

118TH CONGRESS
1ST SESSION

H. R. 5385

To amend title XVIII of the Social Security Act to establish pharmacy benefit manager reporting requirements with respect to prescription drug plans and MA–PD plans under Medicare part D.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 12, 2023

Mr. LANDSMAN (for himself and Mrs. HARSHBARGER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

A BILL

To amend title XVIII of the Social Security Act to establish pharmacy benefit manager reporting requirements with respect to prescription drug plans and MA–PD plans 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 “Medicare PBM Ac-
5 countability Act”.

1 **SEC. 2. PHARMACY BENEFIT MANAGER REPORTING RE-**
2 **QUIREMENTS WITH RESPECT TO PRESCRIP-**
3 **TION DRUG PLANS AND MA-PD PLANS.**

4 (a) IN GENERAL.—

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

9 “(h) PHARMACY BENEFIT MANAGER REPORTING
10 REQUIREMENTS.—For plan years beginning on or after
11 January 1, 2026:

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 agrees to meet the following re-
20 quirements:

21 “(A) TRANSPARENCY REGARDING GUARAN-
22 TEES AND COST PERFORMANCE EVALUA-
23 TIONS.—The pharmacy benefit manager shall—

24 “(i) define, interpret, and apply terms
25 (such as generic drug, brand name drug
26 (consistent with the definition of those

1 terms under section 423.4 of title 42, Code
2 of Federal Regulations, or a successor reg-
3 ulation), specialty drug, rebate, and dis-
4 count) in a fully transparent and con-
5 sistent manner for purposes of calculating
6 or otherwise evaluating pharmacy benefit
7 manager performance against pricing guar-
8 antees or similar cost performance meas-
9 urements related to rebates, discounts,
10 price concessions, or net costs;

11 “(ii) identify any drugs, claims, or
12 price concessions excluded from any pric-
13 ing guarantee or other cost performance
14 calculation or evaluation in a clear and
15 consistent manner; and

16 “(iii) where a pricing guarantee or
17 other cost performance measure is based
18 on a pricing benchmark other than the
19 wholesale acquisition cost (as defined in
20 section 1847A(c)(6)(B)) of a drug, cal-
21 culate and provide a wholesale acquisition
22 cost-based equivalent to the pricing guar-
23 antee or other cost performance measure
24 in the contract.

25 “(B) PROVISION OF INFORMATION.—

1 “(i) IN GENERAL.—Not later than
2 July 1 of each year, the pharmacy benefit
3 manager shall submit to the PDP sponsor,
4 and to the Secretary upon request, a re-
5 port, in accordance with this subpara-
6 graph, and shall make such report avail-
7 able to the sponsor at no cost to such
8 sponsor in a machine-readable format and,
9 as the Secretary may determine, other for-
10 mats. Each such report shall include, with
11 respect to such PDP sponsor and each
12 plan offered by such sponsor, the following
13 information with respect to the previous
14 plan year:

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

18 “(aa) the brand name, ge-
19 neric or non-proprietary name,
20 and National Drug Code;

21 “(bb) the number of plan
22 enrollees for whom the drug was
23 dispensed, the total number of
24 prescription claims for the drug
25 (including original prescriptions

1 and refills, counted as separate
2 claims), and the total number of
3 dosage units of the drug dis-
4 pensed;

5 “(cc) the number of claims
6 described in item (bb) that were
7 dispensed using each type of dis-
8 pensing channel, including retail,
9 mail order, specialty pharmacy,
10 or other types of pharmacies or
11 providers as defined by the phar-
12 macy benefit manager;

13 “(dd) the average wholesale
14 acquisition cost, listed as cost per
15 day’s supply, cost per dosage
16 unit, and cost per typical course
17 of treatment (as applicable);

18 “(ee) the average wholesale
19 price for the drug, listed as cost
20 per day’s supply, cost per dosage
21 unit, and cost per typical course
22 of treatment (as applicable);

23 “(ff) the total out-of-pocket
24 spending by plan enrollees on
25 such drug after application of

1 any benefits under the plan, in-
2 cluding plan enrollee spending
3 through copayments, coinsurance,
4 and deductibles;

