

Calendar No. 647

117TH CONGRESS
2^D SESSION

S. 4293

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.

IN THE SENATE OF THE UNITED STATES

MAY 24, 2022

Ms. CANTWELL (for herself, Mr. GRASSLEY, Mr. BOOZMAN, Mr. BRAUN, Mr. MORAN, Mr. TILLIS, Mr. TESTER, Mrs. HYDE-SMITH, and Mrs. CAPITO) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

DECEMBER 14, 2022

Reported by Ms. CANTWELL, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Pharmacy Benefit
3 Manager Transparency Act of 2022”.

4 **SEC. 2. PROHIBITION ON UNFAIR OR DECEPTIVE PRE-**
5 **SCRIPTION DRUG PRICING PRACTICES.**

6 (a) **CONDUCT PROHIBITED.**—Except as provided in
7 subsection (b), it shall be unlawful for any pharmacy ben-
8 efit manager (or affiliate, subsidiary, or agent of a phar-
9 macy benefit manager), directly or indirectly, to engage
10 in any of the following activities related to pharmacy ben-
11 efit management services:

12 (1) Charge a health plan or payer a different
13 amount for a prescription drug’s ingredient cost or
14 dispensing fee than the amount the pharmacy ben-
15 efit manager reimburses a pharmacy for the pre-
16 scription drug’s ingredient cost or dispensing fee
17 where the pharmacy benefit manager retains the
18 amount of any such difference.

19 (2) Arbitrarily, unfairly, or deceptively, by con-
20 tract or any other means, reduce, rescind, or other-
21 wise claw back any reimbursement payment, in
22 whole or in part, to a pharmacist or pharmacy for
23 a prescription drug’s ingredient cost or dispensing
24 fee.

25 (3) Arbitrarily, unfairly, or deceptively, by con-
26 tract or any other means, increase fees or lower re-

1 reimbursement to a pharmacy in order to offset reim-
2 bursement changes instructed by the Federal Gov-
3 ernment under any health plan funded by the Fed-
4 eral Government.

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

8 (1) The pharmacy benefit manager, affiliate,
9 subsidiary, or agent passes along or returns 100 per-
10 cent of any price concession to a health plan or
11 payer, including any rebate, discount, or other price
12 concession.

13 (2) The pharmacy benefit manager, affiliate,
14 subsidiary, or agent provides full and complete dis-
15 closure of—

16 (A) the cost, price, and reimbursement of
17 the prescription drug to each health plan,
18 payer, and pharmacy with which the pharmacy
19 benefit manager, affiliate, subsidiary, or agent
20 has a contract or agreement to provide phar-
21 macy benefit management services;

22 (B) each fee, markup, and discount
23 charged or imposed by the pharmacy benefit
24 manager, affiliate, subsidiary, or agent to each
25 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, discount, 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

1 compiled by the Federal department or agency for
 2 statistical or analytical purposes with respect to the
 3 market for pharmacy benefit management services.

4 **SEC. 4. TRANSPARENCY.**

5 (a) REPORTING BY PHARMACY BENEFIT MAN-
 6 AGERS.—Not later than 1 year after the date of enactment
 7 of this Act, and annually thereafter, each pharmacy ben-
 8 efit manager (or affiliate, subsidiary, or agent of a phar-
 9 macy benefit manager) shall report to the Commission the
 10 following information:

11 (1) The aggregate amount of the difference be-
 12 tween the amount the pharmacy benefit manager
 13 was paid by each health plan and the amount that
 14 the pharmacy benefit manager paid each pharmacy
 15 on behalf of the health plan for prescription drugs.

16 (2) The aggregate amount of any—

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

19 (B) direct and indirect remuneration fee
 20 charged or other price concession to each phar-
 21 macy; and

22 (C) payment rescinded or otherwise clawed
 23 back from a reimbursement made to each phar-
 24 macy.

(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 Com-

merce 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 Trans-

portation 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 (45 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.

