

119TH CONGRESS
1ST SESSION

S. _____

To amend title XVIII of the Social Security Act to assure pharmacy access and choice for beneficiaries under prescription drug plans and MA–PD plans and to establish requirements of pharmacy benefit managers under Medicare part D.

IN THE SENATE OF THE UNITED STATES

Mrs. BLACKBURN (for herself, Ms. HASSAN, Mr. LANKFORD, and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to assure pharmacy access and choice for beneficiaries under prescription drug plans and MA–PD plans and to establish requirements of pharmacy benefit managers under Medicare part D.

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 “Patients Before Mid-
5 dlemen Act”.

1 **SEC. 2. ASSURING PHARMACY ACCESS AND CHOICE FOR**
2 **MEDICARE BENEFICIARIES.**

3 (a) IN GENERAL.—Section 1860D–4(b)(1) of the So-
4 cial Security Act (42 U.S.C. 1395w–104(b)(1)) is amend-
5 ed by striking subparagraph (A) and inserting the fol-
6 lowing:

7 “(A) IN GENERAL.—

8 “(i) PARTICIPATION OF ANY WILLING
9 PHARMACY.—A PDP sponsor offering a
10 prescription drug plan shall permit any
11 pharmacy that meets the standard contract
12 terms and conditions under such plan to
13 participate as a network pharmacy of such
14 plan.

15 “(ii) CONTRACT TERMS AND CONDI-
16 TIONS.—

17 “(I) IN GENERAL.—Notwith-
18 standing any other provision of law,
19 for plan years beginning on or after
20 January 1, 2028, in accordance with
21 clause (i), contract terms and condi-
22 tions offered by such PDP sponsor
23 shall be reasonable and relevant ac-
24 cording to standards established by
25 the Secretary under subclause (II).

1 “(II) STANDARDS.—Not later
2 than the first Monday in April of
3 2027, the Secretary shall establish
4 standards for reasonable and relevant
5 contract terms and conditions for pur-
6 poses of this clause.

7 “(III) REQUEST FOR INFORMA-
8 TION.—Not later than April 1, 2026,
9 for purposes of establishing the stand-
10 ards under subclause (II), the Sec-
11 retary shall issue a request for infor-
12 mation to seek input on trends in pre-
13 scription drug plan and network phar-
14 macy contract terms and conditions,
15 current prescription drug plan and
16 network pharmacy contracting prac-
17 tices, whether pharmacy reimburse-
18 ment and dispensing fees paid by
19 PDP sponsors to network pharmacies
20 sufficiently cover the ingredient and
21 operational costs of such pharmacies,
22 the use and application of pharmacy
23 quality measures by PDP sponsors for
24 network pharmacies, PDP sponsor re-
25 strictions or limitations on the dis-

1 pensing of covered part D drugs by
2 network pharmacies (or any subsets of
3 such pharmacies), PDP sponsor au-
4 diting practices for network phar-
5 macies, areas in current regulations or
6 program guidance related to con-
7 tracting between prescription drug
8 plans and network pharmacies requir-
9 ing clarification or additional speci-
10 ficity, factors for consideration in de-
11 termining the reasonableness and rel-
12 evance of contract terms and condi-
13 tions between prescription drug plans
14 and network pharmacies, and other
15 issues as determined appropriate by
16 the Secretary.”.

17 (b) **ESSENTIAL RETAIL PHARMACIES.**—Section
18 1860D–42 of the Social Security Act (42 U.S.C. 1395w–
19 152) is amended by adding at the end the following new
20 subsection:

21 “(e) **ESSENTIAL RETAIL PHARMACIES.**—

22 “(1) **IN GENERAL.**—With respect to plan years
23 beginning on or after January 1, 2028, the Sec-
24 retary shall publish reports, at least once every 2

1 years until 2034, and periodically thereafter, that
2 provide information, to the extent feasible, on—

3 “(A) trends in ingredient cost reimburse-
4 ment, dispensing fees, incentive payments and
5 other fees paid by PDP sponsors offering pre-
6 scription drug plans and MA organizations of-
7 fering MA–PD plans under this part to essen-
8 tial retail pharmacies (as defined in paragraph
9 (2)) with respect to the dispensing of covered
10 part D drugs, including a comparison of such
11 trends between essential retail pharmacies and
12 pharmacies that are not essential retail phar-
13 macies;

14 “(B) trends in amounts paid to PDP spon-
15 sors offering prescription drug plans and MA
16 organizations offering MA–PD plans under this
17 part by essential retail pharmacies with respect
18 to the dispensing of covered part D drugs, in-
19 cluding a comparison of such trends between
20 essential retail pharmacies and pharmacies that
21 are not essential retail pharmacies;

22 “(C) trends in essential retail pharmacy
23 participation in pharmacy networks and pre-
24 ferred pharmacy networks for prescription drug
25 plans offered by PDP sponsors and MA–PD

