

13 **SEC. 103. ESTABLISHMENT OF MODIFIER FOR RECERTIFICATIONS OF HOSPICE CARE ELIGIBILITY CONDUCTED THROUGH TELEHEALTH.**

14 Section 1814(a)(7)(D)(i)(II) of the Social Security Act

15 (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by section

16 101(f), is further amended by inserting “, provided that,

17 in the case of such an encounter occurring on or after the

18 date that is 2 years after the date of the enactment of the

19 ‘Preserving Telehealth, Hospital, and Ambulance Access

1 *Act', such physician or nurse practitioner includes in any*
2 *claim for such encounter one or more modifiers or codes*
3 *specified by the Secretary to indicate that such encounter*
4 *was furnished through telehealth" after "as determined ap-*
5 *propriate by the Secretary".*

6 **SEC. 104. EXTENDING ACUTE HOSPITAL CARE AT HOME**

7 **WAIVER FLEXIBILITIES.**

8 *Section 1866G of the Social Security Act (42 U.S.C.*
9 *1395cc-7) is amended—*

10 *(1) in subsection (a)(1), by striking "2024" and*
11 *inserting "2029"; and*

12 *(2) in subsection (b)—*

13 *(A) in the header, by striking "STUDY AND*
14 *REPORT" and inserting "STUDIES AND RE-*
15 *PORTS";*

16 *(B) in paragraph (1)—*

17 *(i) in the matter preceding subparagraph (A), by striking "The Secretary" and*
18 *inserting "Not later than September 30,*
19 *2024, and again not later than September*
20 *30, 2028, the Secretary";*

21 *(ii) in clause (iv), by striking "and" at*
22 *the end;*

23 *(iii) in clause (v), by striking the pe-*
24 *riod and inserting ";" and"; and*

1 (iv) by adding at the end the following
2 new clause:

3 “(vi) in the case of the second study
4 conducted under this paragraph, the quality
5 of care, outcomes, costs, quantity and inten-
6 sity of services, and other relevant metrics
7 between individuals who entered into the
8 Acute Hospital Care at Home initiative di-
9 rectly from an emergency department com-
10 pared with individuals who entered into the
11 Acute Hospital Care at Home initiative di-
12 rectly from an existing inpatient stay in a
13 hospital.”; and

14 (C) in paragraph (2)—

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

17 (ii) by inserting “and again not later
18 than September 30, 2028,” after “2024,”;
19 and

20 (iii) by striking “on the study con-
21 ducted under paragraph (1).” and inserting
22 the following: “on—

23 “(A) with respect to the first report sub-
24 mitted under this paragraph, the first study con-
25 ducted under paragraph (1); and

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

4 **SEC. 105. REPORT ON WEARABLE MEDICAL DEVICES.**

5 Not later than 18 months after the date of the enact-
6 ment of this Act, the Comptroller General of the United
7 States shall conduct a technology assessment of, and submit
8 to Congress a report on, the capabilities and limitations
9 of wearable medical devices used to support clinical deci-
10 sion-making. Such report shall include a description of—

11 (1) the potential for such devices to accurately
12 prescribe treatments;

13 (2) an examination of the benefits and challenges
14 of artificial intelligence to augment such capabilities;
15 and

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

19 **SEC. 106. ENHANCING CERTAIN PROGRAM INTEGRITY RE-
20 QUIREMENTS FOR DME UNDER MEDICARE.**

21 (a) **DURABLE MEDICAL EQUIPMENT.**—Section
22 1834(a) of the Social Security Act (42 U.S.C. 1395m(a))
23 is amended by adding at the end the following new para-
24 graph:

1 “(23) *MASTER LIST INCLUSION AND CLAIM RE-*
2 *VIEW FOR CERTAIN ITEMS.*—

3 “(A) *MASTER LIST INCLUSION.*—Beginning
4 *January 1, 2027, for purposes of the Master List*
5 *described in section 414.234(b) of title 42, Code*
6 *of Federal Regulations (or any successor regula-*
7 *tion), an item for which payment may be made*
8 *under this subsection shall be treated as having*
9 *aberrant billing patterns (as such term is used*
10 *for purposes of such section) if the Secretary de-*
11 *termines that, without explanatory contributing*
12 *factors (such as furnishing emergent care serv-*
13 *ices), a substantial number of claims for such*
14 *items under this subsection are from an ordering*
15 *physician or practitioner with whom the indi-*
16 *vidual involved does not have a prior relation-*
17 *ship, as determined on the basis of claims.*

18 “(B) *CLAIM REVIEW.*—With respect to items
19 *furnished on or after January 1, 2027 that are*
20 *included on the Master List pursuant to sub-*
21 *paragraph (A), if such an item is not subject to*
22 *a determination of coverage in advance pursuant*
23 *to paragraph (15)(C), the Secretary may conduct*
24 *prepayment review of claims for payment for*
25 *such item.”.*

1 (b) *REPORT ON IDENTIFYING CLINICAL DIAGNOSTIC*
2 *LABORATORY TESTS AT HIGH RISK FOR FRAUD AND EF-*
3 *EFFECTIVE MITIGATION MEASURES.*—Not later than January
4 1, 2026, the Inspector General of the Department of Health
5 and Human Services shall submit to Congress a report as-
6 sessing fraudulent claims for clinical diagnostic laboratory
7 tests for which payment may be made under section 1834A
8 of the Social Security Act (42 U.S.C. 1395m–1) and effec-
9 tive tools for reducing such fraudulent claims. The report
10 shall include—

