AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 2880

Offered by M_..

Strike all after the enacting clause and insert the following:

| 1 | SECTION 1. SHORT TITLE. |
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| 2 | This Act may be cited as the "Protecting Patients |
| 3 | Against PBM Abuses Act". |
| 4 | SEC. 2. ARRANGEMENTS WITH PHARMACY BENEFIT MAN- |
| 5 | AGERS WITH RESPECT TO PRESCRIPTION |
| 6 | DRUG PLANS AND MA-PD PLANS. |
| 7 | (a) Prescription Drug Plans.—Section 1860D— |
| 8 | 12 of the Social Security Act (42 U.S.C. 1395w-112) is |
| 9 | amended by adding at the end the following new sub- |
| 10 | section: |
| 11 | "(h) Requirements Relating to Pharmacy Ben- |
| 12 | EFIT MANAGERS.—For plan years beginning on or after |
| 13 | January 1, 2027: |
| 14 | "(1) AGREEMENTS WITH PHARMACY BENEFIT |
| 15 | MANAGERS.—Each contract entered into with a |
| 16 | PDP sponsor under this part with respect to a pre- |
| 17 | scription drug plan offered by such sponsor shall |
| 18 | provide that any pharmacy benefit manager acting |

| 1 | on behalf of such sponsor has a written agreement |
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| 2 | with the PDP sponsor under which the pharmacy |
| 3 | benefit manager agrees to meet the following re- |
| 4 | quirements: |
| 5 | "(A) No income other than bona fide |
| 6 | SERVICE FEES.— |
| 7 | "(i) In General.—The pharmacy |
| 8 | benefit manager and any affiliate of such |
| 9 | pharmacy benefit manager shall not derive |
| 10 | any remuneration with respect to any serv- |
| 11 | ices provided in connection with the utiliza- |
| 12 | tion of covered part D drugs from any en- |
| 13 | tity or individual other than bona fide serv- |
| 14 | ice fees, subject to clauses (ii) and (iii). |
| 15 | "(ii) Incentive payments.—For the |
| 16 | purposes of this subsection, an incentive |
| 17 | payment paid by a PDP sponsor to a phar- |
| 18 | macy benefit manager that is performing |
| 19 | services on behalf of such sponsor shall be |
| 20 | deemed a 'bona fide service fee' if such |
| 21 | payment is a flat dollar amount, is con- |
| 22 | sistent with fair market value, and is re- |
| 23 | lated to services actually performed by the |
| 24 | pharmacy benefit manager or affiliate of |
| 25 | such pharmacy benefit manager in connec- |

| 1 | tion with the utilization of covered part D |
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| 2 | drugs. |
| 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 from manufacturers, even if such |
| 8 | price concessions are calculated as a per- |
| 9 | centage of a drug's price, shall not be con- |
| 10 | sidered a violation of the requirements of |
| 11 | clause (i) if they are fully passed through |
| 12 | to a PDP sponsor and exclusively used to |
| 13 | lower costs for prescription drugs under |
| 14 | this part, including in cases where a PDP |
| 15 | sponsor is acting as a pharmacy benefit |
| 16 | manager on behalf of a prescription drug |
| 17 | plan offered by such PDP sponsor. |
| 18 | "(iv) Evaluation of remuneration |
| 19 | ARRANGEMENTS.—Remuneration arrange- |
| 20 | ments between pharmacy benefit managers |
| 21 | or affiliates of such pharmacy benefit man- |
| 22 | agers, as applicable, and other entities in- |
| 23 | volved in the dispensing or utilization of |
| 24 | covered part D drugs (including PDP |
| 25 | sponsors, manufacturers, pharmacies, and |

| 1 | other entities as determined appropriate by |
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| 2 | the Secretary) shall be subject to review by |
| 3 | the Secretary and the Office of the Inspec- |
| 4 | tor General of the Department of Health |
| 5 | and Human Services. The Secretary, in |
| 6 | consultation with the Office of the Inspec- |
| 7 | tor General, shall evaluate whether remu- |
| 8 | neration under such arrangements is con- |
| 9 | sistent with fair market value through re- |
| 10 | views and assessments of such remunera- |
| 11 | tion, as determined appropriate. |
| 12 | "(B) Enforcement.—The pharmacy ben- |
| 13 | efit manager shall— |
| 14 | "(i) disgorge to a PDP sponsor (or, in |
| 15 | a case where the PDP sponsor is an affil- |
| 16 | iate of such pharmacy benefit manager, to |
| 17 | the Secretary) any payment, remuneration, |
| 18 | or other amount received by the pharmacy |
| 19 | benefit manager or an affiliate of such |
| 20 | pharmacy benefit manager in violation of |
| 21 | subparagraph (A) or the written agreement |
| 22 | entered into with such sponsor under this |
| 23 | part with respect to a prescription drug |
| 24 | plan; |