1 plans offered by MA organizations under this
2 part, including a comparison of such trends be-
3 tween essential retail pharmacies and phar-
4 macies that are not essential retail pharmacies;

5 “(D) trends in the number of essential re-
6 tail pharmacies, including variation in such
7 trends by geographic region or other factors;

8 “(E) a comparison of cost-sharing for cov-
9 ered part D drugs dispensed by essential retail
10 pharmacies that are network pharmacies for
11 prescription drug plans offered by PDP spon-
12 sors and MA–PD plans offered by MA organi-
13 zations under this part and cost-sharing for
14 covered part D drugs dispensed by other net-
15 work pharmacies for such plans located in simi-
16 lar geographic areas that are not essential retail
17 pharmacies;

18 “(F) a comparison of the volume of cov-
19 ered part D drugs dispensed by essential retail
20 pharmacies that are network pharmacies for
21 prescription drug plans offered by PDP spon-
22 sors and MA–PD plans offered by MA organi-
23 zations under this part and such volume of dis-
24 pensing by network pharmacies for such plans
25 located in similar geographic areas that are not

1 essential retail pharmacies, including informa-
2 tion on any patterns or trends in such compari-
3 son specific to certain types of covered part D
4 drugs, such as generic drugs or drugs specified
5 as specialty drugs by a PDP sponsor under a
6 prescription drug plan or an MA organization
7 under an MA–PD plan; and

8 “(G) a comparison of the information de-
9 scribed in subparagraphs (A) through (F) be-
10 tween essential retail pharmacies that are net-
11 work pharmacies for prescription drug plans of-
12 fered by PDP sponsors under this part and es-
13 sential retail pharmacies that are network phar-
14 macies for MA–PD plans offered by MA organi-
15 zations under this part.

16 “(2) DEFINITION OF ESSENTIAL RETAIL PHAR-
17 MACY.—In this subsection, the term ‘essential retail
18 pharmacy’ means, with respect to a plan year, a re-
19 tail pharmacy that—

20 “(A) is not a pharmacy that is an affiliate
21 as defined in paragraph (4); and

22 “(B) is located in—

23 “(i) a medically underserved area (as
24 designated pursuant to section

1 330(b)(3)(A) of the Public Health Service
2 Act);

3 “(ii) a rural area in which there is no
4 other retail pharmacy within 10 miles, as
5 determined by the Secretary;

6 “(iii) a suburban area in which there
7 is no other retail pharmacy within 2 miles,
8 as determined by the Secretary; or

9 “(iv) an urban area in which there is
10 no other retail pharmacy within 1 mile, as
11 determined by the Secretary.

12 “(3) LIST OF ESSENTIAL RETAIL PHAR-
13 MACIES.—

14 “(A) PUBLICATION OF LIST OF ESSENTIAL
15 RETAIL PHARMACIES.—For each plan year (be-
16 ginning with plan year 2028), the Secretary
17 shall publish, on a publicly available internet
18 website of the Centers for Medicare & Medicaid
19 Services, a list of pharmacies that meet the cri-
20 teria described in subparagraphs (A) and (B) of
21 paragraph (2) to be considered an essential re-
22 tail pharmacy.

23 “(B) REQUIRED SUBMISSIONS FROM PDP
24 SPONSORS.—For each plan year (beginning
25 with plan year 2028), each PDP sponsor offer-

1 ing a prescription drug plan and each MA orga-
2 nization offering an MA–PD plan shall submit
3 to the Secretary, for the purposes of deter-
4 mining retail pharmacies that meet the criterion
5 specified in subparagraph (A) of paragraph (2),
6 a list of retail pharmacies that are affiliates of
7 such sponsor or organization, or are affiliates of
8 a pharmacy benefit manager acting on behalf of
9 such sponsor or organization, at a time, and in
10 a form and manner, specified by the Secretary.

11 “(C) REPORTING BY PDP SPONSORS AND
12 MA ORGANIZATIONS.—For each plan year be-
13 ginning with plan year 2027, each PDP sponsor
14 offering a prescription drug plan and each MA
15 organization offering an MA–PD plan under
16 this part shall submit to the Secretary informa-
17 tion on incentive payments and other fees paid
18 by such sponsor or organization to pharmacies,
19 insofar as any such payments or fees are not
20 otherwise reported, at a time, and in a form
21 and manner, specified by the Secretary.

22 “(D) IMPLEMENTATION.—Notwithstanding
23 any other provision of law, the Secretary may
24 implement this paragraph by program instruc-
25 tion or otherwise.

1 Secretary an allegation of a violation
2 by a PDP sponsor offering a prescrip-
3 tion drug plan of the standards for
4 reasonable and relevant contract
5 terms and conditions under subpara-
6 graph (A)(ii), or of subclause (VIII)
7 of this clause.