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

15 (2) with respect to a clinical diagnostic labora-
16 tory test identified under subparagraph (A) as being
17 at high risk of fraudulent claims—

18 (A) the amount payable under such section
19 1834A with respect to such test;

20 (B) the number of such tests furnished to
21 individuals enrolled under part B of title XVIII
22 of the Social Security Act (42 U.S.C. 1395j et
23 seq.);

24 (C) whether an order for such a test was
25 more likely to come from a provider with whom

1 *the individual involved did not have a prior re-*
2 *lationship, as determined on the basis of prior*
3 *payment experience; and*

4 *(D) the frequency with which a claim for*
5 *payment under such section 1834A included the*
6 *payment modifier identified by code 59 or 91;*
7 *and*

8 *(3) suggested strategies for reducing the number*
9 *of fraudulent claims made with respect to tests so*
10 *identified as being at high risk, including—*

11 *(A) an analysis of whether the Centers for*
12 *Medicare & Medicaid Services can detect aber-*
13 *rant billing patterns with respect to such tests in*
14 *a timely manner;*

15 *(B) any strategies for identifying and mon-*
16 *itoring the providers who are outliers with re-*
17 *spect to the number of such tests that such pro-*
18 *viders order; and*

19 *(C) targeted education efforts to mitigate*
20 *improper billing for such tests.*

1 **TITLE II—SUSTAINING ACCESS**
2 **TO HOSPITAL AND EMER-**
3 **GENCY SERVICES**

4 **SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL**
5 **PAYMENT ADJUSTMENT FOR CERTAIN LOW-**
6 **VOLUME HOSPITALS.**

7 (a) *IN GENERAL.*—Section 1886(d)(12) of the Social
8 Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

9 (1) in subparagraph (B), by striking “during the
10 portion of fiscal year 2025 beginning on January 1,
11 2025, and ending on September 30, 2025, and”;

12 (2) in subparagraph (C)(i)—

13 (A) in the matter preceding subclause (I)—
14 (i) by striking “or portion of a fiscal
15 year”; and

16 (ii) by striking “2024 and the portion
17 of fiscal year 2025 beginning on October 1,
18 2024, and ending on December 31, 2024”
19 and inserting “2025”;

20 (B) in subclause (III), by striking “2024
21 and the portion of fiscal year 2025 beginning on
22 October 1, 2024, and ending on December 31,
23 2024” and inserting “2025”; and

24 (C) in subclause (IV), by striking “the por-
25 tion of fiscal year 2025 beginning on January 1,

1 *2025, and ending on September 30, 2025, and”;*

2 *and*

3 *(3) in subparagraph (D)—*

4 *(A) in the matter preceding clause (i), by*
5 *striking “2024 or during the portion of fiscal*
6 *year 2025 beginning on October 1, 2024, and*
7 *ending on December 31, 2024” and inserting*
8 *“2025”; and*

9 *(B) in clause (ii), by striking “ 2024 and*
10 *the portion of fiscal year 2025 beginning on Oc-*
11 *tober 1, 2024, and ending on December 31,*
12 *2024” and inserting “2025”.*

13 *(b) IMPLEMENTATION.—Notwithstanding any other*
14 *provision of law, the Secretary of Health and Human Serv-*
15 *ices may implement the provisions of, including the amend-*
16 *ments made by, this section by program instruction or oth-*
17 *erwise.*

18 **SEC. 202. EXTENSION OF THE MEDICARE-DEPENDENT HOS-**
19 **PITAL PROGRAM.**

20 *(a) IN GENERAL.—Section 1886(d)(5)(G) of the Social*
21 *Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amended—*

22 *(1) in clause (i), by striking “January 1, 2025”*
23 *and inserting “October 1, 2025”; and*

24 *(2) in clause (ii)(II), by striking “January 1,*
25 *2025” and inserting “October 1, 2025”.*

1 (b) CONFORMING AMENDMENTS.—

2 (1) EXTENSION OF TARGET AMOUNT.—Section
3 1886(b)(3)(D) of the Social Security Act (42 U.S.C.
4 1395ww(b)(3)(D)) is amended—

5 (A) in the matter preceding clause (i), by
6 striking “January 1, 2025” and inserting “Octo-
7 ber 1, 2025”; and

8 (B) in clause (iv), by striking “2024 and
9 the portion of fiscal year 2025 beginning on Oc-
10 tober 1, 2024, and ending on December 31,
11 2024” and inserting “2025”.

12 (2) PERMITTING HOSPITALS TO DECLINE RE-
13 CLASSIFICATION.—Section 13501(e)(2) of the Omni-
14 bus Budget Reconciliation Act of 1993 (42 U.S.C.
15 1395ww note) is amended by striking “2024, or the
16 portion of fiscal year 2025 beginning on October 1,
17 2024, and ending on December 31, 2024” and insert-
18 ing “2025”.

