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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

FEBRUARY 11, 2025

Mr. GRASSLEY (for himself, Ms. CANTWELL, Ms. ERNST, Mr. WELCH, Mrs. CAPITO, Mrs. SHAHEEN, Mr. MARSHALL, Mr. HEINRICH, Mr. MORAN, Mrs. HYDE-SMITH, Mr. TILLIS, and Mr. ROUNDS) introduced the following bill; which was read twice and referred to the Committee on Commerce, Science, and Transportation

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pharmacy Benefit
5 Manager Transparency Act of 2025”.

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

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

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

16 (2) Arbitrarily, unfairly, or deceptively, by con-
17 tract or any other means, reduce, rescind, or other-
18 wise claw back any reimbursement payment, in
19 whole or in part, to a pharmacist or pharmacy for
20 a prescription drug's ingredient cost or dispensing
21 fee, unless—

22 (A) the original claim was submitted
23 fraudulently;

24 (B) the original claim payment was incon-
25 sistent with the reimbursement terms in the
26 contract; or

1 (C) the pharmacist services were not ren-
2 dered by the pharmacy or pharmacist.

3 (3) Arbitrarily, unfairly, or deceptively, by con-
4 tract or any other means, increase fees or lower re-
5 imbursement to a pharmacy in order to offset reim-
6 bursement changes instructed by the Federal Gov-
7 ernment under any health plan funded by the Fed-
8 eral Government.

9 (b) EXCEPTIONS.—A pharmacy benefit manager
10 shall not be in violation of paragraph (1) or (3) of sub-
11 section (a) if the pharmacy benefit manager meets the fol-
12 lowing conditions:

13 (1) The pharmacy benefit manager, affiliate,
14 subsidiary, or agent passes along or returns 100 per-
15 cent of any price concession to a health plan or
16 payer, including any rebate, discount, or other price
17 concession.

18 (2) The pharmacy benefit manager, affiliate,
19 subsidiary, or agent provides full and complete dis-
20 closure of—

21 (A) the cost, price, and reimbursement of
22 a prescription drug to each health plan, payer,
23 and pharmacy with which the pharmacy benefit
24 manager, affiliate, subsidiary, or agent has a

1 contract or agreement to provide pharmacy ben-
2 efit management services;

3 (B) each fee, markup, and discount
4 charged or imposed by the pharmacy benefit
5 manager, affiliate, subsidiary, or agent to each
6 health plan, payer, and pharmacy with which
7 the pharmacy benefit manager, affiliate, sub-
8 sidiary, or agent has a contract or agreement
9 for pharmacy benefit management services; or

10 (C) the aggregate amount of all remunera-
11 tion the pharmacy benefit manager receives
12 from a prescription drug manufacturer for a
13 prescription drug, including any rebate, dis-
14 count, administration fee, and any other pay-
15 ment or credit obtained or retained by the phar-
16 macy benefit manager, or affiliate, subsidiary,
17 or agent of the pharmacy benefit manager, pur-
18 suant to a contract or agreement for pharmacy
19 benefit management services to a health plan,
20 payer, or any Federal agency (upon the request
21 of the agency).

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

23 It shall be unlawful for any person to report informa-
24 tion related to pharmacy benefit management services to
25 a Federal department or agency if—

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

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

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

10 **SEC. 4. TRANSPARENCY.**

11 (a) REPORTING BY PHARMACY BENEFIT MAN-
12 AGERS.—Subject to subsection (d), not later than 1 year
13 after the date of enactment of this Act, and annually
14 thereafter, each pharmacy benefit manager (or affiliate,
15 subsidiary, or agent of a pharmacy benefit manager) shall
16 report to the Commission and the Secretary of Health and
17 Human Services the following information:

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

23 (2) The aggregate amount of any—

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

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

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

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

17 (4) With respect to any pharmacy benefit man-
18 ager that owns, controls, or is affiliated with a phar-
19 macy, a report regarding any difference in reim-
20 bursement rates or practices, direct and indirect re-
21 muneration fees or other price concessions, and
22 clawbacks between a pharmacy that is owned, con-
23 trolled, or affiliated with the pharmacy benefit man-
24 ager and any other pharmacy.

25 (b) REPORT TO CONGRESS.—

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

8 (A) the number actions brought by the
9 Commission during the reporting year to en-
10 force this Act and the outcome of each such en-
11 forcement action;

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

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

19 (D) an anonymized summary of the re-
20 ports filed with the Commission pursuant to
21 subsection (a) for the reporting year;

22 (E) an analysis of the requirements of this
23 Act and whether the implementation of such re-
24 quirements leads to mergers (including hori-
25 zontal mergers or vertical mergers) amongst

any pharmacy benefit managers, or any pharmacy benefit manager that owns, controls, or is affiliated with a pharmacy, or any pharmacy benefit manager that owns, controls, or is affiliated with a health plan, and the effect of such merger (including the likelihood of a substantial decrease in competition or the potential for a monopoly); and

(F) policy or legislative recommendations to strengthen any enforcement action relating to a violation of this Act, including recommendations to include additional prohibited conduct in section 2(a), and recommendations to encourage more competition and decrease the likelihood of a monopoly in the pharmaceutical supply chain.