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

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

5 (1) the covered individual, or anyone perceived
6 as assisting the covered individual, takes (or is sus-
7 pected to have taken or will take) a lawful action in
8 providing to Congress, an agency of the Federal
9 Government, the attorney general of a State, a State
10 regulator with authority over the distribution or in-
11 surance coverage of prescription drugs, or a law en-
12 forcement agency relating to any act or omission
13 that the covered individual reasonably believes to be
14 a violation of this Act;

15 (2) the covered individual provides information
16 that the covered individual reasonably believes evi-
17 dences such a violation to—

18 (A) a person with supervisory authority
19 over the covered individual at the pharmacy
20 benefit manager, health plan, pharmaceutical
21 manufacturer, pharmacy, or any affiliate, sub-
22 sidiary, or agent thereof; or

23 (B) another individual working for the
24 pharmacy benefit manager, health plan, phar-
25 maceutical manufacturer, pharmacy, or any af-

1 filiate, subsidiary, or agent thereof who the cov-
 2 ered individual reasonably believes has the au-
 3 thority to investigate, discover, or terminate the
 4 violation or to take any other action to address
 5 the violation;

6 ~~(3) the covered individual testifies (or it is sus-~~
 7 ~~pected that the covered individual will testify) in an~~
 8 ~~investigation or judicial or administrative proceeding~~
 9 ~~concerning such a violation;~~

10 ~~(4) the covered individual assists or participates~~
 11 ~~(or it is expected that the covered individual will as-~~
 12 ~~sist or participate) in such an investigation or judi-~~
 13 ~~cial or administrative proceeding; or~~

14 ~~(5) the covered individual takes any other ac-~~
 15 ~~tion to assist in carrying out the purposes of this~~
 16 ~~Act.~~

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

21 ~~(1) Temporary relief while the case is pending.~~

22 ~~(2) Reinstatement with the same seniority sta-~~
 23 ~~tus that the individual would have had, but for the~~
 24 ~~discharge or discrimination.~~

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

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

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

10 ~~(d)~~ PREDISPUTE ARBITRATION AGREEMENTS.—No
 11 predispute arbitration agreement shall be valid or enforce-
 12 able if the agreement requires arbitration of a dispute
 13 arising under this section.

14 **SEC. 6. ENFORCEMENT.**

15 ~~(a)~~ ENFORCEMENT BY THE COMMISSION.—

16 ~~(1)~~ UNFAIR AND DECEPTIVE ACTS OR PRAC-
 17 TICES.—A violation of this Act shall be treated as
 18 a violation of a rule defining an unfair or deceptive
 19 act or practice under section 18(a)(1)(B) of the Fed-
 20 eral Trade Commission Act (15 U.S.C.
 21 57a(a)(1)(B)).

22 ~~(2)~~ POWERS OF THE COMMISSION.—

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

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

6 (B) PRIVILEGES AND IMMUNITIES.—Sub-
7 ject to paragraph (3), any person who violates
8 this Act shall be subject to the penalties and
9 entitled to the privileges and immunities pro-
10 vided in the Federal Trade Commission Act (15
11 U.S.C. 41 et. seq.).

12 (C) NONPROFIT ORGANIZATIONS AND IN-
13 SURANCE.—Notwithstanding section 4 or 6 of
14 the Federal Trade Commission Act (15 U.S.C.
15 44, 46), section 2 of McCarran-Ferguson Act
16 (15 U.S.C. 1012), or any other jurisdictional
17 limitation of the Commission, the Commission
18 shall also enforce this Act, in the same manner
19 provided in subparagraphs (A) and (B) of this
20 paragraph, with respect to—

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

24 (ii) the business of insurance, and
25 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—

1 (I) the seriousness of the viola-
2 tion;

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

7 (III) whether the violation was
8 intentional.

9 (b) ENFORCEMENT BY STATES.—

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

18 (2) RIGHTS OF THE COMMISSION.—

19 (A) NOTICE TO THE COMMISSION.—

20 (i) IN GENERAL.—Except as provided
21 in clause (iii), the attorney general of a
22 State, before initiating a civil action under
23 paragraph (1), shall provide written notifi-
24 cation to the Commission that the attorney
25 general intends to bring such civil action.

