Cantwell_Substitute (as modified)

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.

S. 127

To prevent unfair and deceptive acts or practices and the dissemination of false information related to pharmacy benefit management services for prescription drugs, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by Ms. CANTWELL (for herself and Mr. GRASSLEY)

Viz:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Pharmacy Benefit Manager Transparency Act of 2023".

SEC. 2. PROHIBITION ON UNFAIR OR DECEPTIVE PRESCRIPTION DRUG PRICING PRACTICES.

(a) CONDUCT PROHIBITED.—Except as provided in subsection (b), it shall be unlawful for any pharmacy benefit manager (or affiliate, subsidiary, or agent of a phar-

macy benefit manager), directly or indirectly, to engage in any of the following activities related to pharmacy benefit management services:

(1) Charge a health plan or payer a different amount for a prescription drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses a pharmacy for the prescription drug's ingredient cost or dispensing fee where the pharmacy benefit manager retains the amount of any such difference.

(2) Arbitrarily, unfairly, or deceptively, by contract or any other means, reduce, rescind, or otherwise claw back any reimbursement payment, in whole or in part, to a pharmacist or pharmacy for a prescription drug's ingredient cost or dispensing fee.

(3) Arbitrarily, unfairly, or deceptively, by contract or any other means, increase fees or lower reimbursement to a pharmacy in order to offset reimbursement changes instructed by the Federal Government under any health plan funded by the Federal Government.

(b) EXCEPTIONS.—A pharmacy benefit manager shall not be in violation of subsection (a) if the pharmacy benefit manager meets the following conditions:

(1) The pharmacy benefit manager, affiliate, subsidiary, or agent passes along or returns 100 percent of any price concession to a health plan or payer, including any rebate, discount, or other price concession.

(2) The pharmacy benefit manager, affiliate, subsidiary, or agent provides full and complete disclosure of—

(A) the cost, price, and reimbursement of a prescription drug to each health plan, payer, and pharmacy with which the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement to provide pharmacy benefit management services;

(B) each fee, markup, and discount charged or imposed by the pharmacy benefit manager, affiliate, subsidiary, or agent to each health plan, payer, and pharmacy with which the pharmacy benefit manager, affiliate, subsidiary, or agent has a contract or agreement for pharmacy benefit management services; or

(C) the aggregate amount of all remuneration the pharmacy benefit manager receives from a prescription drug manufacturer for a prescription drug, including any rebate, dis-

count, administration fee, and any other payment or credit obtained or retained by the pharmacy benefit manager, or affiliate, subsidiary, or agent of the pharmacy benefit manager, pursuant to a contract or agreement for pharmacy benefit management services to a health plan, payer, or any Federal agency (upon the request of the agency).

SEC. 3. PROHIBITION ON FALSE INFORMATION.

It shall be unlawful for any person to report information related to pharmacy benefit management services to a Federal department or agency if—

(1) the person knew, or reasonably should have known, the information to be false or misleading;

(2) the information was required by law to be reported; and

(3) the false or misleading information reported by the person would affect analysis or information compiled by the Federal department or agency for statistical or analytical purposes with respect to the market for pharmacy benefit management services.

SEC. 4. TRANSPARENCY.

(a) REPORTING BY PHARMACY BENEFIT MANAGERS.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, each pharmacy ben-

efit manager (or affiliate, subsidiary, or agent of a pharmacy benefit manager) shall report to the Commission the following information:

(1) The aggregate amount of the difference between the amount the pharmacy benefit manager was paid by each health plan and the amount that the pharmacy benefit manager paid each pharmacy on behalf of the health plan for prescription drugs.

(2) The aggregate amount of any—

(A) generic effective rate fee charged to each pharmacy;

(B) direct and indirect remuneration fee charged or other price concession to each pharmacy; and

(C) payment rescinded or otherwise clawed back from a reimbursement made to each pharmacy.

(3) If, during the reporting year, the pharmacy benefit manager moved or reassigned a prescription drug to a formulary tier that has a higher cost, higher copayment, higher coinsurance, or higher deductible to a consumer, or a lower reimbursement to a pharmacy, an explanation of the reason why the drug was moved or reassigned from 1 tier to another, including whether the move or reassignment

was determined or requested by a prescription drug manufacturer or other entity.