19 **SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBU-**
20 **LANCE SERVICES.**

21 (a) IN GENERAL.—Section 1834(l) of the Social Secu-
22 rity Act (42 U.S.C. 1395m(l)) is amended—

23 (1) in paragraph (12)(A), by striking “January
24 1, 2025” and inserting “October 1, 2025”; and

1 (2) in paragraph (13), by striking “January 1,
2 2025” in each place it appears and inserting “Octo-
3 ber 1, 2025” in each such place.

4 (b) **PROGRAM INSTRUCTION AUTHORITY.**—Notwith-
5 standing any other provision of law, the Secretary of
6 Health and Human Services may implement the provisions
7 of, including amendments made by, this section through
8 program instruction or otherwise.

9 **TITLE III—OFFSETS**

10 **SEC. 301. REVISING PHASE-IN OF MEDICARE CLINICAL LAB- 11 ORATORY TEST PAYMENT CHANGES.**

12 (a) **REVISED PHASE-IN OF REDUCTIONS FROM PRI-
13 VATE PAYOR RATE IMPLEMENTATION.**—Section
14 1834A(b)(3) of the Social Security Act (42 U.S.C. 1395m–
15 1(b)(3)) is amended—

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

18 (2) in subparagraph (B)—

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

21 (B) in clause (iii), by striking “2025
22 through 2027” and inserting “2026 through
23 2028”.

24 (b) **REVISED REPORTING PERIOD FOR REPORTING OF
25 PRIVATE SECTOR PAYMENT RATES FOR ESTABLISHMENT**

1 OF MEDICARE PAYMENT RATES.—Section 1834A(a)(1)(B)
2 of the Social Security Act (42 U.S.C. 1395m–1(a)(1)(B))
3 is amended—

4 (1) in clause (i), by striking “2024” and inserting
5 “2025”; and

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

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

11 **SEC. 302. ARRANGEMENTS WITH PHARMACY BENEFIT MAN-**
12 **AGERS WITH RESPECT TO PRESCRIPTION**
13 **DRUG PLANS AND MA-PD PLANS.**

14 (a) IN GENERAL.—

15 (1) PRESCRIPTION DRUG PLANS.—Section
16 1860D–12 of the Social Security Act (42 U.S.C.
17 1395w–112) is amended by adding at the end the fol-
18 lowing new subsection:

19 “(h) REQUIREMENTS RELATING TO PHARMACY BEN-
20 EFIT MANAGERS.—For plan years beginning on or after
21 January 1, 2027:

22 “(1) AGREEMENTS WITH PHARMACY BENEFIT
23 MANAGERS.—Each contract entered into with a PDP
24 sponsor under this part with respect to a prescription
25 drug plan offered by such sponsor shall provide that

1 *any pharmacy benefit manager acting on behalf of*
2 *such sponsor has a written agreement with the PDP*
3 *sponsor under which the pharmacy benefit manager,*
4 *and any affiliates of such pharmacy benefit manager,*
5 *as applicable, agree to meet the following require-*
6 *ments:*

7 “(A) NO INCOME OTHER THAN BONA FIDE
8 SERVICE FEES.—

9 “(i) IN GENERAL.—*The pharmacy ben-*
10 *efit manager and any affiliate of such phar-*
11 *macy benefit manager shall not derive any*
12 *remuneration with respect to any services*
13 *provided on behalf of any entity or indi-*
14 *vidual, in connection with the utilization of*
15 *covered part D drugs, from any such entity*
16 *or individual other than bona fide service*
17 *fees, subject to clauses (ii) and (iii).*

18 “(ii) INCENTIVE PAYMENTS.—*For the*
19 *purposes of this subsection, an incentive*
20 *payment paid by a PDP sponsor to a phar-*
21 *macy benefit manager that is performing*
22 *services on behalf of such sponsor shall be*
23 *deemed a ‘bona fide service fee’(even if such*
24 *payment does not otherwise meet the defini-*
25 *tion of such term under paragraph (7)(B))*

1 *if such payment is a flat dollar amount, is*
2 *consistent with fair market value (as speci-*
3 *fied by the Secretary), is related to services*
4 *actually performed by the pharmacy benefit*
5 *manager or affiliate of such pharmacy ben-*
6 *efit manager, on behalf of the entity making*
7 *such payment, in connection with the utili-*
8 *zation of covered part D drugs, and meets*
9 *additional requirements, if any, as deter-*
10 *mined appropriate by the Secretary.*

11 “*(iii) CLARIFICATION ON REBATES AND*
12 *DISCOUNTS USED TO LOWER COSTS FOR*
13 *COVERED PART D DRUGS.—Rebates, dis-*
14 *counts, and other price concessions received*
15 *by a pharmacy benefit manager or an affil-*
16 *iate of a pharmacy benefit manager from*
17 *manufacturers, even if such price conces-*
18 *sions are calculated as a percentage of a*
19 *drug’s price, shall not be considered a viola-*
20 *tion of the requirements of clause (i) if they*
21 *are fully passed through to a PDP sponsor*
22 *and are compliant with all regulatory and*
23 *subregulatory requirements related to direct*
24 *and indirect remuneration for manufac-*
25 *turer rebates under this part, including in*

1 *cases where a PDP sponsor is acting as a*
2 *pharmacy benefit manager on behalf of a*
3 *prescription drug plan offered by such PDP*
4 *sponsor.*