1 (ii) ~~CONTENTS.~~—The notification re-
 2 quired under clause (i) shall include a copy
 3 of the complaint to be filed to initiate the
 4 civil action.

5 (iii) ~~EXCEPTION.~~—If it is not feasible
 6 for the attorney general of a State to pro-
 7 vide the notification required under clause
 8 (i) before initiating a civil action under
 9 paragraph (1), the attorney general shall
 10 notify the Commission immediately upon
 11 instituting the civil action.

12 (B) ~~INTERVENTION BY THE COMMISS-~~
 13 ~~SION.~~—The Commission may—

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

17 (ii) upon intervening—

18 (I) be heard on all matters aris-
 19 ing in the civil action; and

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

22 (3) ~~CONSTRUCTION.~~—Nothing in this sub-
 23 section may be construed to prevent the attorney
 24 general of a State from exercising the powers con-
 25 ferred on the attorney general by the laws of the

1 State to conduct investigations, to administer oaths
 2 or affirmations, or to compel the attendance of wit-
 3 nesses or the production of documentary or other
 4 evidence.

5 ~~(4) VENUE; SERVICE OF PROCESS.—~~

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

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

12 ~~(ii) another court of competent juris-~~
 13 ~~diction.~~

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

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

19 ~~(ii) venue is proper under section~~
 20 ~~1391 of title 28, United States Code.~~

21 ~~(5) ACTIONS BY OTHER STATE OFFICIALS.—~~

22 ~~(A) IN GENERAL.—In addition to a civil~~
 23 ~~action brought by an attorney general under~~
 24 ~~paragraph (1), any other officer of a State who~~
 25 ~~is authorized by the State to do so may bring~~

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

5 (B) SAVINGS PROVISION.—Nothing in this
 6 subsection may be construed to prohibit an au-
 7 thorized official of a State from initiating or
 8 continuing any proceeding in a court of the
 9 State for a violation of any civil or criminal law
 10 of the State.

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

17 (1) prevent a violation of, or comply with, Fed-
 18 eral or State law;

19 (2) protect patient safety; or

20 (3) protect patient access.

21 **SEC. 7. EFFECT ON STATE LAWS.**

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

1 **SEC. 8. DEFINITIONS.**

2 In this Act:

3 (1) COMMISSION.—The term “Commission”
4 means the Federal Trade Commission.

5 (2) COVERED INDIVIDUAL.—The term “covered
6 individual” means a current or former employee,
7 contractor, subcontractor, service provider, or agent
8 of a pharmacy benefit manager, health plan, phar-
9 maceutical manufacturer, pharmacy, or any affiliate,
10 subsidiary, or agent thereof.

11 (3) HEALTH PLAN.—The term “health plan”
12 means any group or individual health insurance plan
13 or coverage, including any health insurance plan or
14 coverage sponsored or funded by the Federal Gov-
15 ernment or the government of any State, Territory,
16 or subdivision thereof.

17 (4) PHARMACY BENEFIT MANAGER.—The term
18 “pharmacy benefit manager” means any entity that
19 provides pharmacy benefit management services on
20 behalf of a health plan, a payer, or health insurance
21 issuer.

22 (5) PHARMACY BENEFIT MANAGEMENT SERV-
23 ICES.—The term “pharmacy benefit management
24 services” means, pursuant to a written agreement
25 with a payer or health plan offering group or indi-

vidual 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

1 (ii) subject to the requirements of sec-
 2 tion 503(b)(1) of such Act (21 U.S.C.
 3 353(b)(1));

4 (B) a biological product as that term is de-
 5 fined in section 351 of the Public Health Serv-
 6 ice Act (42 U.S.C. 262(i)(1)); or

7 (C) a product that is biosimilar to, or
 8 interchangeable with, a biologic product under
 9 section 351 of the Public Health Service Act
 10 (42 U.S.C. 262(i)).

