AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 6610 OFFERED BY MR. COMER OF KENTUCKY

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Pharmacists Fight Back in Federal Employee Health Benefit Plans Act''.

SEC. 2. PHARMACY PAYMENT AND REIMBURSEMENT REQUIREMENTS.

(a) IN GENERAL.—Section 8904 of title 5, United States Code, is amended by adding at the end the following new subsection:

''(c)(1) The Office of Personnel Management may not contract for or approve a health benefits plan under section 8903 of this title unless such plan—

''(A) requires any pharmacy benefits manager administering prescription drug benefits on behalf of such health benefits plan, either directly or through an affiliate of such pharmacy benefits manager, to—

''(i) reimburse an in-network pharmacy for the ingredient cost of a prescription drug in an amount equal to the sum of—

''(I) the national average drug acquisition cost for the drug on the day of claim adjudication (or, in the case of a drug that does not appear on the national average drug acquisition cost index, the wholesale acquisition cost for such prescription drug);

''(II) the lesser of the amount that is equal to 4 percent of the amount described in subclause (I) or $50; and

''(III) pay an in-network pharmacy a professional dispensing fee that is equal to the professional dispensing fee paid by the State in which the pharmacy is located under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for dispensing a prescription drug; and

''(ii) for any manufacturer rebate such pharmacy benefits manager or affiliate thereof receives in connection with a drug obtained at an in-network pharmacy by an individual pursuant to such prescription drug benefits, such pharmacy benefits manager or affiliate shall—

''(I) apply, at the point of sale of such drug, the full amount of any coinsurance

or copayment owed by such individual with respect to such drug, such that the amount of coinsurance or copayment so owed is calculated based on the net cost of the drug, including such rebate; and

''(II) remit to the carrier for such health benefits plan an amount equal to the amount of such rebate, less the amount by which the coinsurance or copayment owed by such individual with respect to such drug was reduced under subclause (I);

''(B) prohibits such pharmacy benefits manager and any affiliate thereof from—

''(i) directing, ordering, or requiring an enrollee in such health benefits plan to use a specific pharmacy, including a pharmacy that is an affiliate of such pharmacy benefits manager, for the purpose of filling a prescription for a prescription drug or receiving services;

''(ii) advertising, marketing, or promoting a specific pharmacy, including a pharmacy that is an affiliate of such pharmacy benefits manager, over another in-network pharmacy;

''(iii) creating any network or engaging in any practice, including accreditation or credentialing standards, day supply limitations, or delivery method limitations, that excludes an in-network pharmacy or restricts an in-network pharmacy from filling a prescription for a prescription drug for which benefits are available under such health benefits plan;

''(iv) directly or indirectly engaging in any practice that attempts to influence or induce a pharmaceutical manufacturer to limit the distribution of a prescription drug to a small number of pharmacies or certain types of pharmacies, or to restrict distribution of such drug to non-affiliate pharmacies; or

''(v) requiring an enrollee in such health benefits plan to reimburse the pharmacy benefits manager or affiliate for the dispensing fee paid to an in-network pharmacy pursuant to subparagraph (A)(ii) with respect to a prescription drug obtained at such pharmacy by such individual, or otherwise increasing the amount owed by such individual with respect to such drug to account for such dispensing fee;

''(C) prohibits any such pharmacy benefits manager from lowering, imposing a fee on, or otherwise make any adjustment to a prescription drug claim at the time the claim for such drug is adjudicated or after the claim is adjudicated that reduces the amount a pharmacy is reimbursed for such drug pursuant to subparagraph (A), including by charging any fee to such pharmacy that is not associated with a prescription drug claim;

''(D) requires the carrier providing such health benefits plan to cooperate with any inspection of such carrier carried out under section 8902b(a)(3)(B) of this title, including by making available to the Office such documents, personnel, and facilities of the carrier as and when determined necessary to Office to carry out such inspection; and

''(E) does not—

''(i) direct, order, or require an individual enrolled in such health benefits plan to use a specific pharmacy, including a pharmacy that is an affiliate of such pharmacy benefit manager, for the purpose of filling a prescription for a prescription drug or receiving services; or

''(ii) increase the costs to an individual for using an in-network pharmacy that is not an

affiliate of such pharmacy benefit manager, including by requiring such individual to pay a higher cost-sharing obligation when such individual chooses to use an in-network pharmacy that is not such an affiliate.