5 “*(iv) EVALUATION OF REMUNERATION*
6 *ARRANGEMENTS.—Components of subsets of*
7 *remuneration arrangements (such as fees or*
8 *other forms of compensation paid to or re-*
9 *tained by the pharmacy benefit manager or*
10 *affiliate of such pharmacy benefit manager),*
11 *as determined appropriate by the Secretary,*
12 *between pharmacy benefit managers or af-*
13 *filiates of such pharmacy benefit managers,*
14 *as applicable, and other entities involved in*
15 *the dispensing or utilization of covered part*
16 *D drugs (including PDP sponsors, manu-*
17 *facturers, pharmacies, and other entities as*
18 *determined appropriate by the Secretary)*
19 *shall be subject to review by the Secretary,*
20 *in consultation with the Office of the In-*
21 *spector General of the Department of Health*
22 *and Human Services, as determined appro-*
23 *priate by the Secretary. The Secretary, in*
24 *consultation with the Office of the Inspector*
25 *General, shall review whether remuneration*

1 *under such arrangements is consistent with*
2 *fair market value (as specified by the Sec-*
3 *retary) through reviews and assessments of*
4 *such remuneration, as determined appro-*
5 *priate.*

6 “(v) *DISGORGEMENT.*—*The pharmacy*
7 *benefit manager shall disgorge any remu-*
8 *neration paid to such pharmacy benefit*
9 *manager or an affiliate of such pharmacy*
10 *benefit manager in violation of this sub-*
11 *paragraph to the PDP sponsor.*

12 “(vi) *ADDITIONAL REQUIREMENTS.*—

13 *The pharmacy benefit manager shall—*

14 “(I) *enter into a written agree-*
15 *ment with any affiliate of such phar-*
16 *macy benefit manager, under which the*
17 *affiliate shall identify and disgorge*
18 *any remuneration described in clause*
19 *(v) to the pharmacy benefit manager;*
20 *and*

21 “(II) *attest, subject to any re-*
22 *quirements determined appropriate by*
23 *the Secretary, that the pharmacy ben-*
24 *efit manager has entered into a written*
25 *agreement described in subclause (I)*

1 *with any relevant affiliate of the phar-*
2 *macy benefit manager.*

3 “*(B) TRANSPARENCY REGARDING GUARAN-*
4 *TEES AND COST PERFORMANCE EVALUATIONS.—*

5 *The pharmacy benefit manager shall—*

6 “*(i) define, interpret, and apply, in a*
7 *fully transparent and consistent manner for*
8 *purposes of calculating or otherwise evalu-*
9 *ating pharmacy benefit manager perform-*
10 *ance against pricing guarantees or similar*
11 *cost performance measurements related to*
12 *rebates, discounts, price concessions, or net*
13 *costs, terms such as—*

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

19 “*(II) ‘brand name drug’, in a*
20 *manner consistent with the definition*
21 *of the term under section 423.4 of title*
22 *42, Code of Federal Regulations, or a*
23 *successor regulation;*

24 “*(III) ‘specialty drug’;*

25 “*(IV) ‘rebate’; and*

1 “(V) ‘discount’;

2 “(ii) identify any drugs, claims, or
3 price concessions excluded from any pricing
4 guarantee or other cost performance calcula-
5 tion or evaluation in a clear and consistent
6 manner; and

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

16 “(C) PROVISION OF INFORMATION.—

17 “(i) IN GENERAL.—Not later than July
18 1 of each year, beginning in 2027, the phar-
19 macy benefit manager shall submit to the
20 PDP sponsor, and to the Secretary, a re-
21 port, in accordance with this subparagraph,
22 and shall make such report available to
23 such sponsor at no cost to such sponsor in
24 a format specified by the Secretary under
25 paragraph (5). Each such report shall in-

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

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

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

11 “(bb) *the number of plan en-*
12 *rollees for whom the drug was dis-*
13 *pensed, the total number of pre-*
14 *scription claims for the drug (in-*
15 *cluding original prescriptions and*
16 *refills, counted as separate*
17 *claims), and the total number of*
18 *dosage units of the drug dis-*
19 *pensed;*

20 “(cc) *the number of prescrip-*
21 *tion claims described in item (bb)*
22 *by each type of dispensing chan-*
23 *nel through which the drug was*
24 *dispensed, including retail, mail*
25 *order, specialty pharmacy, long*

1 *term care pharmacy, home infusion*
2 *pharmacy, or other types of*
3 *pharmacies or providers;*

4 “(dd) *the average wholesale*
5 *acquisition cost, listed as cost per*
6 *day’s supply, cost per dosage unit,*
7 *and cost per typical course of*
8 *treatment (as applicable);*

9 “(ee) *the average wholesale*
10 *price for the drug, listed as cost*
11 *per day’s supply, cost per dosage*
12 *unit, and cost per typical course*
13 *of treatment (as applicable);*

14 “(ff) *the total out-of-pocket*
15 *spending by plan enrollees on*
16 *such drug after application of any*
17 *benefits under the plan, including*
18 *plan enrollee spending through co-*
19 *payments, coinsurance, and*
20 *deductibles;*

21 “(gg) *total rebates paid by*
22 *the manufacturer on the drug as*
23 *reported under the Detailed DIR*
24 *Report (or any successor report)*
25 *submitted by such sponsor to the*

1 *Centers for Medicare & Medicaid*
2 *Services;*

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

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

16 “(jj) the average National
17 Average Drug Acquisition Cost
18 (NADAC); and

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

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

7 “(aa) The percentage of total
8 prescriptions that were dispensed
9 by pharmacies that are an affil-
10 iate of the pharmacy benefit man-
11 ager for each drug.