11 **SECTION 1. SHORT TITLE.**

12 *This Act may be cited as the “Pharmacy Benefit Man-*
 13 *ager Transparency Act of 2022”.*

14 **SEC. 2. PROHIBITION ON UNFAIR OR DECEPTIVE PRESCRIP-**
 15 **TION DRUG PRICING PRACTICES.**

16 (a) *CONDUCT PROHIBITED.—Except as provided in*
 17 *subsection (b), it shall be unlawful for any pharmacy ben-*
 18 *efit manager (or affiliate, subsidiary, or agent of a phar-*
 19 *macy benefit manager), directly or indirectly, to engage in*
 20 *any of the following activities related to pharmacy benefit*
 21 *management services:*

22 (1) *Charge a health plan or payer a different*
 23 *amount for a prescription drug’s ingredient cost or*
 24 *dispensing fee than the amount the pharmacy benefit*
 25 *manager reimburses a pharmacy for the prescription*

1 *drug's ingredient cost or dispensing fee where the*
 2 *pharmacy benefit manager retains the amount of any*
 3 *such difference.*

4 *(2) Arbitrarily, unfairly, or deceptively, by con-*
 5 *tract or any other means, reduce, rescind, or other-*
 6 *wise claw back any reimbursement payment, in whole*
 7 *or in part, to a pharmacist or pharmacy for a pre-*
 8 *scription drug's ingredient cost or dispensing fee.*

9 *(3) Arbitrarily, unfairly, or deceptively, by con-*
 10 *tract or any other means, increase fees or lower reim-*
 11 *bursement to a pharmacy in order to offset reimburse-*
 12 *ment changes instructed by the Federal Government*
 13 *under any health plan funded by the Federal Govern-*
 14 *ment.*

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

18 *(1) The pharmacy benefit manager, affiliate,*
 19 *subsidiary, or agent passes along or returns 100 per-*
 20 *cent of any price concession to a health plan or*
 21 *payer, including any rebate, discount, or other price*
 22 *concession.*

23 *(2) The pharmacy benefit manager, affiliate,*
 24 *subsidiary, or agent provides full and complete disclo-*
 25 *sure of—*

1 (A) the cost, price, and reimbursement of
2 the prescription drug to each health plan, payer,
3 and pharmacy with which the pharmacy benefit
4 manager, affiliate, subsidiary, or agent has a
5 contract or agreement to provide pharmacy ben-
6 efit management services;

7 (B) each fee, markup, and discount charged
8 or imposed by the pharmacy benefit manager, af-
9 filiate, subsidiary, or agent to each health plan,
10 payer, and pharmacy with which the pharmacy
11 benefit manager, affiliate, subsidiary, or agent
12 has a contract or agreement for pharmacy ben-
13 efit management services; or

14 (C) the aggregate amount of all remunera-
15 tion the pharmacy benefit manager receives from
16 a prescription drug manufacturer for a prescrip-
17 tion drug, including any rebate, discount, ad-
18 ministration fee, and any other payment or
19 credit obtained or retained by the pharmacy ben-
20 efit manager, or affiliate, subsidiary, or agent of
21 the pharmacy benefit manager, pursuant to a
22 contract or agreement for pharmacy benefit man-
23 agement services to a health plan, payer, or any
24 Federal agency (upon the request of the agency).

1 **SEC. 3. PROHIBITION ON FALSE INFORMATION.**

2 *It shall be unlawful for any person to report informa-*
 3 *tion related to pharmacy benefit management services to*
 4 *a Federal department or agency if—*

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

7 *(2) the information was required by law to be re-*
 8 *ported; and*

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

14 **SEC. 4. TRANSPARENCY.**

15 *(a) REPORTING BY PHARMACY BENEFIT MANAGERS.—*
 16 *Not later than 1 year after the date of enactment of this*
 17 *Act, and annually thereafter, each pharmacy benefit man-*
 18 *ager (or affiliate, subsidiary, or agent of a pharmacy ben-*
 19 *efit manager) shall report to the Commission the following*
 20 *information:*

21 *(1) The aggregate amount of the difference be-*
 22 *tween the amount the pharmacy benefit manager was*
 23 *paid by each health plan and the amount that the*
 24 *pharmacy benefit manager paid each pharmacy on*
 25 *behalf of the health plan for prescription drugs.*

26 *(2) The aggregate amount of any—*

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

3 (B) direct and indirect remuneration fee
4 charged or other price concession to each phar-
5 macy; and

6 (C) payment rescinded or otherwise clawed
7 back from a reimbursement made to each phar-
8 macy.

