

**AMENDMENT TO THE AMENDMENT IN THE
NATURE OF A SUBSTITUTE TO H.R. 3281
OFFERED BY MR. CARTER OF GEORGIA**

Add at the end of title III the following new section:

1 **SEC. 304. PROTECTING PATIENTS AGAINST PBM ABUSES.**

2 (a) ESTABLISHING CERTAIN REQUIREMENTS FOR
3 PHARMACY BENEFIT MANAGERS UNDER PART D OF THE
4 MEDICARE PROGRAM.—

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

9 “(9) RESPONSIBILITY OF PHARMACY BENEFIT
10 MANAGERS.—

11 “(A) IN GENERAL.—Each contract entered
12 into with a PDP sponsor under this part with
13 respect to a prescription drug plan offered by
14 such sponsor shall provide that any pharmacy
15 benefit manager acting on behalf of such spon-
16 sor complies with the following provisions:

17 “(i) The pharmacy benefit manager
18 derives no income with respect to any serv-
19 ices provided in connection with covered

1 part D drugs furnished under such plan
2 from any entity other than flat dollar
3 amount service fees.

4 “(ii) The pharmacy benefit manager
5 receives such service fees only pursuant to
6 a written agreement between the manager
7 and such sponsor that sets forth the
8 amount of any such fees. Any such fee
9 may not be directly or indirectly based on,
10 or contingent upon—

11 “(I) the price of any covered part
12 D drug;

13 “(II) discounts, rebates, fees, or
14 other remuneration with respect to
15 such drugs; or

16 “(III) any other circumstance
17 specified by the Secretary.

18 “(iii) With respect to a covered part
19 D drug dispensed by a pharmacy, the
20 pharmacy benefit manager may not charge
21 such sponsor a different amount for such
22 drug’s ingredient cost or dispensing fee
23 than the amount the pharmacy benefit
24 manager reimburses such pharmacy for

1 such drug’s ingredient cost or dispensing
2 fee.

3 “(iv) With respect to a covered part D
4 drug dispensed by a network pharmacy,
5 the pharmacy benefit manager may not re-
6 imburse such pharmacy an amount less
7 than the amount the pharmacy benefit
8 manager would reimburse an affiliated
9 pharmacy for such drug.

10 “(v) With respect to each covered part
11 D drug included on the formulary of such
12 plan for which there is a drug that is not
13 included on such formulary with a thera-
14 peutic equivalence rating of AB (as estab-
15 lished pursuant to section 505(j)(7) of the
16 Federal Food, Drug, and Cosmetic Act) in
17 the same therapeutic class or category of
18 such covered part D drug, the pharmacy
19 benefit manager shall submit to such plan
20 a report specifying the difference between
21 the national average drug acquisition cost
22 (as published by the Secretary) for such
23 drug not included in such formulary and
24 the negotiated prices for such drug that is
25 included in such formulary.

1 “(B) CERTIFICATION.—Each PDP sponsor
2 (and each pharmacy benefit manager providing
3 services under a prescription drug plan fur-
4 nished by such sponsor) shall furnish to the
5 Secretary (in a time and manner specified by
6 the Secretary) an annual certification of compli-
7 ance with this paragraph, as well as such infor-
8 mation as the Secretary determines necessary
9 to carry out this paragraph.

10 “(C) DISGORGEMENT OF PROHIBITED PAY-
11 MENTS.—A pharmacy benefit manager shall
12 disgorge to the Secretary any payment, remu-
13 neration, or other amount received in violation
14 of this paragraph or the contract entered into
15 with a PDP sponsor under this part with re-
16 spect to a prescription drug plan. A PDP spon-
17 sor shall suspend payments to a pharmacy ben-
18 efit manager for failure to disgorge such
19 amounts pursuant to the preceding sentence or
20 for other violations of this paragraph.

21 “(D) CLARIFICATION.—The requirements
22 of this paragraph shall apply regardless of
23 whether a PDP sponsor is acting as its own
24 pharmacy benefit manager and regardless of
25 whether a pharmacy benefit manager is under

1 common ownership or control of the PDP spon-
2 sor with respect to which the manager is fur-
3 nishing services.