12 “(bb) The interquartile range
13 of the total combined costs paid
14 by the plan and plan enrollees,
15 per dosage unit, per course of
16 treatment, per 30-day supply, and
17 per 90-day supply for each drug
18 dispensed by pharmacies that are
19 not an affiliate of the pharmacy
20 benefit manager and that are in-
21 cluded in the pharmacy network
22 of such plan.

23 “(cc) The interquartile range
24 of the total combined costs paid
25 by the plan and plan enrollees,

1 *per dosage unit, per course of*
2 *treatment, per 30-day supply, and*
3 *per 90-day supply for each drug*
4 *dispensed by pharmacies that are*
5 *an affiliate of the pharmacy ben-*
6 *efit manager and that are in-*
7 *cluded in the pharmacy network*
8 *of such plan.*

9 “(dd) *The lowest total com-*
10 *bined cost paid by the plan and*
11 *plan enrollees, per dosage unit,*
12 *per course of treatment, per 30-*
13 *day supply, and per 90-day sup-*
14 *ply, for each drug that is avail-*
15 *able from any pharmacy included*
16 *in the pharmacy network of such*
17 *plan.*

18 “(ee) *The difference between*
19 *the average acquisition cost of the*
20 *affiliate, such as a pharmacy or*
21 *other entity that acquires pre-*
22 *scription drugs, that initially ac-*
23 *quires the drug and the amount*
24 *reported under subclause (I)(jj)*
25 *for each drug.*

1 “(ff) A list inclusive of the
2 brand name, generic or non-pro-
3 prietary name, and National
4 Drug Code of covered part D
5 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 man-
11 ager had a contract or other ar-
12 rangement with such a covered en-
13 tity 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 (referred
18 to in this subclause as the ‘listed drug’)
19 is covered by the plan, the following
20 information:

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

1 *references such listed drug that*
2 *are not covered by the plan, are*
3 *covered on the same formulary*
4 *tier or a formulary tier typically*
5 *associated with higher cost-shar-*
6 *ing than the listed drug, or are*
7 *subject to utilization management*
8 *that the listed drug is not subject*
9 *to.*

10 “(bb) *The estimated average*
11 *beneficiary cost-sharing under the*
12 *plan for a 30-day supply of the*
13 *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 average*
19 *cost-sharing that a beneficiary*
20 *would have paid for a 30-day*
21 *supply of each of the generic drugs*
22 *described in item (aa), had the*
23 *plan provided coverage for such*
24 *drugs on the same formulary tier*
25 *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 ap-
8 proved under section 505(j) of the
9 Federal Food, Drug, and Cosmetic
10 Act pursuant to an application
11 that references such listed drug.

12 “(IV) Where a reference product
13 (as defined in section 351(i) of the
14 Public Health Service Act) is covered
15 by the plan, the following information:

16 “(aa) A list of currently
17 marketed biosimilar biological
18 products licensed under section
19 351(k) of the Public Health Serv-
20 ice Act pursuant to an applica-
21 tion that refers to such reference
22 product that are not covered by
23 the plan, are covered on the same
24 formulary tier or a formulary tier
25 typically associated with higher

1 *cost-sharing than the reference*
2 *product, or are subject to utiliza-*
3 *tion management that the ref-*
4 *erence product is not subject to.*

5 “(bb) *The estimated average*
6 *beneficiary cost-sharing under the*
7 *plan for a 30-day supply of the*
8 *reference product.*

9 “(cc) *Where a biosimilar bio-*
10 *logical product listed under item*
11 *(aa) is on a formulary tier typi-*
12 *cally associated with higher cost-*
13 *sharing than the listed drug, the*
14 *estimated average cost-sharing*
15 *that a beneficiary would have*
16 *paid for a 30-day supply of each*
17 *of the biosimilar biological prod-*
18 *ucts described in item (aa), had*
19 *the plan provided coverage for*
20 *such products on the same for-*
21 *mulary tier as the reference prod-*
22 *uct.*

23 “(dd) *A written justification*
24 *for providing more favorable cov-*
25 *erage of the reference product than*

1 *the biosimilar biological product*
2 *described in item (aa).*

3 “(ee) *The number of cur-*
4 *rently marketed biosimilar bio-*
5 *logical products licensed under*
6 *section 351(k) of the Public*
7 *Health Service Act, pursuant to*
8 *an application that refers to such*
9 *reference product.*

10 “(V) *Total gross spending on cov-*
11 *ered part D drugs by the plan, not net*
12 *of rebates, fees, discounts, or other di-*
13 *rect or indirect remuneration.*

14 “(VI) *The total amount retained*
15 *by the pharmacy benefit manager or*
16 *an affiliate of such pharmacy benefit*
17 *manager in revenue related to utiliza-*
18 *tion of covered part D drugs under*
19 *that plan, inclusive of bona fide service*
20 *fees.*

21 “(VII) *The total spending on cov-*
22 *ered part D drugs net of rebates, fees,*
23 *discounts, or other direct and indirect*
24 *remuneration by the plan.*

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

9 “(IX) The following information:

10 “(aa) A list of all brokers,
11 consultants, advisors, and audi-
12 tors that receive compensation
13 from the pharmacy benefit man-
14 ager or an affiliate of such phar-
15 macy benefit manager for refer-
16 rals, consulting, auditing, or other
17 services offered to PDP sponsors
18 related to pharmacy benefit man-
19 agement services.