(4) With respect to any pharmacy benefit manager that owns, controls, or is affiliated with a pharmacy, a report regarding any difference in reimbursement rates or practices, direct and indirect remuneration fees or other price concessions, and clawbacks between a pharmacy that is owned, controlled, or affiliated with the pharmacy benefit manager and any other pharmacy.

(b) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, and annually thereafter, the Commission shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that addresses, at a minimum—

(A) the number actions brought by the Commission during the reporting year to enforce this Act and the outcome of each such enforcement action;

(B) the number of open investigations or inquiries into potential violations of this Act as of the time the report is submitted;

(C) the number and nature of complaints received by the Commission relating to an allegation of a violation of this Act during the reporting year;

(D) an anonymized summary of the reports filed with the Commission pursuant to subsection (a) for the reporting year; and

(E) policy or legislative recommendations to strengthen any enforcement action relating to a violation of this Act, including recommendations to include additional prohibited conducted in section 2(a).

(2) FORMULARY DESIGN OR PLACEMENT PRACTICES.—Not later than 1 year after the date of enactment of this Act, the Commission shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that addresses the policies, practices, and role of pharmacy benefit managers (including their affiliates, subsidiaries, and agents) regarding formulary design or placement, including whether—

(A) pharmacy benefit managers (including their affiliates, subsidiaries, and agents) use formulary design or placement to increase their

gross revenue without an accompanying increase in patient access or decrease in patient cost; or

(B) such policies or practices of pharmacy benefit managers regarding formulary design or placement violate section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45(a)).

(3) CONSTRUCTION.—Nothing in this section shall be construed as authorizing the Commission to disclose any information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

(c) GAO STUDY.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Commerce, Science, and Transportation, the Committee on Finance, and the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report that—

(1) addresses, at minimum—

(A) the role that pharmacy benefit managers play in the pharmaceutical supply chain;

(B) the state of competition among pharmacy benefit managers, including the market share for the Nation's 10 largest pharmacy benefit managers;

(C) the use of rebates and fees by pharmacy benefit managers, including data for each of the 10 largest pharmacy benefit managers that reflects, for each drug in the formulary of each such pharmacy benefit manager—

(i) the amount of the rebate passed on to patients;

(ii) the amount of the rebate passed on to payors;

(iii) the amount of the rebate kept by the pharmacy benefit manager; and

(iv) the role of fees charged by the pharmacy benefit manager;

(D) whether pharmacy benefit managers structure their formularies in favor of high-rebate prescription drugs over lower-cost, lower-rebate alternatives;

(E) the average prior authorization approval time for each of the 10 largest pharmacy benefit managers;

(F) factors affecting the use of step therapy in each of the 10 largest pharmacy benefit managers; and

(G) the extent to which the price that pharmacy benefit managers charge payors, such as the Medicare program under title XXVIII of the Social Security Act (42 U.S.C. 1395 et seq.), State Medicaid programs under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), the Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code, or private payors, for a drug is more than such pharmacy benefit managers pay the pharmacy for the drug; and

(2) provides recommendations for legislative action to lower the cost of prescription drugs for consumers and payors, improve the efficiency of the pharmaceutical supply chain by lowering intermediary costs, improve competition in pharmacy benefit management, and provide transparency in pharmacy benefit management.

SEC. 5. WHISTLEBLOWER PROTECTIONS.

(a) IN GENERAL.—A pharmacy benefit manager, health plan, pharmaceutical manufacturer, pharmacy, or any affiliate, subsidiary, or agent thereof shall not, directly

or indirectly, discharge, demote, suspend, diminish, or withdraw benefits from, threaten, harass, or in any other manner discriminate against or adversely impact a covered individual because—

(1) the covered individual, or anyone perceived as assisting the covered individual, takes (or is suspected to have taken or will take) a lawful action in providing to Congress, an agency of the Federal Government, the attorney general of a State, a State regulator with authority over the distribution or insurance coverage of prescription drugs, or a law enforcement agency relating to any act or omission that the covered individual reasonably believes to be a violation of this Act;

(2) the covered individual provides information that the covered individual reasonably believes evidences such a violation to—

(A) a person with supervisory authority over the covered individual at the pharmacy benefit manager, health plan, pharmaceutical manufacturer, pharmacy, or any affiliate, subsidiary, or agent thereof; or

(B) another individual working for the pharmacy benefit manager, health plan, pharmaceutical manufacturer, pharmacy, or any af-

filiate, subsidiary, or agent thereof who the covered individual reasonably believes has the authority to investigate, discover, or terminate the violation or to take any other action to address the violation;

(3) the covered individual testifies (or it is suspected that the covered individual will testify) in an investigation or judicial or administrative proceeding concerning such a violation;

(4) the covered individual assists or participates (or it is expected that the covered individual will assist or participate) in such an investigation or judicial or administrative proceeding; or

(5) the covered individual takes any other action to assist in carrying out the purposes of this Act.