9 (3) If, during the reporting year, the pharmacy
10 benefit manager moved or reassigned a prescription
11 drug to a formulary tier that has a higher cost, higher
12 copayment, higher coinsurance, or higher deductible
13 to a consumer, or a lower reimbursement to a phar-
14 macy, an explanation of the reason why the drug was
15 moved or reassigned from 1 tier to another, including
16 whether the move or reassignment was determined or
17 requested by a prescription drug manufacturer or
18 other entity.

19 (4) With respect to any pharmacy benefit man-
20 ager that owns, controls, or is affiliated with a phar-
21 macy, a report regarding any difference in reimburse-
22 ment rates or practices, direct and indirect remunera-
23 tion fees or other price concessions, and clawbacks be-
24 tween a pharmacy that is owned, controlled, or affili-

1 *ated with the pharmacy benefit manager and any*
2 *other pharmacy.*

3 *(b) REPORT TO CONGRESS.—*

4 *(1) IN GENERAL.—Not later than 1 year after*
5 *the date of enactment of this Act, and annually there-*
6 *after, the Commission shall submit to the Committee*
7 *on Commerce, Science, and Transportation of the*
8 *Senate and the Committee on Energy and Commerce*
9 *of the House of Representatives a report that address-*
10 *es, at a minimum—*

11 *(A) the number actions brought by the Com-*
12 *mission during the reporting year to enforce this*
13 *Act and the outcome of each such enforcement ac-*
14 *tion;*

15 *(B) the number of open investigations or in-*
16 *quiries into potential violations of this Act as of*
17 *the time the report is submitted;*

18 *(C) the number and nature of complaints*
19 *received by the Commission relating to an alle-*
20 *gation of a violation of this Act during the re-*
21 *porting year;*

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

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

6 (2) *FORMULARY DESIGN OR PLACEMENT PRAC-*
 7 *TICES.*—Not later than 1 year after the date of enact-
 8 ment of this Act, the Commission shall submit to the
 9 Committee on Commerce, Science, and Transpor-
 10 tation of the Senate and the Committee on Energy
 11 and Commerce of the House of Representatives a re-
 12 port that addresses the policies, practices, and role of
 13 pharmacy benefit managers (including their affiliates,
 14 subsidiaries, and agents) regarding formulary design
 15 or placement, including whether—

16 (A) pharmacy benefit managers (including
 17 their affiliates, subsidiaries, and agents) use for-
 18 mulary design or placement to increase their
 19 gross revenue without an accompanying increase
 20 in patient access or decrease in patient cost; or

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

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

6 (c) *GAO STUDY.*—*Not later than 1 year after the date*
 7 *of enactment of this Act, the Comptroller General of the*
 8 *United States shall submit to the Committee on Finance*
 9 *and the Committee on Health, Education, Labor, and Pen-*
 10 *sions of the Senate and to the Committee on Ways and*
 11 *Means and the Committee on Energy and Commerce of the*
 12 *House of Representatives a report that—*

13 (1) *addresses, at minimum—*

14 (A) *the role that pharmacy benefit man-*
 15 *agers play in the pharmaceutical supply chain;*

16 (B) *the state of competition among phar-*
 17 *macy benefit managers, including the market*
 18 *share for the Nation’s 10 largest pharmacy ben-*
 19 *efit managers;*

20 (C) *the use of rebates and fees by pharmacy*
 21 *benefit managers, including data for each of the*
 22 *10 largest pharmacy benefit managers that re-*
 23 *flects, for each drug in the formulary of each*
 24 *such pharmacy benefit manager—*