8 “(II) FREQUENCY OF SUBMIS-
9 SION.—

10 “(aa) IN GENERAL.—Except
11 as provided in item (bb), the alle-
12 gation submission process under
13 this clause shall allow pharmacies
14 to submit any allegations of vio-
15 lations described in subclause (I)
16 not more frequently than once
17 per plan year per contract be-
18 tween a pharmacy and a PDP
19 sponsor.

20 “(bb) ALLEGATIONS RELAT-
21 ING TO CONTRACT MODIFICA-
22 TIONS.—In the case where a con-
23 tract between a pharmacy and a
24 PDP sponsor is modified fol-
25 lowing the submission of allega-

1 tions by a pharmacy with respect
2 to such contract and plan year,
3 the allegation submission process
4 under this clause shall allow such
5 pharmacy to submit an additional
6 allegation related to those modi-
7 fications with respect to such
8 contract and plan year.

9 “(III) ACCESS TO RELEVANT
10 DOCUMENTS AND MATERIALS.—A
11 PDP sponsor subject to an allegation
12 under this clause—

13 “(aa) shall provide docu-
14 ments or materials, as specified
15 by the Secretary, including con-
16 tract offers made by such spon-
17 sor to such pharmacy or cor-
18 respondence related to such of-
19 fers, to the Secretary at a time,
20 and in a form and manner, speci-
21 fied by the Secretary; and

22 “(bb) shall not prohibit or
23 otherwise limit the ability of a
24 pharmacy to submit such docu-
25 ments or materials to the Sec-

1 retary for the purpose of submit-
2 ting an allegation or providing
3 evidence for such an allegation
4 under this clause.

5 “(IV) STANDARDIZED TEM-
6 PLATE.—The Secretary shall establish
7 a standardized template for phar-
8 macies to use for the submission of al-
9 legations described in subclause (I).
10 Such template shall require that the
11 submission include a certification by
12 the pharmacy that the information in-
13 cluded is accurate, complete, and true
14 to the best of the knowledge, informa-
15 tion, and belief of such pharmacy.

16 “(V) PREVENTING FRIVOLOUS
17 ALLEGATIONS.—In the case where the
18 Secretary determines that a pharmacy
19 has submitted frivolous allegations
20 under this clause on a routine basis,
21 the Secretary may temporarily pro-
22 hibit such pharmacy from using the
23 allegation submission process under
24 this clause, as determined appropriate
25 by the Secretary.

1 “(VI) EXEMPTION FROM FREE-
2 DOM OF INFORMATION ACT.—Allega-
3 tions submitted under this clause shall
4 be exempt from disclosure under sec-
5 tion 552 of title 5, United States
6 Code.

7 “(VII) RULE OF CONSTRUC-
8 TION.—Nothing in this clause shall be
9 construed as limiting the ability of a
10 pharmacy to pursue other legal ac-
11 tions or remedies, consistent with ap-
12 plicable Federal or State law, with re-
13 spect to a potential violation of a re-
14 quirement described in this subpara-
15 graph.

16 “(VIII) ANTI-RETALIATION AND
17 ANTI-COERCION.—Consistent with ap-
18 plicable Federal or State law, a PDP
19 sponsor shall not—

20 “(aa) retaliate against a
21 pharmacy for submitting any al-
22 legations under this clause; or

23 “(bb) coerce, intimidate,
24 threaten, or interfere with the

1 ability of a pharmacy to submit
2 any such allegations.

3 “(ii) INVESTIGATION.—The Secretary
4 shall investigate, as determined appro-
5 priate by the Secretary, allegations sub-
6 mitted pursuant to clause (i).

7 “(iii) ENFORCEMENT.—

8 “(I) IN GENERAL.—In the case
9 where the Secretary determines that a
10 PDP sponsor offering a prescription
11 drug plan has violated the standards
12 for reasonable and relevant contract
13 terms and conditions under subpara-
14 graph (A)(ii), the Secretary may use
15 authorities under sections 1857(g)
16 and 1860D–12(b)(3)(E) to impose
17 civil monetary penalties or other inter-
18 mediate sanctions.

19 “(II) APPLICATION OF CIVIL
20 MONETARY PENALTIES.—The provi-
21 sions of section 1128A (other than
22 subsections (a) and (b)) shall apply to
23 a civil monetary penalty under this
24 clause in the same manner as such

1 provisions apply to a penalty or pro-
2 ceeding under section 1128A(a).”.