''(2)(A) Each carrier offering a health benefits plan under this chapter, and any pharmacy benefit manager or subcontractor providing prescription drug benefit services on behalf of such carrier, shall submit to the Office of Personnel Management, on an annual basis, the information described in section 1860D–12(h)(1)(C)(i) of the Social Security Act (42 U.S.C. 1395w–112(h)(1)(C)(i)) and such additional pseudonymized information as the Director of the Office may require relating to prescription drug spending, pricing, and utilization.

''(B) Compliance with this subsection shall be a condition of participation in the program under this chapter by a carrier and subject to such statutory and contractual remedies and penalties as the Director determines appropriate.

''(C) Each carrier shall require any pharmacy benefits manager administering prescription drug benefits on its behalf to maintain records sufficient to demonstrate compliance with this subsection including records relating to affiliate pharmacy transactions, transfer pricing ar-

rangements, acquisition costs, reimbursement determinations, fees, incentive payments, and other remuneration.

''(D) Such records shall be made available to the Office upon request solely for purposes of inspection, audit, investigation, or enforcement.

''(3) A carrier and any contracted pharmacy benefits manager shall permit any pharmacy that agrees to the standard contract terms and conditions to participate as an in-network pharmacy, and all contract terms and conditions shall be consistent with the requirements of this subsection and shall be reasonable and relevant according to standards approved by the Office.

''(4) In this subsection—

''(A) the term 'affiliate' means an entity, including a pharmacy, that directly or indirectly through one or more intermediaries—

''(i) owns, in whole or in part, or controls a pharmacy benefits manager;

''(ii) is owned, in whole or in part, or controlled by that is a pharmacy benefits manager; or

''(iii) is a subsidiary of or owned, in whole or in part, or controlled by an entity that owns or controls a pharmacy benefits manager;

''(B) the term 'in-network pharmacy' means a pharmacy that—

''(i) is licensed by the State board of pharmacy in the State in which the pharmacy is located;

''(ii) has a valid contract or participation agreement with a carrier or contracted pharmacy benefits manager to provide covered prescription drug services to the carrier's enrollees;

''(iii) fills or seeks to fill a prescription drug for an enrollee; and

''(iv) is not barred under section 8902a of this chapter;

''(v) the term 'manufacturer rebate' means any price concession (including any payment, discount, administration fee, credit, incentive, or penalty) provided by the manufacturer of a covered prescription drug (or any affiliate, subsidiary, third party, or intermediary of such manufacturer) to a carrier (or any pharmacy benefits manager acting on behalf of such carrier, including any affiliate of such manager, as applicable), in connection with the furnishing of such covered prescription drug to an individual

enrolled in a health benefits plan offered by such carrier;

''(C) the term 'pharmacy benefits manager' means a person, business entity, affiliate, or other entity that performs pharmacy benefits management services;

''(D) the term 'pharmacy benefits management services'—

''(i) means the managing or administration of a plan or program that pays for, reimburses, and covers the cost of prescription drugs and medical devices; and

''(ii) includes the processing and payment of claims for prescription drugs and the adjudication of appeals or grievances related to the prescription drug benefit;

''(E) the term 'prescription drug' means a prescription drug covered by a health benefits plan that is dispensed to an enrollee; and

''(F) the term 'professional dispensing fee' means a fee paid to a pharmacy to cover the pharmacy's costs associated with ensuring that a covered individual receives a prescribed drug, product, or supply separate from and in addition to the ingre-

dient cost reimbursement described in paragraph (1).''.

(b) NONCOMPLIANCE PENALTIES.—

(1) IN GENERAL.—Chapter 89 of title 5, United States Code, is amended by inserting after section 8902a the following new section:

''§ 8902b. Pharmacy benefit manager-related sanctions

''(a) MONETARY PENALTIES.—

''(1) IN GENERAL.—Except as otherwise provided by this subsection and subsection (c), if the Office of Personnel Management determines that a pharmacy benefits manager violated a requirement or prohibition applicable to such pharmacy benefits manager with respect to a health benefits plan pursuant to section 8904(c)(1) of this title, the Office shall, in addition to any other penalties that may be prescribed by law and after consultation with the Attorney General, impose a civil monetary penalty of $10,000,000 for each such violation—

''(A) on such pharmacy benefits manager; and

''(B) if, during the 10-year period ending on the imposition of such civil monetary penalty, not fewer than five civil monetary pen-

alties have been imposed on such pharmacy benefits manager under this paragraph with respect to health benefit plans provided by the carrier providing such health benefits plan, on such carrier.