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

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

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

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

9 (D) whether pharmacy benefit managers
10 structure their formularies in favor of high-re-
11 bate prescription drugs over lower-cost, lower-re-
12 bate alternatives;

13 (E) the average prior authorization ap-
14 proval time for each of the 10 largest pharmacy
15 benefit managers;

16 (F) factors affecting the use of step therapy
17 in each of the 10 largest pharmacy benefit man-
18 agers; and

19 (G) the extent to which the price that phar-
20 macy benefit managers charge payors, such as
21 the Medicare program under title XXVIII of the
22 Social Security Act (42 U.S.C. 1395 et seq.),
23 State Medicaid programs under title XIX of the
24 Social Security Act (42 U.S.C. 1396 et seq.), the
25 Federal Employees Health Benefits Program

1 *under chapter 89 of title 5, United States Code,*
 2 *or private payors, for a drug is more than such*
 3 *pharmacy benefit managers pay the pharmacy*
 4 *for the drug; and*

5 *(2) provides recommendations for legislative ac-*
 6 *tion to lower the cost of prescription drugs for con-*
 7 *sumers and payors, improve the efficiency of the*
 8 *pharmaceutical supply chain by lowering inter-*
 9 *mediary costs, improve competition in pharmacy ben-*
 10 *efit management, and provide transparency in phar-*
 11 *macy benefit management.*

12 **SEC. 5. WHISTLEBLOWER PROTECTIONS.**

13 *(a) IN GENERAL.—A pharmacy benefit manager,*
 14 *health plan, pharmaceutical manufacturer, pharmacy, or*
 15 *any affiliate, subsidiary, or agent thereof shall not, directly*
 16 *or indirectly, discharge, demote, suspend, diminish, or*
 17 *withdraw benefits from, threaten, harass, or in any other*
 18 *manner discriminate against or adversely impact a covered*
 19 *individual because—*

20 *(1) the covered individual, or anyone perceived*
 21 *as assisting the covered individual, takes (or is sus-*
 22 *pected to have taken or will take) a lawful action in*
 23 *providing to Congress, an agency of the Federal Gov-*
 24 *ernment, the attorney general of a State, a State reg-*
 25 *ulator with authority over the distribution or insur-*

1 *ance coverage of prescription drugs, or a law enforce-*
2 *ment agency relating to any act or omission that the*
3 *covered individual reasonably believes to be a viola-*
4 *tion of this Act;*

5 *(2) the covered individual provides information*
6 *that the covered individual reasonably believes evi-*
7 *dences such a violation to—*

8 *(A) a person with supervisory authority*
9 *over the covered individual at the pharmacy ben-*
10 *efit manager, health plan, pharmaceutical man-*
11 *ufacturer, pharmacy, or any affiliate, sub-*
12 *sidiary, or agent thereof; or*

13 *(B) another individual working for the*
14 *pharmacy benefit manager, health plan, phar-*
15 *maceutical manufacturer, pharmacy, or any af-*
16 *ffiliate, subsidiary, or agent thereof who the cov-*
17 *ered individual reasonably believes has the au-*
18 *thority to investigate, discover, or terminate the*
19 *violation or to take any other action to address*
20 *the violation;*

21 *(3) the covered individual testifies (or it is sus-*
22 *pected that the covered individual will testify) in an*
23 *investigation or judicial or administrative proceeding*
24 *concerning such a violation;*

1 (4) *the covered individual assists or participates*
 2 *(or it is expected that the covered individual will as-*
 3 *sist or participate) in such an investigation or judi-*
 4 *cial or administrative proceeding; or*

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

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

11 (1) *Temporary relief while the case is pending.*

12 (2) *Reinstatement with the same seniority status*
 13 *that the individual would have had, but for the dis-*
 14 *charge or discrimination.*

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

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

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

24 (d) *PREDISPUTE ARBITRATION AGREEMENTS.—No*
 25 *predispute arbitration agreement shall be valid or enforce-*

1 *able if the agreement requires arbitration of a dispute aris-*
 2 *ing under this section.*