5 “(gg) total rebates paid by
6 the manufacturer on the drug as
7 reported under the Detailed DIR
8 Report (or any successor report)
9 submitted by such sponsor to the
10 Centers for Medicare & Medicaid
11 Services;

12 “(hh) all other direct or in-
13 direct remuneration on the drug
14 as reported under the Detailed
15 DIR Report (or any successor re-
16 port) submitted by such sponsor
17 to the Centers for Medicare &
18 Medicaid Services;

19 “(ii) the average pharmacy
20 reimbursement amount charged
21 to the plan for the drug by dis-
22 pensing channel identified in item
23 (cc);

24 “(jj) the average National
25 Average Drug Acquisition Cost

1 (NADAC) for retail community
2 pharmacies; and

3 “(kk) total manufacturer-de-
4 rived revenue, inclusive of bona
5 fide service fees, retained by the
6 pharmacy benefit manager and
7 any affiliate of such pharmacy
8 benefit manager attributable to
9 the drug.

10 “(II) In the case of a pharmacy
11 benefit manager that has an affiliate
12 that is a retail, mail order, or spe-
13 cialty pharmacy, with respect to drugs
14 covered by such plan that were dis-
15 pensed, the following information:

16 “(aa) The percentage of
17 total prescriptions that were dis-
18 pensed by pharmacies that are an
19 affiliate of the pharmacy benefit
20 manager for each drug.

21 “(bb) The interquartile
22 range of the total combined costs
23 paid by the plan and plan enroll-
24 ees, per dosage unit, per course
25 of treatment, per 30-day supply,

1 and per 90-day supply for each
2 drug dispensed by pharmacies
3 that are not with an affiliate of
4 the pharmacy benefit manager
5 and that are included in the
6 pharmacy network of such plan.

7 “(cc) The interquartile
8 range of the total combined costs
9 paid by the plan and plan enroll-
10 ees, per dosage unit, per course
11 of treatment, per 30-day supply,
12 and per 90-day supply for each
13 drug dispensed by pharmacies
14 that are an affiliate of the phar-
15 macy benefit manager that are
16 included in the pharmacy net-
17 work of such plan.

18 “(dd) The lowest total com-
19 bined cost paid by the plan and
20 plan enrollees, per dosage unit,
21 per course of treatment, per 30-
22 day supply, and per 90-day sup-
23 ply, for each drug that is avail-
24 able from any pharmacy included
25 in the network of the plan.

1 “(ee) The difference between
2 the average acquisition cost of
3 the affiliate that initially acquires
4 the drug and the amount re-
5 ported under subclause (I)(jj) for
6 each drug.

7 “(ff) A list of prescription
8 drugs for which the pharmacy
9 benefit manager or an affiliate of
10 the pharmacy benefit manager
11 had a contract or other arrange-
12 ment with a covered entity under
13 section 340B of the Public
14 Health Service Act in the service
15 area of such plan.

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

22 “(aa) A list of currently
23 marketed generic drugs approved
24 under section 505(j) of the Fed-
25 eral Food, Drug, and Cosmetic

1 Act pursuant to an application
2 that references such listed drug
3 that are not covered by the plan,
4 are covered on a formulary tier
5 typically associated with higher
6 cost-sharing than the listed drug,
7 or are subject to utilization man-
8 agement that the listed drug is
9 not subject to.

10 “(bb) The estimated average
11 beneficiary cost-sharing under
12 the plan for a 30-day supply of
13 the listed drug.

14 “(cc) The estimated average
15 cost-sharing that a beneficiary
16 would have paid for a 30-day
17 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 “(IV) Where a reference product
4 (as defined in section 351(i) of the
5 Public Health Service Act) is covered
6 by the plan, the following information:

7 “(aa) A list of currently
8 marketed biosimilar biological
9 products licensed under section
10 351(k) of the Public Health
11 Service Act pursuant to an appli-
12 cation that refers to such ref-
13 erence product that are not cov-
14 ered by the plan, are covered on
15 a formulary tier typically associ-
16 ated with higher cost-sharing
17 than the reference product, or
18 are subject to utilization manage-
19 ment that the reference product
20 is not subject to.