20 “(bb) The amount of com-
21 pensation provided by such phar-
22 macy benefit manager or affiliate
23 to each such broker, consultant,
24 advisor, and auditor.

1 “(cc) The methodology for
2 calculating the amount of com-
3 pensation provided by such phar-
4 macy benefit manager or affiliate,
5 for each such broker, consultant,
6 advisor, and auditor.

7 “(X) A list of all affiliates of the
8 pharmacy benefit manager.

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

14 “(ii) WRITTEN EXPLANATION OF CON-
15 TRACTS OR AGREEMENTS WITH DRUG MANU-
16 FACTURERS.—

17 “(I) IN GENERAL.—The pharmacy
18 benefit manager shall, not later than
19 30 days after the finalization of any
20 contract or agreement between such
21 pharmacy benefit manager or an affil-
22 iate of such pharmacy benefit manager
23 and a drug manufacturer (or sub-
24 sidiary, agent, or entity affiliated with
25 such drug manufacturer) that makes

1 rebates, discounts, payments, or other
2 financial incentives related to one or
3 more covered part D drugs or other
4 prescription drugs, as applicable, of
5 the manufacturer directly or indirectly
6 contingent upon coverage, formulary
7 placement, or utilization management
8 conditions on any other covered part D
9 drugs or other prescription drugs, as
10 applicable, submit to the PDP sponsor
11 a written explanation of such contract
12 or agreement.

13 “(II) REQUIREMENTS.—A written
14 explanation under subclause (I)
15 shall—

16 “(aa) include the manufac-
17 turer subject to the contract or
18 agreement, all covered part D
19 drugs and other prescription
20 drugs, as applicable, subject to the
21 contract or agreement and the
22 manufacturers of such drugs, and
23 a high-level description of the
24 terms of such contract or agree-

1 *ment and how such terms apply*
2 *to such drugs; and*

3 “*(bb) be certified by the Chief*
4 *Executive Officer, Chief Financial*
5 *Officer, or General Counsel of*
6 *such pharmacy benefit manager,*
7 *or affiliate of such pharmacy ben-*
8 *efit manager, as applicable, or an*
9 *individual delegated with the au-*
10 *thority to sign on behalf of one of*
11 *these officers, who reports directly*
12 *to the officer.*

13 “*(III) DEFINITION OF OTHER*
14 *PREScription DRUGS.—For purposes*
15 *of this clause, the term ‘other prescrip-*
16 *tion drugs’ means prescription drugs*
17 *covered as supplemental benefits under*
18 *this part or prescription drugs paid*
19 *outside of this part.*

20 “*(D) AUDIT RIGHTS.—*

21 “*(i) IN GENERAL.—Not less than once*
22 *a year, at the request of the PDP sponsor,*
23 *the pharmacy benefit manager shall allow*
24 *for an audit of the pharmacy benefit man-*
25 *ager to ensure compliance with all terms*

1 *and conditions under the written agreement*
2 *and the accuracy of information reported*
3 *under subparagraph (C).*

4 “(ii) *AUDITOR.*—*The PDP sponsor*
5 *shall have the right to select an auditor. The*
6 *pharmacy benefit manager shall not impose*
7 *any limitations on the selection of such*
8 *auditor.*

9 “(iii) *PROVISION OF INFORMATION.*—
10 *The pharmacy benefit manager shall make*
11 *available to such auditor all records, data,*
12 *contracts, and other information necessary*
13 *to confirm the accuracy of information pro-*
14 *vided under subparagraph (C), subject to*
15 *reasonable restrictions on how such infor-*
16 *mation must be reported to prevent redisclo-*
17 *sure of such information.*

18 “(iv) *TIMING.*—*The pharmacy benefit*
19 *manager must provide information under*
20 *clause (iii) and other information, data,*
21 *and records relevant to the audit to such*
22 *auditor within 6 months of the initiation of*
23 *the audit and respond to requests for addi-*
24 *tional information from such auditor with-*

1 *in 30 days after the request for additional
2 information.*

3 “(v) *INFORMATION FROM AFFILI-
4 ATES.*—*The pharmacy benefit manager
5 shall be responsible for providing to such
6 auditor information required to be reported
7 under subparagraph (C) that is owned or
8 held by an affiliate of such pharmacy ben-
9 efit manager.*

10 “(2) *ENFORCEMENT.*—

11 “(A) *IN GENERAL.*—*Each PDP sponsor
12 shall—*

13 “(i) *disgorge to the Secretary any
14 amounts disgorged to the PDP sponsor by a
15 pharmacy benefit manager under para-
16 graph (1)(A)(v);*

17 “(ii) *require, in a written agreement
18 with any pharmacy benefit manager acting
19 on behalf of such sponsor or affiliate of such
20 pharmacy benefit manager, that such phar-
21 macy benefit manager or affiliate reimburse
22 the PDP sponsor for any civil money pen-
23 alty imposed on the PDP sponsor as a re-
24 sult of the failure of the pharmacy benefit
25 manager or affiliate to meet the require-*