3 **SEC. 6. ENFORCEMENT.**

4 *(a) ENFORCEMENT BY THE COMMISSION.—*

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

10 *(2) POWERS OF THE COMMISSION.—*

11 *(A) IN GENERAL.—Except as provided in*
 12 *subparagraph (C), the Commission shall enforce*
 13 *this Act in the same manner, by the same means,*
 14 *and with the same jurisdiction, powers, and du-*
 15 *ties as though all applicable terms and provi-*
 16 *sions of the Federal Trade Commission Act (15*
 17 *U.S.C. 41 et seq.) were incorporated into and*
 18 *made a part of this Act.*

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

1 (C) *NONPROFIT ORGANIZATIONS AND INSUR-*
 2 *ANCE.*—*Notwithstanding section 4 or 6 of the*
 3 *Federal Trade Commission Act (15 U.S.C. 44,*
 4 *46), section 2 of McCarran-Ferguson Act (15*
 5 *U.S.C. 1012), or any other jurisdictional limita-*
 6 *tion of the Commission, the Commission shall*
 7 *also enforce this Act, in the same manner pro-*
 8 *vided in subparagraphs (A) and (B) of this*
 9 *paragraph, with respect to—*

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

13 (ii) *the business of insurance, and per-*
 14 *sons engaged in such business.*

15 (D) *AUTHORITY PRESERVED.*—*Nothing in*
 16 *this section shall be construed to limit the au-*
 17 *thority of the Commission under any other pro-*
 18 *vision of law.*

19 (3) *PENALTIES.*—

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

1 (B) *METHOD.*—*The penalties provided by*
 2 *subparagraph (A) shall be obtained in the same*
 3 *manner as civil penalties imposed under section*
 4 *18(a)(1)(B) of the Federal Trade Commission*
 5 *Act (15 U.S.C. 57a(a)(1)(B).*

6 (C) *MULTIPLE OFFENSES; MITIGATING FAC-*
 7 *TORS.*—*In assessing a penalty under subpara-*
 8 *graph (A)—*

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

11 (ii) *the court shall take into consider-*
 12 *ation, among other factors—*

13 (I) *the seriousness of the violation;*

14 (II) *the efforts of the person com-*
 15 *mitting the violation to remedy the*
 16 *harm caused by the violation in a*
 17 *timely manner; and*

18 (III) *whether the violation was*
 19 *intentional.*

20 (b) *ENFORCEMENT BY STATES.*—

21 (1) *IN GENERAL.*—*If the attorney general of a*
 22 *State has reason to believe that an interest of the resi-*
 23 *dents of the State has been or is being threatened or*
 24 *adversely affected by a practice that violates this Act,*
 25 *the attorney general of the State may bring a civil ac-*

tion 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—

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

4 (ii) *upon intervening—*

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

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

9 (3) *CONSTRUCTION.—Nothing in this subsection*
 10 *may be construed to prevent the attorney general of*
 11 *a State from exercising the powers conferred on the*
 12 *attorney general by the laws of the State to conduct*
 13 *investigations, to administer oaths or affirmations, or*
 14 *to compel the attendance of witnesses or the produc-*
 15 *tion of documentary or other evidence.*

16 (4) *VENUE; SERVICE OF PROCESS.—*

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

19 (i) *the district court of the United*
 20 *States that meets applicable requirements*
 21 *relating to venue under section 1391 of title*
 22 *28, United States Code; or*

23 (ii) *another court of competent juris-*
 24 *diction.*

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

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

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

8 (5) *ACTIONS BY OTHER STATE OFFICIALS.*—

9 (A) *IN GENERAL.*—*If an attorney general*
 10 *lacks appropriate jurisdiction to bring a civil*
 11 *action under paragraph (1), any other officer of*
 12 *a State who is authorized by the State to do so*
 13 *may bring a civil action under paragraph (1),*
 14 *subject to the same requirements and limitations*
 15 *that apply under this subsection to civil actions*
 16 *brought by attorneys general.*

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

21 (C) *SAVINGS PROVISION.*—*Nothing in this*
 22 *subsection may be construed to prohibit an au-*
 23 *thorized official of a State from initiating or*
 24 *continuing any proceeding in a court of the*