4 “(E) DEFINITIONS.—For purposes of this
5 paragraph:

6 “(i) AFFILIATED PHARMACY.—The
7 term ‘affiliated pharmacy’ means, with re-
8 spect to a pharmacy benefit manager, a
9 pharmacy that directly or indirectly
10 through one or more intermediaries is
11 owned by, controlled by, or is under com-
12 mon ownership or control of such manager,
13 or a pharmacy in which such manager has
14 a financial interest.

15 “(ii) PHARMACY BENEFIT MAN-
16 AGER.—The term ‘pharmacy benefit man-
17 ager’ means any entity (and any affiliate,
18 subsidiary, or agent of such entity) that,
19 pursuant to an agreement with a PDP
20 sponsor either directly or through an inter-
21 mediary acts as a price negotiator or group
22 purchaser on behalf of such sponsor, or
23 manages the prescription drug benefits
24 provided by such sponsor, including by
25 processing and paying claims for covered

1 part D drugs, performing drug utilization
2 review, processing drug prior authorization
3 requests, adjudicating appeals or griev-
4 ances related to covered part D drugs, con-
5 tracting with network pharmacies, control-
6 ling the cost of such drugs, or providing
7 any related services.

8 “(F) NONDISCLOSURE OF CERTAIN INFOR-
9 MATION.—Nothing in this paragraph shall be
10 construed to require public disclosure of any in-
11 formation that is a trade secret or confidential
12 information (as described in section 552(b)(4)
13 of title 5, United States Code).”

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

18 “(F) RESPONSIBILITY OF PHARMACY BEN-
19 EFIT MANAGERS.—Section 1860D–12(b)(9).”

20 (b) CONFLICT OF INTEREST.—Section 1860D–
21 4(b)(3)(A)(ii)(I) of the Social Security Act (42 U.S.C.
22 1395w–104(b)(3)(A)(ii)(I)) is amended by striking “with
23 respect to the sponsor and plan” and replacing it with
24 “with respect to the sponsor, plan, and any pharmacy ben-
25 efit manager furnishing services to such sponsor or plan”.

1 (c) PBM TRANSPARENCY.—Section 1150A of the So-
2 cial Security Act (42 U.S.C. 1320b–23) is amended—

3 (1) in subsection (b), by adding at the end the
4 following new paragraph:

5 “(4) In the case of the provision of information
6 by a PBM that manages prescription drug coverage
7 under a contract with a sponsor described in sub-
8 section (a)(1) for a plan so described—

9 “(A) the aggregate dollar amount of all re-
10 bates that the PBM received with respect to
11 drugs furnished under such plan from drug
12 manufacturers;

13 “(B) the aggregate dollar amount of all
14 administrative fees that the PBM received with
15 respect to drugs furnished under such plan
16 from drug manufacturers;

17 “(C) the aggregate dollar amount of all re-
18 bates described in subparagraph (A) that the
19 PBM did not pass through to such sponsor;

20 “(D) the percentage of the aggregate dol-
21 lar amount of all rebates described in subpara-
22 graph (A) that the PBM did not pass through
23 to such sponsor; and

24 “(E) with respect to all plans described in
25 subsection (a)(1) for which the PBM manages

1 prescription drug coverage, the highest percent-
2 age calculated under subparagraph (D) and the
3 lowest such percentage.”;

4 (2) by redesignating subsections (c) and (d) as
5 subsections (d) and (e), respectively; and

6 (3) by inserting after subsection (b), the fol-
7 lowing new subsection:

8 “(c) PUBLICATION OF PART D INFORMATION.—The
9 Secretary shall publish, not less frequently than annually,
10 the information reported under subsection (b) by or on
11 behalf of sponsors described in subsection (a)(1) on a pub-
12 licly available website, provided that such information
13 shall be made available in a form that does not disclose
14 the identity of a specific plan, the prices charged for spe-
15 cific drugs or classes of drugs, or the amount of any re-
16 bates provided for specific drugs or classes of drugs.”.

17 (d) EFFECTIVE DATE.—The amendments made by
18 this section shall take effect January 1, 2024.

19 (e) REGULATIONS.—Notwithstanding any other pro-
20 vision of law, the Secretary shall initially implement the
21 amendments made by this section through interim final
22 regulations.