3 (2) CONFORMING AMENDMENT.—Section
4 1857(g)(1) of the Social Security Act (42 U.S.C.
5 1395w–27(g)(1)) is amended—

6 (A) in subparagraph (J), by striking “or”
7 after the semicolon;

8 (B) by redesignating subparagraph (K) as
9 subparagraph (L);

10 (C) by inserting after subparagraph (J),
11 the following new subparagraph:

12 “(K) fails to comply with the standards for
13 reasonable and relevant contract terms and con-
14 ditions under subparagraph (A)(ii) of section
15 1860D–4(b)(1); or”;

16 (D) in subparagraph (L), as redesignated
17 by subparagraph (B), by striking “through (J)”
18 and inserting “through (K)”; and

19 (E) in the flush matter following subpara-
20 graph (L), as so redesignated, by striking “sub-
21 paragraphs (A) through (K)” and inserting
22 “subparagraphs (A) through (L)”.

23 (d) ACCOUNTABILITY OF PHARMACY BENEFIT MAN-
24 AGERS FOR VIOLATIONS OF REASONABLE AND RELEVANT
25 CONTRACT TERMS AND CONDITIONS.—

1 (1) IN GENERAL.—Section 1860D–12(b) of the
2 Social Security Act (42 U.S.C. 1395w–112) is
3 amended by adding at the end the following new
4 paragraph:

5 “(9) ACCOUNTABILITY OF PHARMACY BENEFIT
6 MANAGERS FOR VIOLATIONS OF REASONABLE AND
7 RELEVANT CONTRACT TERMS AND CONDITIONS.—
8 For plan years beginning on or after January 1,
9 2028, each contract entered into with a PDP spon-
10 sor under this part with respect to a prescription
11 drug plan offered by such sponsor shall provide that
12 any pharmacy benefit manager acting on behalf of
13 such sponsor has a written agreement with the PDP
14 sponsor under which the pharmacy benefit manager
15 agrees to reimburse the PDP sponsor for any
16 amounts paid by such sponsor under section 1860D–
17 4(b)(1)(F)(iii)(I) to the Secretary as a result of a
18 violation described in such section if such violation
19 is related to a responsibility delegated to the phar-
20 macy benefit manager by such PDP sponsor.”.

21 (2) MA–PD PLANS.—Section 1857(f)(3) of the
22 Social Security Act (42 U.S.C. 1395w–27(f)(3)) is
23 amended by adding at the end the following new
24 subparagraph:

1 “(F) ACCOUNTABILITY OF PHARMACY
2 BENEFIT MANAGERS FOR VIOLATIONS OF REA-
3 SONABLE AND RELEVANT CONTRACT TERMS.—
4 For plan years beginning on or after January
5 1, 2028, section 1860D–12(b)(9).”.

6 (e) BIENNIAL REPORT ON ENFORCEMENT AND
7 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—
8 Section 1860D–42 of the Social Security Act (42 U.S.C.
9 1395w–152), as amended by subsection (b), is amended
10 by adding at the end the following new subsection:

11 “(f) BIENNIAL REPORT ON ENFORCEMENT AND
12 OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.—

13 “(1) IN GENERAL.—Not later than 2 years
14 after the date of enactment of this subsection, and
15 at least once every 2 years thereafter, the Secretary
16 shall publish a report on enforcement and oversight
17 actions and activities undertaken by the Secretary
18 with respect to the requirements under section
19 1860D–4(b)(1).

20 “(2) LIMITATION.—A report under paragraph
21 (1) shall not disclose—

22 “(A) identifiable information about individ-
23 uals or entities unless such information is oth-
24 erwise publicly available; or

1 “(B) trade secrets with respect to any enti-
2 ties.”.

3 **SEC. 3. REQUIREMENTS OF PHARMACY BENEFIT MAN-**
4 **AGERS UNDER MEDICARE PART D.**

5 (a) PRESCRIPTION DRUG PLANS.—Section 1860D–
6 12 of the Social Security Act (42 U.S.C. 1395w–112) is
7 amended by adding at the end the following new sub-
8 section:

9 “(h) REQUIREMENTS RELATING TO PHARMACY BEN-
10 EFIT MANAGERS.—For plan years beginning on or after
11 January 1, 2028:

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

22 “(A) NO INCOME OTHER THAN BONA FIDE
23 SERVICE FEES.—

24 “(i) IN GENERAL.—The pharmacy
25 benefit manager and any affiliate of such

1 pharmacy benefit manager shall not derive
2 any remuneration with respect to any serv-
3 ices provided on behalf of any entity or in-
4 dividual, in connection with the utilization
5 of covered part D drugs, from any such en-
6 tity or individual other than bona fide serv-
7 ice fees, subject to clauses (ii) and (iii).