| 1 | "(ii) reimburse the PDP sponsor for |
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| 2 | any civil money penalty imposed on the |
| 3 | PDP sponsor as a result of the failure of |
| 4 | the pharmacy benefit manager to meet the |
| 5 | requirements of this paragraph that are |
| 6 | applicable to the pharmacy benefit man- |
| 7 | ager under the agreement; and |
| 8 | "(iii) be subject to punitive remedies |
| 9 | for breach of contract for failure to comply |
| 10 | with the requirements applicable under this |
| 11 | paragraph. |
| 12 | "(2) CERTIFICATION OF COMPLIANCE.—Each |
| 13 | PDP sponsor shall furnish to the Secretary (in a |
| 14 | time and manner specified by the Secretary) an an- |
| 15 | nual certification of compliance with this subsection, |
| 16 | as well as such information as the Secretary deter- |
| 17 | mines necessary to carry out this subsection. |
| 18 | "(3) Definitions.—For purposes of this sub- |
| 19 | section: |
| 20 | "(A) AFFILIATE.—The term 'affiliate' |
| 21 | means any entity that is owned by, controlled |
| 22 | by, or related under a common ownership struc- |
| 23 | ture with a pharmacy benefit manager or PDP |
| 24 | sponsor, or that acts as a contractor or agent |
| 25 | to such pharmacy benefit manager or PDP |

| 1 | sponsor, insofar as such contractor or agent |
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| 2 | performs any of the functions described under |
| 3 | subparagraph (C). |
| 4 | "(B) Bona fide service fee.—The term |
| 5 | 'bona fide service fee' means a fee that is reflec- |
| 6 | tive of the fair market value for a bona fide, |
| 7 | itemized service actually performed on behalf of |
| 8 | an entity, that the entity would otherwise per- |
| 9 | form (or contract for) in the absence of the |
| 10 | service arrangement and that are not passed on |
| 11 | in whole or in part to a client or customer, |
| 12 | whether or not the entity takes title to the |
| 13 | drug. Such fee must be a flat dollar amount |
| 14 | and shall not be directly or indirectly based on, |
| 15 | or contingent upon— |
| 16 | "(i) drug price, such as wholesale ac- |
| 17 | quisition cost or drug benchmark price |
| 18 | (such as average wholesale price); |
| 19 | "(ii) discounts, rebates, fees, or other |
| 20 | direct or indirect remuneration amounts |
| 21 | with respect to covered part D drugs dis- |
| 22 | pensed to enrollees in a prescription drug |
| 23 | plan, except as permitted pursuant to |
| 24 | paragraph (1)(A)(ii); |

| 1 | "(iii) coverage or formulary placement |
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| 2 | decisions or the volume or value of any re- |
| 3 | ferrals or business generated between the |
| 4 | parties to the arrangement; or |
| 5 | "(iv) any other amounts or meth- |
| 6 | odologies prohibited by the Secretary. |
| 7 | "(C) Pharmacy benefit manager.—The |
| 8 | term 'pharmacy benefit manager' means any |
| 9 | person or entity that, either directly or through |
| 10 | an intermediary, acts as a price negotiator or |
| 11 | group purchaser on behalf of a PDP sponsor or |
| 12 | prescription drug plan, or manages the pre- |
| 13 | scription drug benefits provided by such spon- |
| 14 | sor or plan, including the processing and pay- |
| 15 | ment of claims for prescription drugs, the per- |
| 16 | formance of drug utilization review, the proc- |
| 17 | essing of drug prior authorization requests, the |
| 18 | adjudication of appeals or grievances related to |
| 19 | the prescription drug benefit, contracting with |
| 20 | network pharmacies, controlling the cost of cov- |
| 21 | ered part D drugs, or the provision of related |
| 22 | services. Such term includes any person or enti- |
| 23 | ty that carries out one or more of the activities |
| 24 | described in the preceding sentence, irrespective |