1 *ments of paragraph (1) that are applicable*
2 *to the pharmacy benefit manager or affil-*
3 *iate under the agreement; and*

4 “*(iii) require, in a written agreement*
5 *with any such pharmacy benefit manager*
6 *acting on behalf of such sponsor or affiliate*
7 *of such pharmacy benefit manager, that*
8 *such pharmacy benefit manager or affiliate*
9 *be subject to punitive remedies for breach of*
10 *contract for failure to comply with the re-*
11 *quirements applicable under paragraph (1).*

12 “(B) *REPORTING OF ALLEGED VIOLA-*
13 *TIONS.*—*The Secretary shall make available and*
14 *maintain a mechanism for manufacturers, PDP*
15 *sponsors, pharmacies, and other entities that*
16 *have contractual relationships with pharmacy*
17 *benefit managers or affiliates of such pharmacy*
18 *benefit managers to report, on a confidential*
19 *basis, alleged violations of paragraph (1)(A) or*
20 *subparagraph (C).*

21 “(C) *ANTI-RETALIATION AND ANTI-COER-*
22 *CION.*—*Consistent with applicable Federal or*
23 *State law, a PDP sponsor shall not—*

1 “(i) retaliate against an individual or
2 entity for reporting an alleged violation
3 under subparagraph (B); or

4 “(ii) coerce, intimidate, threaten, or
5 interfere with the ability of an individual
6 or entity to report any such alleged viola-
7 tions.

8 “(3) CERTIFICATION OF COMPLIANCE.—

9 “(A) IN GENERAL.—Each PDP sponsor
10 shall furnish to the Secretary (in a time and
11 manner specified by the Secretary) an annual
12 certification of compliance with this subsection,
13 as well as such information as the Secretary de-
14 termines necessary to carry out this subsection.

15 “(B) IMPLEMENTATION.—Notwithstanding
16 any other provision of law, the Secretary may
17 implement this paragraph by program instruc-
18 tion or otherwise.

19 “(4) RULE OF CONSTRUCTION.—Nothing in this
20 subsection shall be construed as prohibiting payments
21 related to reimbursement for ingredient costs to any
22 entity that acquires prescription drugs, such as a
23 pharmacy or wholesaler.

24 “(5) STANDARD FORMATS.—

1 “(A) *IN GENERAL.*—Not later than June 1,
2 2026, the Secretary shall specify standard, ma-
3 chine-readable formats for pharmacy benefit
4 managers to submit annual reports required
5 under paragraph (1)(C)(i).

6 “(B) *IMPLEMENTATION.*—Notwithstanding
7 any other provision of law, the Secretary may
8 implement this paragraph by program instruc-
9 tion or otherwise.

10 “(6) *CONFIDENTIALITY.*—

11 “(A) *IN GENERAL.*—Information disclosed
12 by a pharmacy benefit manager, an affiliate of
13 a pharmacy benefit manager, a PDP sponsor, or
14 a pharmacy under this subsection that is not
15 otherwise publicly available or available for pur-
16 chase shall not be disclosed by the Secretary or
17 a PDP sponsor receiving the information, except
18 that the Secretary may disclose the information
19 for 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 Director
5 of the Medicare Payment Advisory Commis-
6 sion to review the information provided.

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

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

16 “(B) RESTRICTION ON USE OF INFORMA-
17 TION.—The Secretary, the Comptroller General,
18 the Director of the Congressional Budget Office,
19 and the Executive Director of the Medicare Pay-
20 ment Advisory Commission shall not report on
21 or disclose information disclosed pursuant to
22 subparagraph (A) to the public in a manner that
23 would identify—

1 “(i) a specific pharmacy benefit manager,
2 affiliate, pharmacy, manufacturer,
3 wholesaler, PDP sponsor, or plan; or

4 “(ii) contract prices, rebates, discounts,
5 or other remuneration for specific drugs in
6 a manner that may allow the identification
7 of specific contracting parties or of such
8 specific drugs.

9 “(7) DEFINITIONS.—For purposes of this sub-
10 section:

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

20 “(B) BONA FIDE SERVICE FEE.—The term
21 ‘bona fide service fee’ means a fee that is reflec-
22 tive of the fair market value (as specified by the
23 Secretary) for a bona fide, itemized service actu-
24 ally performed on behalf of an entity, that the
25 entity would otherwise perform (or contract for)

1 *in the absence of the service arrangement and*
2 *that is not passed on in whole or in part to a*
3 *client or customer, whether or not the entity*
4 *takes title to the drug. Such fee must be a flat*
5 *dollar amount and shall not be directly or indi-*
6 *rectly based on, or contingent upon—*

7 “(i) *drug price, such as wholesale ac-*
8 *quisition cost or drug benchmark price*
9 *(such as average wholesale price);*

10 “(ii) *the amount of discounts, rebates,*
11 *fees, or other direct or indirect remunera-*
12 *tion with respect to covered part D drugs*
13 *dispensed to enrollees in a prescription drug*
14 *plan, except as permitted pursuant to para-*
15 *graph (1)(A)(ii);*

16 “(iii) *coverage or formulary placement*
17 *decisions or the volume or value of any re-*
18 *ferrals or business generated between the*
19 *parties to the arrangement; or*