8 “(ii) INCENTIVE PAYMENTS.—For the
9 purposes of this subsection, an incentive
10 payment (as determined by the Secretary)
11 paid by a PDP sponsor to a pharmacy
12 benefit manager that is performing serv-
13 ices on behalf of such sponsor shall be
14 deemed a ‘bona fide service fee’ (even if
15 such payment does not otherwise meet the
16 definition of such term under paragraph
17 (7)(B)) if such payment is a flat dollar
18 amount, is consistent with fair market
19 value (as specified by the Secretary), is re-
20 lated to services actually performed by the
21 pharmacy benefit manager or affiliate of
22 such pharmacy benefit manager, on behalf
23 of the PDP sponsor making such payment,
24 in connection with the utilization of cov-
25 ered part D drugs, and meets additional

1 requirements, if any, as determined appro-
2 priate by the Secretary.

3 “(iii) CLARIFICATION ON REBATES
4 AND DISCOUNTS USED TO LOWER COSTS
5 FOR COVERED PART D DRUGS.—Rebates,
6 discounts, and other price concessions re-
7 ceived by a pharmacy benefit manager or
8 an affiliate of a pharmacy benefit manager
9 from manufacturers, even if such price
10 concessions are calculated as a percentage
11 of a drug’s price, shall not be considered a
12 violation of the requirements of clause (i)
13 if they are fully passed through to a PDP
14 sponsor and are compliant with all regu-
15 latory and subregulatory requirements re-
16 lated to direct and indirect remuneration
17 for manufacturer rebates under this part,
18 including in cases where a PDP sponsor is
19 acting as a pharmacy benefit manager on
20 behalf of a prescription drug plan offered
21 by such PDP sponsor.

22 “(iv) EVALUATION OF REMUNERATION
23 ARRANGEMENTS.—Components of subsets
24 of remuneration arrangements (such as
25 fees or other forms of compensation paid

1 to or retained by the pharmacy benefit
2 manager or affiliate of such pharmacy ben-
3 efit manager), as determined appropriate
4 by the Secretary, between pharmacy ben-
5 efit managers or affiliates of such phar-
6 macy benefit managers, as applicable, and
7 other entities involved in the dispensing or
8 utilization of covered part D drugs (includ-
9 ing PDP sponsors, manufacturers, phar-
10 macies, and other entities as determined
11 appropriate by the Secretary) shall be sub-
12 ject to review by the Secretary, in con-
13 sultation with the Office of the Inspector
14 General of the Department of Health and
15 Human Services, as determined appro-
16 priate by the Secretary. The Secretary, in
17 consultation with the Office of the Inspec-
18 tor General, shall review whether remu-
19 neration under such arrangements is con-
20 sistent with fair market value (as specified
21 by the Secretary) through reviews and as-
22 sessments of such remuneration, as deter-
23 mined appropriate.

24 “(v) DISGORGEMENT.—The pharmacy
25 benefit manager shall disgorge any remu-

1 for purposes of calculating or otherwise
2 evaluating pharmacy benefit manager per-
3 formance against pricing guarantees or
4 similar cost performance measurements re-
5 lated to rebates, discounts, price conces-
6 sions, or net costs, terms such as—

7 “(I) ‘generic drug’, in a manner
8 consistent with the definition of the
9 term under section 423.4 of title 42,
10 Code of Federal Regulations, or a suc-
11 cessor regulation;

12 “(II) ‘brand name drug’, in a
13 manner consistent with the definition
14 of the term under section 423.4 of
15 title 42, Code of Federal Regulations,
16 or a successor regulation;

17 “(III) ‘specialty drug’;

18 “(IV) ‘rebate’; and

19 “(V) ‘discount’;

20 “(ii) identify any drugs, claims, or
21 price concessions excluded from any pric-
22 ing guarantee or other cost performance
23 measure in a clear and consistent manner;
24 and

1 “(iii) where a pricing guarantee or
2 other cost performance measure is based
3 on a pricing benchmark other than the
4 wholesale acquisition cost (as defined in
5 section 1847A(e)(6)(B)) of a drug, cal-
6 culate and provide a wholesale acquisition
7 cost-based equivalent to the pricing guar-
8 antee or other cost performance measure.

9 “(C) PROVISION OF INFORMATION.—

10 “(i) IN GENERAL.—Not later than
11 July 1 of each year, beginning in 2028, the
12 pharmacy benefit manager shall submit to
13 the PDP sponsor, and to the Secretary, a
14 report, in accordance with this subpara-
15 graph, and shall make such report avail-
16 able to such sponsor at no cost to such
17 sponsor in a format specified by the Sec-
18 retary under paragraph (5). Each such re-
19 port shall include, with respect to such
20 PDP sponsor and each plan offered by
21 such sponsor, the following information
22 with respect to the previous plan year:

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

1 “(aa) the brand name, ge-
2 neric or non-proprietary name,
3 and National Drug Code;

4 “(bb) the number of plan
5 enrollees for whom the drug was
6 dispensed, the total number of
7 prescription claims for the drug
8 (including original prescriptions
9 and refills, counted as separate
10 claims), and the total number of
11 dosage units of the drug dis-
12 pensed;