(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, the Committee on Finance of the Senate, the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Ways and Means of the House of Representatives, and the Committee on Energy and Commerce

1 of the House of Representatives a report that ad-
2 dresses the policies, practices, and role of pharmacy
3 benefit managers (including their affiliates, subsidi-
4 aries, and agents) regarding formulary design or
5 placement, including—

6 (A) whether pharmacy benefit managers
7 (including their affiliates, subsidiaries, and
8 agents) use formulary design or placement to
9 increase their gross revenue without an accom-
10 panying increase in patient access or decrease
11 in patient cost; or

12 (B) recommendations to Congress for leg-
13 islative action addressing such policies, prac-
14 tices, and role of pharmacy benefit managers
15 (including their affiliates, subsidiaries, and
16 agents).

17 (3) CONSTRUCTION.—Nothing in this section
18 shall be construed as authorizing the Commission to
19 disclose any information that is a trade secret or
20 confidential information described in section
21 552(b)(4) of title 5, United States Code, except as
22 necessary to enforce this Act.

23 (4) CONFIDENTIALITY.—The Commission may
24 disclose the information in a form which does not
25 disclose the identity of a specific pharmacy benefit

1 manager, pharmacy, or health plan for the following
2 purposes:

3 (A) To permit the Comptroller General of
4 the United States to review the information
5 provided to carry out this Act.

6 (B) To permit the Director of the Congres-
7 sional Budget Office to review the information
8 provided.

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

18 (1) addresses, at minimum—

19 (A) the role that pharmacy benefit man-
20 agers play in the pharmaceutical supply chain;

21 (B) the state of competition among phar-
22 macy benefit managers, including the market
23 share for the Nation's 10 largest pharmacy
24 benefit managers;

1 (C) the use of rebates and fees by phar-
2 macy benefit managers, including data for each
3 of the 10 largest pharmacy benefit managers
4 that reflects, for each drug in the formulary of
5 each such pharmacy benefit manager—

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

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

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

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

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

18 (E) the average prior authorization ap-
19 proval time for each of the 10 largest pharmacy
20 benefit managers;

21 (F) factors affecting the use of step ther-
22 apy in each of the 10 largest pharmacy benefit
23 managers;

24 (G) the extent to which the price that
25 pharmacy benefit managers charge payors, such

1 as the Medicare program under title XXVIII of
2 the Social Security Act (42 U.S.C. 1395 et
3 seq.), State Medicaid programs under title XIX
4 of the Social Security Act (42 U.S.C. 1396 et
5 seq.), the Federal Employees Health Benefits
6 Program under chapter 89 of title 5, United
7 States Code, or private payors, for a drug is
8 more than such pharmacy benefit managers pay
9 the pharmacy for the drug; and

10 (H) the competitive impact of pharmacy
11 benefit managers' business practices, including
12 the impact that such business practices have on
13 the cost of health plan premiums or prescrip-
14 tion drugs for consumers; and

15 (2) provides recommendations for legislative ac-
16 tion to lower the cost of prescription drugs for con-
17 sumers and payors, improve the efficiency of the
18 pharmaceutical supply chain by lowering inter-
19 mediary costs, improve competition in pharmacy
20 benefit management, and provide transparency in
21 pharmacy benefit management.

22 (d) PRIVACY REQUIREMENTS.—Any entity shall pro-
23 vide information under subsection (a) in a manner con-
24 sistent with the privacy, security, and breach notification
25 regulations promulgated under section 264(c) of the

1 Health Insurance Portability and Accountability Act of
 2 1996 (42 U.S.C. 1320d–2 note) (or any successor regula-
 3 tion), and shall restrict the use and disclosure of such in-
 4 formation according to such regulations.