21 “(bb) The estimated average
22 beneficiary cost-sharing under
23 the plan for a 30-day supply of
24 the reference product.

1 “(cc) The estimated average
2 cost-sharing that a beneficiary
3 would have paid for a 30-day
4 supply of each of the biosimilar
5 biological products described in
6 item (aa), had the plan provided
7 coverage for such products on the
8 same formulary tier as the ref-
9 erence product.

10 “(dd) A written justification
11 for providing more favorable cov-
12 erage of the reference product
13 than the biosimilar biological
14 product described in item (aa).

15 “(V) Total gross spending on
16 prescription drugs by the plan, not
17 net of rebates, fees, discounts, or
18 other direct or indirect remuneration.

19 “(VI) The total amount retained
20 by the pharmacy benefit manager or
21 an affiliate of such pharmacy benefit
22 manager in revenue related to utiliza-
23 tion of prescription drugs under that
24 plan, inclusive of bona fide service
25 fees.

1 “(VII) The total spending on
2 prescription drugs net of rebates, fees,
3 discounts, or other direct and indirect
4 remuneration by the plan.

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

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

22 “(X) A list of all pharmacies,
23 wholesalers, distributors, private label-
24 ers, providers, group purchasing orga-
25 nizations, health plans, or any other

1 entity that is an affiliate of the phar-
2 macy benefit manager.

3 “(XI) A summary document sub-
4 mitted in a standardized template de-
5 veloped by the Secretary that includes
6 such information described in sub-
7 clauses (I) through (X).

8 “(ii) STANDARD FORMATS.—Not later
9 than June 1, 2025, the Secretary shall
10 specify standard formats for pharmacy
11 benefit managers to submit annual reports
12 required under clause (i).

13 “(iii) CONFIDENTIALITY.—

14 “(I) IN GENERAL.—Information
15 disclosed by a pharmacy benefit man-
16 ager or PDP sponsor under this sub-
17 section that is not otherwise publicly
18 available shall not be disclosed by the
19 Secretary or a PDP sponsor receiving
20 the information, except that the Sec-
21 retary may disclose the information
22 for the following purposes:

23 “(aa) As the Secretary de-
24 termines to be necessary to carry
25 out this part.

1 “(bb) To permit the Comp-
2 troller General to review the in-
3 formation provided.

4 “(cc) To permit the Director
5 of the Congressional Budget Of-
6 fice to review the information
7 provided.

8 “(dd) To permit the Execu-
9 tive Director of the Medicare
10 Payment Advisory Commission to
11 review the information provided.

12 “(ee) To the Attorney Gen-
13 eral for the purposes of con-
14 ducting oversight and enforce-
15 ment under this title.

16 “(II) RESTRICTION ON USE OF
17 INFORMATION.—The Secretary, the
18 Comptroller General, the Director of
19 the Congressional Budget Office, and
20 the Executive Director of the Medi-
21 care Payment Advisory Commission
22 shall not report on or disclose infor-
23 mation disclosed pursuant to sub-
24 clause (I) to the public in a manner
25 that would identify a specific phar-

1 macy benefit manager, affiliate, PDP
2 sponsor, or plan, or prices charged for
3 specific drugs.

4 “(C) AUDIT RIGHTS.—

5 “(i) IN GENERAL.—Not less than once
6 a year, at the request of the PDP sponsor,
7 the pharmacy benefit manager shall allow
8 for an audit of the pharmacy benefit man-
9 ager to ensure compliance with all terms
10 and conditions under the contract and the
11 accuracy of information reported under
12 subparagraph (B).

13 “(ii) AUDITOR.—The PDP sponsor
14 shall have the right to select an auditor.
15 The pharmacy benefit manager shall not
16 impose any limitations on the selection of
17 such auditor.

18 “(iii) PROVISION OF INFORMATION.—
19 The pharmacy benefit manager shall make
20 available to such auditor all records, data,
21 contracts, and other information necessary
22 to confirm the accuracy of information
23 provided under subparagraph (B), subject
24 to reasonable restrictions on how such in-
25 formation must be reported (as determined

1 by the Secretary) to prevent redisclosure of
2 such information.