13 “(cc) the number of pre-
14 scription claims described in item
15 (bb) by each type of dispensing
16 channel through which the drug
17 was dispensed, including retail,
18 mail order, specialty pharmacy,
19 long term care pharmacy, home
20 infusion pharmacy, or other types
21 of pharmacies or providers;

22 “(dd) the average wholesale
23 acquisition cost, listed as cost per
24 day’s supply, cost per dosage

1 unit, and cost per typical course
2 of treatment (as applicable);

3 “(ee) the average wholesale
4 price for the drug, listed as price
5 per day’s supply, price per dos-
6 age unit, and price per typical
7 course of treatment (as applica-
8 ble);

9 “(ff) the total out-of-pocket
10 spending by plan enrollees on
11 such drug after application of
12 any benefits under the plan, in-
13 cluding plan enrollee spending
14 through copayments, coinsurance,
15 and deductibles;

16 “(gg) total rebates paid by
17 the manufacturer on the drug as
18 reported under the Detailed DIR
19 Report (or any successor report)
20 submitted by such sponsor to the
21 Centers for Medicare & Medicaid
22 Services;

23 “(hh) all other direct or in-
24 direct remuneration on the drug
25 as reported under the Detailed

1 DIR Report (or any successor re-
2 port) submitted by such sponsor
3 to the Centers for Medicare &
4 Medicaid Services;

5 “(ii) the average pharmacy
6 reimbursement amount paid by
7 the plan for the drug in the ag-
8 gregate and disaggregated by dis-
9 pensing channel identified in item
10 (cc);

11 “(jj) the average National
12 Average Drug Acquisition Cost
13 (NADAC); and

14 “(kk) total manufacturer-de-
15 rived revenue, inclusive of bona
16 fide service fees, attributable to
17 the drug and retained by the
18 pharmacy benefit manager and
19 any affiliate of such pharmacy
20 benefit manager.

21 “(II) In the case of a pharmacy
22 benefit manager that has an affiliate
23 that is a retail, mail order, or spe-
24 cialty pharmacy, with respect to drugs

1 covered by such plan that were dis-
2 pensed, the following information:

3 “(aa) The percentage of
4 total prescriptions that were dis-
5 pensed by pharmacies that are an
6 affiliate of the pharmacy benefit
7 manager for each drug.

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

19 “(cc) The interquartile
20 range of the total combined costs
21 paid by the plan and plan enroll-
22 ees, per dosage unit, per course
23 of treatment, per 30-day supply,
24 and per 90-day supply for each
25 drug dispensed by pharmacies

1 that are an affiliate of the phar-
2 macy benefit manager and that
3 are included in the pharmacy
4 network of such plan.

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

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

22 “(ff) A list inclusive of the
23 brand name, generic or non-pro-
24 prietary name, and National
25 Drug Code of covered part D

1 drugs subject to an agreement
2 with a covered entity under sec-
3 tion 340B of the Public Health
4 Service Act for which the phar-
5 macy benefit manager or an affil-
6 iate of the pharmacy benefit
7 manager had a contract or other
8 arrangement with such a covered
9 entity in the service area of such
10 plan.

11 “(III) Where a drug approved
12 under section 505(c) of the Federal
13 Food, Drug, and Cosmetic Act (re-
14 ferred to in this subclause as the ‘list-
15 ed drug’) is covered by the plan, the
16 following information:

17 “(aa) A list of currently
18 marketed generic drugs approved
19 under section 505(j) of the Fed-
20 eral Food, Drug, and Cosmetic
21 Act pursuant to an application
22 that references such listed drug
23 that are not covered by the plan,
24 are covered on the same for-
25 mulary tier or a formulary tier

1 typically associated with higher
2 cost-sharing than the listed drug,
3 or are subject to utilization man-
4 agement that the listed drug is
5 not subject to.

6 “(bb) The estimated average
7 beneficiary cost-sharing under
8 the plan for a 30-day supply of
9 the listed drug.

10 “(cc) Where a generic drug
11 listed under item (aa) is on a for-
12 mulary tier typically associated
13 with higher cost-sharing than the
14 listed drug, the estimated aver-
15 age cost-sharing that a bene-
16 ficiary would have paid for a 30-
17 day supply of each of the generic
18 drugs described in item (aa), had
19 the plan provided coverage for
20 such drugs on the same for-
21 mulary tier as the listed drug.

22 “(dd) A written justification
23 for providing more favorable cov-
24 erage of the listed drug than the

1 generic drugs described in item
2 (aa).

3 “(ee) The number of cur-
4 rently marketed generic drugs
5 approved under section 505(j) of
6 the Federal Food, Drug, and
7 Cosmetic Act pursuant to an ap-
8 plication that references such
9 listed drug.