20 “(iv) *any other amounts or methodolo-*
21 *gies prohibited by the Secretary.*

22 “(C) *PHARMACY BENEFIT MANAGER.—The*
23 *term ‘pharmacy benefit manager’ means any*
24 *person or entity that, either directly or through*
25 *an intermediary, acts as a price negotiator or*

1 *group purchaser on behalf of a PDP sponsor or*
2 *prescription drug plan, or manages the prescrip-*
3 *tion drug benefits provided by such sponsor or*
4 *plan, including the processing and payment of*
5 *claims for prescription drugs, the performance of*
6 *drug utilization review, the processing of drug*
7 *prior authorization requests, the adjudication of*
8 *appeals or grievances related to the prescription*
9 *drug benefit, contracting with network phar-*
10 *macies, controlling the cost of covered part D*
11 *drugs, or the provision of related services. Such*
12 *term includes any person or entity that carries*
13 *out one or more of the activities described in the*
14 *preceding sentence, irrespective of whether such*
15 *person or entity calls itself a ‘pharmacy benefit*
16 *manager’.”.*

17 (2) *MA–PD PLANS.—Section 1857(f)(3) of the*
18 *Social Security Act (42 U.S.C. 1395w–27(f)(3)) is*
19 *amended by adding at the end the following new sub-*
20 *paragraph:*

21 “(F) REQUIREMENTS RELATING TO PHAR-
22 MACY BENEFIT MANAGERS.—*For plan years be-*
23 *ginning on or after January 1, 2027, section*
24 *1860D–12(h).”.*

1 (3) NONAPPLICATION OF PAPERWORK REDUCTION

2 *ACT.—Chapter 35 of title 44, United States Code,*
3 *shall not apply to the implementation of this sub-*
4 *section.*

5 (4) FUNDING.—

6 (A) SECRETARY.—*In addition to amounts*
7 *otherwise available, there is appropriated to the*
8 *Centers for Medicare & Medicaid Services Pro-*
9 *gram Management Account, out of any money in*
10 *the Treasury not otherwise appropriated,*
11 *\$113,000,000 for fiscal year 2025, to remain*
12 *available until expended, to carry out this sub-*
13 *section.*

14 (B) OIG.—*In addition to amounts other-*
15 *wise available, there is appropriated to the In-*
16 *spector General of the Department of Health and*
17 *Human Services, out of any money in the Treas-*
18 *ury not otherwise appropriated, \$20,000,000 for*
19 *fiscal year 2025, to remain available until ex-*
20 *pended, to carry out this subsection.*

21 (b) GAO STUDY AND REPORT ON CERTAIN REPORTING
22 REQUIREMENTS.—

23 (1) STUDY.—*The Comptroller General of the*
24 *United States (in this subsection referred to as the*
25 *“Comptroller General”) shall conduct a study on Fed-*

1 *eral and State reporting requirements for health
2 plans and pharmacy benefit managers related to the
3 transparency of prescription drug costs and prices.
4 Such study shall include an analysis of the following:*

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

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

13 *(C) The extent to which the statutory and
14 regulatory reporting requirements identified in
15 subparagraphs (A) and (B) overlap and conflict.*

16 *(D) The resources required by health plans
17 and pharmacy benefit managers to comply with
18 the reporting requirements described in subpara-
19 graphs (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)(C) of the Social
25 Security Act, as added by subsection (a)(1), the*

1 *Comptroller General shall submit to Congress a report*
2 *containing the results of the study conducted under*
3 *paragraph (1), together with recommendations for leg-*
4 *islation and administrative actions that would*
5 *streamline and reduce the burden associated with the*
6 *reporting requirements for health plans and phar-*
7 *macy benefit managers described in paragraph (1).*

8 *(c) MEDPAC REPORTS ON AGREEMENTS WITH PHAR-*
9 *MACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIP-*
10 *TION DRUG PLANS AND MA-PD PLANS.—The Medicare*
11 *Payment Advisory Commission shall submit to Congress the*
12 *following reports:*

13 *(1) Not later than March 31, 2028, a report re-*
14 *garding agreements with pharmacy benefit managers*
15 *with respect to prescription drug plans and MA-PD*
16 *plans. Such report shall include—*

17 *(A) a description of trends and patterns, in-*
18 *cluding relevant averages, totals, and other fig-*
19 *ures for each of the types of information sub-*
20 *mitted;*

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

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

3 (2) Not later than March 31, 2030, 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 ap-
7 propriate.

8 **SEC. 303. EXTENDING THE ADJUSTMENT TO THE CALCULA-**
9 **TION OF HOSPICE CAP AMOUNTS UNDER THE**
10 **MEDICARE PROGRAM.**

11 Section 1814(i)(2)(B) of the Social Security Act (42
12 U.S.C. 1395f(i)(2)(B)) is amended—

13 (1) in clause (ii), by striking “2033” and insert-
14 ing “2034”; and

15 (2) in clause (iii), by striking “2033” and in-
16 serting “2034”.

Union Calendar No. 786

118TH CONGRESS
2D SESSION

H. R. 8261

[Report No. 118-891, Part I]

A BILL

To amend title XVIII of the Social Security Act to extend certain flexibilities and payment adjustments under the Medicare program, and for other purposes.

DECEMBER 19, 2024

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed