

## Discussion Draft

118TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

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.

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IN THE SENATE OF THE UNITED STATES

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Ms. CORTEZ MASTO (for herself, Mr. TILLIS, Mr. WYDEN, and Mr. CRAPO) 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 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(e)(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 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  
18 structure with a pharmacy benefit manager (in-  
19 cluding an entity **【owned or controlled by】** the  
20 PDP sponsor) **【or that acts as a 【contractor or**  
21 **agent】 to such pharmacy benefit manager】 【,**  
22 insofar as such contractor or agent performs  
23 any of the functions described under subpara-  
24 graph (B)】.

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

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) PHARMACY BENEFIT MANAGER RE-  
2                   PORTING REQUIREMENTS.—For plan years be-  
3                   ginning on or after January 1, 2026, section  
4                   1860D–12(h).”.

5                   (b) GAO STUDY AND REPORT ON CERTAIN REPORT-  
6                   ING REQUIREMENTS.—

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

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

19                  **【(B) State statutory and regulatory re-  
20                  porting requirements for health plans and phar-  
21                  macy benefit managers related to prescription  
22                  drug costs and prices.】**

23                  (C) The extent to which the statutory and  
24                  regulatory reporting requirements identified in  
25                  clauses (i) and (ii) overlap and conflict.

1                   (D) The resources required by health plans  
2                   and pharmacy benefit managers to comply with  
3                   the reporting requirements described in clauses  
4                   (i) and (ii).

5                   (E) Other items determined appropriate by  
6                   the Comptroller General.

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