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

14 “(aa) A list of currently
15 marketed biosimilar biological
16 products licensed under section
17 351(k) of the Public Health
18 Service Act pursuant to an appli-
19 cation that refers to such ref-
20 erence product that are not cov-
21 ered by the plan, are covered on
22 the same formulary tier or a for-
23 mulary tier typically associated
24 with higher cost-sharing than the
25 reference product, or are subject

1 to utilization management that
2 the reference product is not sub-
3 ject to.

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

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

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

1 than the biosimilar biological
2 product 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
11 covered part D drugs by the plan, not
12 net of rebates, fees, discounts, or
13 other direct 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 serv-
20 ice 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
17 other services offered to PDP
18 sponsors related to pharmacy
19 benefit management 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 affil-
5 iate, for each such broker, con-
6 sultant, 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
16 MANUFACTURERS.—

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

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

13 “(II) REQUIREMENTS.—A writ-
14 ten 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
21 the contract or agreement and
22 the manufacturers of such drugs,
23 and a high-level description of
24 the terms of such contract or

1 agreement and how such terms
2 apply to such drugs; and

3 “(bb) be certified by the
4 Chief Executive Officer, Chief Fi-
5 nancial Officer, or General Coun-
6 sel of such pharmacy benefit
7 manager, or affiliate of such
8 pharmacy benefit manager, as
9 applicable, or an individual dele-
10 gated with the authority to sign
11 on behalf of one of these officers,
12 who reports directly to the offi-
13 cer.

14 “(III) DEFINITION OF OTHER
15 PRESCRIPTION DRUGS.—For purposes
16 of this clause, the term ‘other pre-
17 scription drugs’ means prescription
18 drugs covered as supplemental bene-
19 fits under this part or prescription
20 drugs paid outside of this part.

21 “(D) AUDIT RIGHTS.—

22 “(i) IN GENERAL.—Not less than once
23 a year, at the request of the PDP sponsor,
24 the pharmacy benefit manager shall allow
25 for an audit of the pharmacy benefit man-

1 ager to ensure compliance with all terms
2 and conditions under the written agree-
3 ment described in this paragraph and the
4 accuracy of information reported under
5 subparagraph (C).

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

11 “(iii) PROVISION OF INFORMATION.—
12 The pharmacy benefit manager shall make
13 available to such auditor all records, data,
14 contracts, and other information necessary
15 to confirm the accuracy of information
16 provided under subparagraph (C), subject
17 to reasonable restrictions on how such in-
18 formation must be reported to prevent re-
19 disclosure of such information.

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

1 tional information from such auditor with-
2 in 30 days after the request for additional
3 information.

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

12 “(2) ENFORCEMENT.—

13 “(A) IN GENERAL.—Each PDP sponsor
14 shall—

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

19 “(ii) require, in a written agreement
20 with any pharmacy benefit manager acting
21 on behalf of such sponsor or affiliate of
22 such pharmacy benefit manager, that such
23 pharmacy benefit manager or affiliate re-
24 imburse the PDP sponsor for any civil
25 money penalty imposed on the PDP spon-

1 sor as a result of the failure of the phar-
2 macy benefit manager or affiliate to meet
3 the requirements of paragraph (1) that are
4 applicable to the pharmacy benefit man-
5 ager or affiliate under the agreement; and
6 “(iii) require, in a written agreement
7 with any such pharmacy benefit manager
8 acting on behalf of such sponsor or affil-
9 iate of such pharmacy benefit manager,
10 that such pharmacy benefit manager or af-
11 filiate be subject to punitive remedies for
12 breach of contract for failure to comply
13 with the requirements applicable under
14 paragraph (1).

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

1 “(C) ANTI-RETALIATION AND ANTI-COER-
2 CION.—Consistent with applicable Federal or
3 State law, a PDP sponsor shall not—

4 “(i) retaliate against an individual or
5 entity for reporting an alleged violation
6 under subparagraph (B); or

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

11 “(3) CERTIFICATION OF COMPLIANCE.—

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

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

22 “(4) RULE OF CONSTRUCTION.—Nothing in
23 this subsection shall be construed as—

24 “(A) prohibiting flat dispensing fees or re-
25 imbursement or payment for ingredient costs

1 (including customary, industry-standard dis-
2 counts directly related to drug acquisition that
3 are retained by pharmacies or wholesalers) to
4 entities that acquire or dispense prescription
5 drugs; or

6 “(B) modifying regulatory requirements or
7 sub-regulatory program instruction or guidance
8 related to pharmacy payment, reimbursement,
9 or dispensing fees.

10 “(5) STANDARD FORMATS.—

11 “(A) IN GENERAL.—Not later than June
12 1, 2027, the Secretary shall specify standard,
13 machine-readable formats for pharmacy benefit
14 managers to submit annual reports required
15 under paragraph (1)(C)(i).