(b) ENFORCEMENT.—An individual who alleges any adverse action in violation of subsection (a) may bring an action for a jury trial in the appropriate district court of the United States for the following relief:

(1) Temporary relief while the case is pending.

(2) Reinstatement with the same seniority status that the individual would have had, but for the discharge or discrimination.

(3) Twice the amount of back pay otherwise owed to the individual, with interest.

(4) Consequential and compensatory damages, and compensation for litigation costs, expert witness fees, and reasonable attorneys' fees.

(c) WAIVER OF RIGHTS AND REMEDIES.—The rights and remedies provided for in this section shall not be waived by any policy form or condition of employment, including by a predispute arbitration agreement.

(d) PREDISPUTE ARBITRATION AGREEMENTS.—No predispute arbitration agreement shall be valid or enforceable if the agreement requires arbitration of a dispute arising under this section.

SEC. 6. ENFORCEMENT.

(a) ENFORCEMENT BY THE COMMISSION.—

(1) UNFAIR AND DECEPTIVE ACTS OR PRACTICES.—A violation of this Act shall be treated as a violation of a rule defining an unfair or deceptive act or practice under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

(2) POWERS OF THE COMMISSION.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the Commission shall enforce this Act in the same manner, by the same

means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this Act.

(B) PRIVILEGES AND IMMUNITIES.—Subject to paragraph (3), any person who violates this Act shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act (15 U.S.C. 41 et. seq.).

(C) NONPROFIT ORGANIZATIONS AND INSURANCE.—Notwithstanding section 4 or 6 of the Federal Trade Commission Act (15 U.S.C. 44, 46), section 2 of McCarran-Ferguson Act (15 U.S.C. 1012), or any other jurisdictional limitation of the Commission, the Commission shall also enforce this Act, in the same manner provided in subparagraphs (A) and (B) of this paragraph, with respect to—

(i) organizations not organized to carry on business for their own profit or that of their members; and

(ii) the business of insurance, and persons engaged in such business.

(D) AUTHORITY PRESERVED.—Nothing in this section shall be construed to limit the authority of the Commission under any other provision of law.

(3) PENALTIES.—

(A) ADDITIONAL CIVIL PENALTY.—In addition to any penalty applicable under the Federal Trade Commission Act (15 U.S.C. 41 et seq.), any person that violates this Act shall be liable for a civil penalty of not more than $1,000,000.

(B) METHOD.—The penalties provided by subparagraph (A) shall be obtained in the same manner as civil penalties imposed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a(1)(B).

(C) MULTIPLE OFFENSES; MITIGATING FACTORS.—In assessing a penalty under subparagraph (A)—

(i) each day of a continuing violation shall be considered a separate violation; and

(ii) the court shall take into consideration, among other factors—

(I) the seriousness of the violation;

(II) the efforts of the person committing the violation to remedy the harm caused by the violation in a timely manner; and

(III) whether the violation was intentional.

(b) ENFORCEMENT BY STATES.—

(1) IN GENERAL.—If the attorney general of a State has reason to believe that an interest of the residents of the State has been or is being threatened or adversely affected by a practice that violates this Act, the attorney general of the State may bring a civil action on behalf of the residents of the State in an appropriate district court of the United States to obtain appropriate relief.

(2) RIGHTS OF THE COMMISSION.—

(A) NOTICE TO THE COMMISSION.—

(i) IN GENERAL.—Except as provided in clause (iii), the attorney general of a State, before initiating a civil action under paragraph (1), shall provide written notification to the Commission that the attorney general intends to bring such civil action.

(ii) CONTENTS.—The notification required under clause (i) shall include a copy of the complaint to be filed to initiate the civil action.

(iii) EXCEPTION.—If it is not feasible for the attorney general of a State to provide the notification required under clause (i) before initiating a civil action under paragraph (1), the attorney general shall notify the Commission immediately upon instituting the civil action.