''(2) MAXIMUM PENALTY AMOUNT.—

''(A) PHARMACY BENEFIT MANAGERS.—For each carrier providing a health benefits plan with respect to which a pharmacy benefits manager is determined to have committed a violation described in paragraph (1), the total amount of civil monetary penalties imposed on such pharmacy benefits manager under such paragraph for violations with respect to the health benefit plans of such carrier may not exceed $100,000,000 during any 10-year period.

''(B) CARRIERS.—The total amount of civil monetary penalties imposed on a carrier under paragraph (1) may not exceed $50,000,000 during any 10-year period.

''(3) REMEDIATION PLAN.—

''(A) IN GENERAL.—Not later than 60 days after the date on which the Office of Personnel Management imposes a civil monetary penalty on a carrier under paragraph (1) with

respect to a pharmacy benefits manager that is the fifth such civil monetary penalty imposed on such carrier with respect to such pharmacy benefits manager in a 10-year period, such carrier shall develop and submit to the Office of Personnel Management a plan to ensure that each pharmacy benefit manager administering prescription drug benefits on behalf of a health benefits plan provided by such carrier complies with the requirements and prohibitions applicable to such pharmacy benefit manager pursuant to section 8904(c)(1).

''(B) OVERSIGHT.—Not later than 60 days after the date on which a carrier submits plan under subparagraph (A), and with such frequency thereafter as determined appropriate by the Office of Personnel Management, the Office of Personnel Management shall inspect such carrier to assess the compliance of such carrier with such plan.

''(4) SEQUENTIAL IMPOSITION.—For the purposes of this subsection, any civil monetary penalties concurrently imposed under paragraph (1) shall be deemed to be imposed sequentially.

''(5) CIVIL ACTION.—

"(A) IN GENERAL.—A civil action to recover a civil monetary penalty imposed under this subsection shall be brought by the Attorney General in the name of the United States, and may be brought in the United States district court for the district where the claim involved was presented or where the pharmacy benefits manager or carrier subject to such civil monetary penalty resides.

"(B) TREATMENT OF AMOUNTS RECOVERED.—Amounts recovered under this subsection shall be paid to the Office of Personnel Management for deposit into the Employees Health Benefits Fund.

"(6) DEDUCTION FROM AMOUNTS OWED.—The amount of a civil monetary penalty imposed under this subsection may be deducted from any sum then or later owing by the United States to the party against whom the penalty or assessment has been levied.

"(7) STATUTE OF LIMITATIONS.—The Office of Personnel Management may not initiate any action to impose a civil monetary penalty on a pharmacy benefits manager or carrier under this subsection later than 6 years after the date of the violation of

the requirement or prohibition by the pharmacy benefits manager for which such civil monetary penalty would be imposed.

''(b) DEBARMENT.—

''(1) IN GENERAL.—The Office of Personnel Management shall bar a pharmacy benefits manager from administering prescription drug benefits on behalf of a health benefits plan, either directly of through an affiliate of such pharmacy benefits manager, under the program under this chapter if, in any 10-year period, the Office of Personnel Management imposes 10 or more civil monetary penalties on such pharmacy benefits manager under subsection (a).

''(2) EFFECTIVE DATE.—Except as provided by subsection (c), debarment of a pharmacy benefits manager under paragraph (1) shall be effective on the date that is 90 days after the date on which the Office of Personnel Management imposes the first civil monetary penalty pursuant to which such pharmacy benefits manager is subject to such debarment.

''(3) PAYMENT PROHIBITED.—

''(A) IN GENERAL.—Notwithstanding section 8902(j) or any other provision of this chapter, if, under this section a pharmacy benefits

manager is debarred under paragraph (1), no payment may be made by a carrier pursuant to any contract under this chapter (either to such pharmacy benefits manager or by reimbursement) for any service or supply furnished by such pharmacy benefits manager during the period of the debarment.

''(B) SUBCONTRACT CONTRACTS.—Each contract under this chapter shall contain such provisions as may be necessary to carry out subparagraph (A) and the other provisions of this section.

''(4) TERMINATION.—The debarment of a pharmacy benefits manager under paragraph (1) shall be immediately terminated if all civil monetary penalties pursuant to which such pharmacy benefits manager is subject to such debarment are overturned or wholly set aside on appeal.