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

20 “(6) CONFIDENTIALITY.—

21 “(A) IN GENERAL.—Information disclosed
22 by a pharmacy benefit manager, an affiliate of
23 a pharmacy benefit manager, a PDP sponsor,
24 or a pharmacy under this subsection that is not
25 otherwise publicly available or available for pur-

1 chase shall not be disclosed by the Secretary or
2 a PDP sponsor receiving the information, ex-
3 cept that the Secretary may disclose the infor-
4 mation for the following purposes:

5 “(i) As the Secretary determines nec-
6 essary to carry out this part.

7 “(ii) To permit the Comptroller Gen-
8 eral to review the information provided.

9 “(iii) To permit the Director of the
10 Congressional Budget Office to review the
11 information provided.

12 “(iv) To permit the Executive Direc-
13 tor of the Medicare Payment Advisory
14 Commission to review the information pro-
15 vided.

16 “(v) To the Attorney General for the
17 purposes of conducting oversight and en-
18 forcement under this title.

19 “(vi) To the Inspector General of the
20 Department of Health and Human Serv-
21 ices in accordance with its authorities
22 under the Inspector General Act of 1978
23 (section 406 of title 5, United States
24 Code), and other applicable statutes.

1 “(B) RESTRICTION ON USE OF INFORMA-
2 TION.—The Secretary, the Comptroller General,
3 the Director of the Congressional Budget Of-
4 fice, and the Executive Director of the Medicare
5 Payment Advisory Commission shall not report
6 on or disclose information disclosed pursuant to
7 subparagraph (A) to the public in a manner
8 that would identify—

9 “(i) a specific pharmacy benefit man-
10 ager, affiliate, pharmacy, manufacturer,
11 wholesaler, PDP sponsor, or plan; or

12 “(ii) contract prices, rebates, dis-
13 counts, or other remuneration for specific
14 drugs in a manner that may allow the
15 identification of specific contracting parties
16 or of such specific drugs.

17 “(7) DEFINITIONS.—For purposes of this sub-
18 section:

19 “(A) AFFILIATE.—The term ‘affiliate’
20 means, with respect to any pharmacy benefit
21 manager or PDP sponsor, any entity that, di-
22 rectly or indirectly—

23 “(i) owns or is owned by, controls or
24 is controlled by, or is otherwise related in

1 any ownership structure to such pharmacy
2 benefit manager or PDP sponsor; or

3 “(ii) acts as a contractor, principal, or
4 agent to such pharmacy benefit manager
5 or PDP sponsor, insofar as such con-
6 tractor, principal, or agent performs any of
7 the functions described under subpara-
8 graph (C).

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

22 “(i) drug price, such as wholesale ac-
23 quisition cost or drug benchmark price
24 (such as average wholesale price);

1 “(ii) the amount of discounts, rebates,
2 fees, or other direct or indirect remunera-
3 tion with respect to covered part D drugs
4 dispensed to enrollees in a prescription
5 drug plan, except as permitted pursuant to
6 paragraph (1)(A)(ii);

7 “(iii) coverage or formulary placement
8 decisions or the volume or value of any re-
9 ferrals or business generated between the
10 parties to the arrangement; or

11 “(iv) any other amounts or meth-
12 odologies prohibited by the Secretary.

13 “(C) PHARMACY BENEFIT MANAGER.—The
14 term ‘pharmacy benefit manager’ means any
15 person or entity that, either directly or through
16 an intermediary, acts as a price negotiator or
17 group purchaser on behalf of a PDP sponsor or
18 prescription drug plan, or manages the pre-
19 scription drug benefits provided by such spon-
20 sor or plan, including the processing and pay-
21 ment of claims for prescription drugs, the per-
22 formance of drug utilization review, the proc-
23 essing of drug prior authorization requests, the
24 adjudication of appeals or grievances related to
25 the prescription drug benefit, contracting with

1 network pharmacies, controlling the cost of cov-
2 ered part D drugs, or the provision of related
3 services. Such term includes any person or enti-
4 ty that carries out one or more of the activities
5 described in the preceding sentence, irrespective
6 of whether such person or entity calls itself a
7 ‘pharmacy benefit manager.’.”

8 (b) MA–PD PLANS.—Section 1857(f)(3) of the So-
9 cial Security Act (42 U.S.C. 1395w–27(f)(3)), as amended
10 by section 2(d)(2), is amended by adding at the end the
11 following new subparagraph:

12 “(G) REQUIREMENTS RELATING TO PHAR-
13 MACY BENEFIT MANAGERS.—For plan years be-
14 ginning on or after January 1, 2028, section
15 1860D–12(h).”.

16 (c) NONAPPLICATION OF PAPERWORK REDUCTION
17 ACT.—Chapter 35 of title 44, United States Code, shall
18 not apply to the implementation of this subsection.