(B) INTERVENTION BY THE COMMISSION.—The Commission may—

(i) intervene in any civil action brought by the attorney general of a State under paragraph (1); and

(ii) upon intervening—

(I) be heard on all matters arising in the civil action; and

(II) file petitions for appeal of a decision in the civil action.

(3) CONSTRUCTION.—Nothing in this subsection may be construed to prevent the attorney general of a State from exercising the powers conferred on the attorney general by the laws of the

State to conduct investigations, to administer oaths or affirmations, or to compel the attendance of witnesses or the production of documentary or other evidence.

(4) VENUE; SERVICE OF PROCESS.—

(A) VENUE.—Any action brought under paragraph (1) may be brought in—

(i) the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code; or

(ii) another court of competent jurisdiction.

(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which—

(i) the defendant is an inhabitant, may be found, or transacts business; or

(ii) venue is proper under section 1391 of title 28, United States Code.

(5) ACTIONS BY OTHER STATE OFFICIALS.—

(A) IN GENERAL.—If an attorney general lacks appropriate jurisdiction to bring a civil action under paragraph (1), any other officer of a State who is authorized by the State to do so

may bring a civil action under paragraph (1), subject to the same requirements and limitations that apply under this subsection to civil actions brought by attorneys general.

(B) CLARIFICATION OF AUTHORITY.—The authority provided by subparagraph (A) shall supplant, and not supplement, the authorities of State attorneys general under paragraph (1).

(C) SAVINGS PROVISION.—Nothing in this subsection may be construed to prohibit an authorized official of a State from initiating or continuing any proceeding in a court of the State for a violation of any civil or criminal law of the State.

(c) AFFIRMATIVE DEFENSE.—In an action brought under this section to enforce section 2, it shall be an affirmative defense, on which the defendant has the burden of persuasion by a preponderance of the evidence, that the conduct alleged to be a violation of section 2 was nonpretextual and reasonably necessary to—

(1) prevent a violation of, or comply with, Federal or State law;

(2) protect patient safety; or

(3) protect patient access.

SEC. 7. PROTECTION OF PERSONAL HEALTH INFORMATION.

In making any disclosure or report required by this Act, a pharmacy benefit manager (including their affiliates, subsidiaries, and agents) shall not include any information that would identify a patient or a provider that issued a prescription.

SEC. 8. EFFECT ON STATE LAWS.

Nothing in this Act shall be construed to preempt, displace, or supplant any State laws, rules, regulations, or requirements, or the enforcement thereof.

SEC. 9. DEFINITIONS.

In this Act:

(1) COMMISSION.—The term ''Commission'' means the Federal Trade Commission.

(2) COVERED INDIVIDUAL.—The term ''covered individual'' means a current or former employee, contractor, subcontractor, service provider, or agent of a pharmacy benefit manager, health plan, pharmaceutical manufacturer, pharmacy, or any affiliate, subsidiary, or agent thereof.

(3) HEALTH PLAN.—The term ''health plan'' means any group or individual health insurance plan or coverage, including any health insurance plan or coverage sponsored or funded by the Federal Gov-

ernment or the government of any State, Territory, or subdivision thereof.

(4) PHARMACY BENEFIT MANAGER.—The term ''pharmacy benefit manager'' means any entity that provides pharmacy benefit management services on behalf of a health plan, a payer, or health insurance issuer.

(5) PHARMACY BENEFIT MANAGEMENT SERVICES.—The term ''pharmacy benefit management services'' means, pursuant to a written agreement with a payer or health plan offering group or individual health insurance coverage, directly or through an intermediary, the service of—

(A) negotiating terms and conditions, including rebates and price concessions, with respect to a prescription drug on behalf of the health plan, coverage, or payer; or

(B) managing the prescription drug benefits provided by the health plan, coverage, or payer, which may include formulary management the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug

benefit, contracting with network pharmacies, or the provision of related services.

(6) PRESCRIPTION DRUG.—The term ''prescription drug'' means—

(A) a drug, as that term is defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)), that is—

(i) approved by the Food and Drug Administration under section 505 of such Act (21 U.S.C. 355); and

(ii) subject to the requirements of section 503(b)(1) of such Act (21 U.S.C. 353(b)(1));

(B) a biological product as that term is defined in section 351 of the Public Health Service Act (42 U.S.C. 262(i)(1)); or

(C) a product that is biosimilar to, or interchangeable with, a biologic product under section 351 of the Public Health Service Act (42 U.S.C. 262(i)).