''(5) RULE OF CONSTRUCTION.—For the purposes of this subsection, a civil monetary penalty is a civil monetary penalty pursuant to which a pharmacy benefits manager is subject to debarment under paragraph (1) if such civil monetary penalty is not less than the tenth civil monetary penalty im-

posed on such pharmacy benefits manager under subsection (a) during a 10-year period that—

''(A) has not been appealed and for which the period of appeal has elapsed; or

''(B) has been appealed, all appeals have been exhausted, and has not be overturned or wholly set aside.

''(c) HEARING.—

''(1) IN GENERAL.—The Office of Personnel Management shall not make a determination adverse to a pharmacy benefits manager or carrier under subsection (a) or a determination adverse to a pharmacy benefits manager under subsection (b) until such pharmacy benefits manager or carrier, as applicable, has been given reasonable notice and an opportunity for the determination to be made after a hearing as provided in accordance with this subsection.

''(2) HEARING REQUIRED.—Any pharmacy benefits manager or carrier that is the subject of an adverse determination by the Office of Personnel Management under this section shall be entitled to reasonable notice and an opportunity to request a hearing on the record, and to judicial review as provided in this subsection after the Office of Personnel Man-

agement makes a final decision regarding such adverse determination.

''(3) HEARING CRITERIA.—The Office of Personnel Management shall grant a request for a hearing under paragraph (2) upon a showing that due process rights have not previously been afforded with respect to any finding of fact which is relied upon as a cause for an adverse determination under this section. Such hearing shall be conducted without regard to subchapter II of chapter 5 and chapter 7 of this title by a hearing officer who shall be designated by the Director of the Office of Personnel Management and who shall not otherwise have been involved in the adverse determination being appealed.

''(4) REQUEST FOR HEARING.—A request for a hearing under paragraph (2) shall be filed within such period and in accordance with such procedures as the Office of Personnel Management shall prescribe by regulation.

''(5) APPEAL.—

''(A) IN GENERAL.—Any pharmacy benefits manager or carrier adversely affected by a final decision of the Office of Personnel Management regarding an adverse determination that is made after a hearing under paragraph

(2) with respect to such adverse determination and to which such pharmacy benefits manager or carrier was a party may seek review of such final decision in the United States District Court for the District of Columbia or for the district in which the pharmacy benefits manager or carrier resides or has his or her principal place of business by filing a notice of appeal in such court within 60 days after the date the decision is issued, and by simultaneously sending copies of such notice by certified mail to the Director of the Office and to the Attorney General.

''(B) ANSWER.—In answer to an appeal filed under subparagraph (A), the Director of the Office of Personnel Management shall promptly file in the relevant court a certified copy of the transcript of the record of the hearing conducted under paragraph (2) and other evidence upon which the findings and final decision complained of are based.

''(C) COURT AUTHORITY.—With respect to an appeal filed under subparagraph (A), the court shall have power to enter, upon the pleadings and evidence of record, a judgment affirm-

ing, modifying, or setting aside, in whole or in part, the final decision of the Office of Personnel Management that is the subject of such appeal, with or without remanding the case for a rehearing. The court shall not set aside or remand such final decision unless there is not substantial evidence on the record, taken as whole, to support such final decision or unless the actions of the Office of Personnel Management with respect to such final decision constitutes an abuse of discretion.

''(6) DEFENSE FORFEITURE.—Matters that were raised or that could have been raised in a hearing under paragraph (2) or an appeal under paragraph (5) may not be raised as a defense to a civil action by the United States to collect a civil monetary penalty imposed under subsection (a).

''(d) AFFILIATE; PHARMACY BENEFITS MANAGER; PRESCRIPTION DRUG DEFINED.—In this section, the terms 'affiliate', 'pharmacy benefits manager', and 'prescription drug' have the meanings given such terms, respectively, in section 8904(c) of this title.''.

(2) CLERICAL AMENDMENT.—The table of sections for chapter 89 of title 5, United States Code,

is amended by inserting after the item relating to section 8902a the following new item:

''8902b. Pharmacy benefit manager-related sanctions.''.

(c) CONFORMING AMENDMENT.—Section 8903a(b) of title 5, United States Code, is amended—

(1) in paragraph (3), by striking ''and'' at the end;

(2) in paragraph (4), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new paragraph:

''(5) complies with the requirements under section 8904(c).''.

(d) EFFECTIVE DATE.—The amendments made by this Act shall take effect on the date that is two years after the date of the enactment of this Act.

Amend the title so as to read: ''A bill to amend chapter 89 of title 5, United States Code, to limit the costs of pharmacy benefit managers with respect to the Federal Employees Health Benefits Program, and for other purposes.''.

☒