1 *State for a violation of any civil or criminal law*
 2 *of the State.*

3 (c) *AFFIRMATIVE DEFENSE.*—*In an action brought*
 4 *under this section to enforce section 2, it shall be an affirm-*
 5 *ative defense, on which the defendant has the burden of per-*
 6 *suasion by a preponderance of the evidence, that the conduct*
 7 *alleged to be a violation of section 2 was nonpretextual and*
 8 *reasonably necessary to—*

9 (1) *prevent a violation of, or comply with, Fed-*
 10 *eral or State law;*

11 (2) *protect patient safety; or*

12 (3) *protect patient access.*

13 **SEC. 7. EFFECT ON STATE LAWS.**

14 *Nothing in this Act shall be construed to preempt, dis-*
 15 *place, or supplant any State laws, rules, regulations, or re-*
 16 *quirements, or the enforcement thereof.*

17 **SEC. 8. DEFINITIONS.**

18 *In this Act:*

19 (1) *COMMISSION.*—*The term “Commission”*
 20 *means the Federal Trade Commission.*

21 (2) *COVERED INDIVIDUAL.*—*The term “covered*
 22 *individual” means a current or former employee, con-*
 23 *tractor, subcontractor, service provider, or agent of a*
 24 *pharmacy benefit manager, health plan, pharma-*

1 *ceutical manufacturer, pharmacy, or any affiliate,*
 2 *subsidiary, or agent thereof.*

3 (3) *HEALTH PLAN.*—*The term “health plan”*
 4 *means any group or individual health insurance plan*
 5 *or coverage, including any health insurance plan or*
 6 *coverage sponsored or funded by the Federal Govern-*
 7 *ment or the government of any State, Territory, or*
 8 *subdivision thereof.*

9 (4) *PHARMACY BENEFIT MANAGER.*—*The term*
 10 *“pharmacy benefit manager” means any entity that*
 11 *provides pharmacy benefit management services on*
 12 *behalf of a health plan, a payer, or health insurance*
 13 *issuer.*

14 (5) *PHARMACY BENEFIT MANAGEMENT SERV-*
 15 *ICES.*—*The term “pharmacy benefit management*
 16 *services” means, pursuant to a written agreement*
 17 *with a payer or health plan offering group or indi-*
 18 *vidual health insurance coverage, directly or through*
 19 *an intermediary, the service of—*

20 (A) *negotiating terms and conditions, in-*
 21 *cluding rebates and price concessions, with re-*
 22 *spect to a prescription drug on behalf of the*
 23 *health plan, coverage, or payer; or*

24 (B) *managing the prescription drug benefits*
 25 *provided by the health plan, coverage, or payer,*

1 *which may include formulary management the*
 2 *processing and payment of claims for prescrip-*
 3 *tion drugs, the performance of drug utilization*
 4 *review, the processing of drug prior authoriza-*
 5 *tion requests, the adjudication of appeals or*
 6 *grievances related to the prescription drug ben-*
 7 *efit, contracting with network pharmacies, or the*
 8 *provision of related services.*

9 (6) *PRESCRIPTION DRUG.*—*The term “prescrip-*
 10 *tion drug” means—*

11 (A) *a drug, as that term is defined in sec-*
 12 *tion 201(g) of the Federal Food, Drug, and Cos-*
 13 *metic Act (21 U.S.C. 321(g)), that is—*

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

17 (ii) *subject to the requirements of sec-*
 18 *tion 503(b)(1) of such Act (21 U.S.C.*
 19 *353(b)(1));*

20 (B) *a biological product as that term is de-*
 21 *finied in section 351 of the Public Health Service*
 22 *Act (42 U.S.C. 262(i)(1)); or*

23 (C) *a product that is biosimilar to, or inter-*
 24 *changeable with, a biologic product under section*

- 1 *351 of the Public Health Service Act (42 U.S.C.*
- 2 *262(i)).*

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S. 4293

A BILL

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.

DECEMBER 14, 2022

Reported with an amendment