| 1 | of whether such person or entity calls itself a |
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| 2 | 'pharmacy benefit manager'.". |
| 3 | (b) MA-PD Plans.—Section 1857(f)(3) of the So- |
| 4 | cial Security Act (42 U.S.C. 1395w–27(f)(3)) is amended |
| 5 | by adding at the end the following new subparagraph: |
| 6 | "(F) REQUIREMENTS RELATING TO PHAR- |
| 7 | MACY BENEFIT MANAGERS.—For plan years be- |
| 8 | ginning on or after January 1, 2027, section |
| 9 | 1860D–12(h).". |
| 10 | SEC. 3. ENHANCING PBM TRANSPARENCY REQUIREMENTS. |
| 11 | (a) In General.—Section 1150A of the Social Secu- |
| 12 | rity Act (42 U.S.C. 1320b-23) is amended— |
| 13 | (1) by striking subsection (a) and inserting the |
| 14 | following: |
| 15 | "(a) Provision of Information.— |
| 16 | "(1) In general.—The following entities shall |
| 17 | provide the information described in subsection (b) |
| 18 | to the Secretary and, in the case of an entity de- |
| 19 | scribed in subparagraph (B) or an affiliate of such |
| 20 | entity described in subparagraph (C), to the health |
| 21 | benefits plan with which the entity is under contract, |
| 22 | at such times, and in such form and manner, as the |
| 23 | Secretary shall specify: |
| 24 | "(A) A health benefits plan. |

| 1 | "(B) Any entity that provides pharmacy |
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| 2 | benefits management services on behalf of a |
| 3 | health benefits plan (in this section referred to |
| 4 | as a 'PBM') that manages prescription drug |
| 5 | coverage under a contract with— |
| 6 | "(i) a PDP sponsor of a prescription |
| 7 | drug plan or an MA organization offering |
| 8 | an MA-PD plan under part D of title |
| 9 | XVIII; or |
| 10 | "(ii) a qualified health benefits plan |
| 11 | offered through an exchange established by |
| 12 | a State under section 1311 of the Patient |
| 13 | Protection and Affordable Care Act. |
| 14 | "(C) Any affiliate of an entity described in |
| 15 | subparagraph (B) that acts as a price nego- |
| 16 | tiator or group purchaser on behalf of such |
| 17 | PBM, PDP sponsor, MA organization, or quali- |
| 18 | fied health benefits plan. |
| 19 | "(2) AFFILIATE DEFINED.—In this section, the |
| 20 | term 'affiliate' means any entity that is owned by, |
| 21 | controlled by, or related under a common ownership |
| 22 | structure with a PBM (including an entity owned or |
| 23 | controlled by the PDP sponsor of a prescription |
| 24 | drug plan, MA organization offering an MA-PD |
| 25 | plan, or qualified health benefits plan for which such |

| 1 | entity is acting as a price negotiator or group pur- |
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| 2 | chaser)."; |
| 3 | (2) in subsection (b)— |
| 4 | (A) in paragraph (2), by inserting "and |
| 5 | percentage" after "and the aggregate amount"; |
| 6 | and |
| 7 | (B) by adding at the end the following new |
| 8 | paragraph: |
| 9 | "(4) The amount (in the aggregate and |
| 10 | disaggregated by type) of all fees the PBM or an af- |
| 11 | filiate of the PBM receives from all pharmaceutical |
| 12 | manufacturers in connection with patient utilization |
| 13 | under the plan, and the amount and percentage (in |
| 14 | the aggregate and disaggregated by type) of such |
| 15 | fees that are passed through to the plan sponsor or |
| 16 | issuer."; and |
| 17 | (3) by adding at the end the following new sub- |
| 18 | section: |
| 19 | "(e) Annual Report.—The Secretary shall make |
| 20 | publicly available on the Internet website of the Centers |
| 21 | for Medicare & Medicaid Services an annual report that |
| 22 | summarizes the trends observed with respect to data re- |
| 23 | ported under subsection (b).". |

- 1 (b) Effective Date.—The amendments made by
- 2 this section shall apply to plan or contract years beginning
- 3 on or after January 1, 2027.
- 4 (c) IMPLEMENTATION.—Notwithstanding any other
- 5 provision of law, the Secretary may implement the amend-
- 6 ments made by this section by program instruction or oth-
- 7 erwise.
- 8 (d) Non-application of the Paperwork Reduc-
- 9 TION ACT.—Chapter 35 of title 44, United States Code
- 10 (commonly referred to as the "Paperwork Reduction Act
- 11 of 1995"), shall not apply to the implementation of the
- 12 amendments made by this section.