3 “(iv) TIMING.—The pharmacy benefit
4 manager must provide information under
5 clause (iii) and other information, data,
6 and records relevant to the audit to such
7 auditor within 6 months of the initiation of
8 the audit and respond to requests for addi-
9 tional information from such auditor with-
10 in 30 days after the request for additional
11 information.

12 “(v) INFORMATION FROM AFFILI-
13 ATES.—The pharmacy benefit manager
14 shall be responsible for providing to such
15 auditor information required to be reported
16 under subparagraph (B) that is owned or
17 held by an affiliate of such pharmacy ben-
18 efit manager.

19 “(D) ENFORCEMENT.—The pharmacy ben-
20 efit manager shall—

21 “(i) reimburse the PDP sponsor for
22 any civil money penalty imposed on the
23 PDP sponsor as a result of the failure of
24 the pharmacy benefit manager to meet the
25 requirements of this paragraph that are

1 applicable to the pharmacy benefit man-
2 ager under the agreement; and

3 “(ii) be subject to punitive remedies
4 for breach of contract for failure to comply
5 with the requirements applicable under this
6 paragraph.

7 “(2) CERTIFICATION OF COMPLIANCE.—Each
8 PDP sponsor shall furnish to the Secretary (in a
9 time and manner specified by the Secretary) an an-
10 nual certification of compliance with this subsection,
11 as well as such information as the Secretary deter-
12 mines necessary to carry out this subsection.

13 “(3) DEFINITIONS.—For purposes of this sub-
14 section:

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

24 “(B) PHARMACY BENEFIT MANAGER.—The
25 term ‘pharmacy benefit manager’ means any

1 person or entity that, either directly or through
2 an intermediary, acts as a price negotiator or
3 group purchaser on behalf of a PDP sponsor or
4 prescription drug plan, or manages the pre-
5 scription drug benefits provided by such spon-
6 sor or plan, including the processing and pay-
7 ment of claims for prescription drugs, the per-
8 formance of drug utilization review, the proc-
9 essing of drug prior authorization requests, the
10 adjudication of appeals or grievances related to
11 the prescription drug benefit, contracting with
12 network pharmacies, controlling the cost of cov-
13 ered part D drugs, or the provision of services
14 related thereto. Such term includes any person
15 or entity that carries out one or more of the ac-
16 tivities described in the preceding sentence, ir-
17 respective of whether such person or entity calls
18 itself a ‘pharmacy benefit manager’.”.

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

23 “(F) PHARMACY BENEFIT MANAGER RE-
24 PORTING REQUIREMENTS.—For plan years be-

1 ginning on or after January 1, 2026, section
2 1860D–12(h).”.

3 (b) GAO STUDY AND REPORT ON CERTAIN REPORT-
4 ING REQUIREMENTS.—

5 (1) STUDY.—The Comptroller General of the
6 United States (in this subsection referred to as the
7 “Comptroller General”) shall conduct a study on
8 Federal and State reporting requirements for health
9 plans and pharmacy benefit managers related to the
10 transparency of prescription drug costs and prices.
11 Such study shall include an analysis of the following:

12 (A) Federal statutory and regulatory re-
13 porting requirements for health plans and phar-
14 macy benefit managers related to prescription
15 drug costs and prices.

16 (B) State statutory and regulatory report-
17 ing requirements for health plans and pharmacy
18 benefit managers related to prescription drug
19 costs and prices.

20 (C) The extent to which the statutory and
21 regulatory reporting requirements identified in
22 clauses (i) and (ii) overlap and conflict.

23 (D) The resources required by health plans
24 and pharmacy benefit managers to comply with

1 the reporting requirements described in clauses
2 (i) and (ii).

3 (E) Other items determined appropriate by
4 the Comptroller General.

5 (2) REPORT.—Not later than 2 years after en-
6 actment, the Comptroller General shall submit to
7 Congress a report containing the results of the study
8 conducted under paragraph (1), together with rec-
9 ommendations for legislation and administrative ac-
10 tions that would streamline and reduce the burden
11 associated with the reporting requirements for
12 health plans and pharmacy benefit managers de-
13 scribed in paragraph (1).

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