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

6 (a) IN GENERAL.—A pharmacy benefit manager,
 7 health plan, pharmaceutical manufacturer, pharmacy, or
 8 any affiliate, subsidiary, or agent thereof shall not, directly
 9 or indirectly, discharge, demote, suspend, diminish, or
 10 withdraw benefits from, threaten, harass, or in any other
 11 manner discriminate against or adversely impact a covered
 12 individual because—

13 (1) the covered individual, or anyone perceived
 14 as assisting the covered individual, takes (or is sus-
 15 pected to have taken or will take) a lawful action in
 16 providing to Congress, an agency of the Federal
 17 Government, the attorney general of a State, a State
 18 regulator with authority over the distribution or in-
 19 surance coverage of prescription drugs, or a law en-
 20 forcement agency relating to any act or omission
 21 that the covered individual reasonably believes to be
 22 a violation of this Act;

23 (2) the covered individual provides information
 24 that the covered individual reasonably believes evi-
 25 dences such a violation to—

1 (A) a person with supervisory authority
2 over the covered individual at the pharmacy
3 benefit manager, health plan, pharmaceutical
4 manufacturer, pharmacy, or any affiliate, sub-
5 sidiary, or agent thereof; or

6 (B) another individual working for the
7 pharmacy benefit manager, health plan, phar-
8 maceutical manufacturer, pharmacy, or any af-
9 filiate, subsidiary, or agent thereof who the cov-
10 ered individual reasonably believes has the au-
11 thority to investigate, discover, or terminate the
12 violation or to take any other action to address
13 the violation;

14 (3) the covered individual testifies (or it is sus-
15 pected that the covered individual will testify) in an
16 investigation or judicial or administrative proceeding
17 concerning such a violation; or

18 (4) the covered individual assists or participates
19 (or it is expected that the covered individual will as-
20 sist or participate) in such an investigation or judi-
21 cial or administrative proceeding.

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

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

2 (2) Reinstatement with the same seniority sta-
3 tus that the individual would have had, but for the
4 discharge or discrimination.

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

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

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

14 (d) PREDISPUTE ARBITRATION AGREEMENTS.—No
15 predispute arbitration agreement shall be valid or enforce-
16 able if the agreement requires arbitration of a dispute
17 arising under this section.

18 **SEC. 6. ENFORCEMENT.**

19 (a) ENFORCEMENT BY THE COMMISSION.—

20 (1) UNFAIR AND DECEPTIVE ACTS OR PRAC-
21 TICES.—A violation of this Act shall be treated as
22 a violation of a rule defining an unfair or deceptive
23 act or practice under section 18(a)(1)(B) of the Fed-
24 eral Trade Commission Act (15 U.S.C.
25 57a(a)(1)(B)).

1 (2) POWERS OF THE COMMISSION.—

2 (A) IN GENERAL.—Except as provided in
3 subparagraph (C), the Commission shall enforce
4 this Act in the same manner, by the same
5 means, and with the same jurisdiction, powers,
6 and duties as though all applicable terms and
7 provisions of the Federal Trade Commission
8 Act (15 U.S.C. 41 et seq.) were incorporated
9 into and made a part of this Act.

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

16 (C) NONPROFIT ORGANIZATIONS AND IN-
17 SURANCE.—Notwithstanding section 4 or 6 of
18 the Federal Trade Commission Act (15 U.S.C.
19 44, 46), section 2 of McCarran-Ferguson Act
20 (15 U.S.C. 1012), or any other jurisdictional
21 limitation of the Commission, the Commission
22 shall also enforce this Act, in the same manner
23 provided in subparagraphs (A) and (B) of this
24 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)—

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

4 (ii) the court shall take into consider-
 5 ation, among other factors—

6 (I) the seriousness of the viola-
 7 tion;

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

12 (III) whether the violation was
 13 intentional.

14 (b) ENFORCEMENT BY STATES.—

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

23 (2) RIGHTS OF THE COMMISSION.—

24 (A) NOTICE TO THE COMMISSION.—

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

7 (ii) CONTENTS.—The notification re-
 8 quired under clause (i) shall include a copy
 9 of the complaint to be filed to initiate the
 10 civil action.

11 (iii) EXCEPTION.—If it is not feasible
 12 for the attorney general of a State to pro-
 13 vide the notification required under clause
 14 (i) before initiating a civil action under
 15 paragraph (1), the attorney general shall
 16 notify the Commission immediately upon
 17 instituting the civil action.

18 (B) INTERVENTION BY THE COMMIS-
 19 SION.—The Commission may—

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

23 (ii) upon intervening—

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

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

3 (3) CONSTRUCTION.—

4 (A) POWERS CONFERRED ON THE ATTOR-
5 NEY GENERAL OF A STATE.—Nothing in this
6 subsection may be construed to prevent the at-
7 torney general of a State from exercising the
8 powers conferred on the attorney general by the
9 laws of the State to conduct investigations, to
10 administer oaths or affirmations, or to compel
11 the attendance of witnesses or the production of
12 documentary or other evidence.

13 (B) ERISA.—No civil action brought pur-
14 suant to this subsection shall conflict with the
15 Employee Retirement Income Security Act of
16 1974 (29 U.S.C. 1001 et seq.).

17 (4) VENUE; SERVICE OF PROCESS.—

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

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

24 (ii) another court of competent juris-
25 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
7 1391 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 ac-
11 tion 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 limita-
15 tions that apply under this subsection to civil
16 actions 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.—

4 (1) IN GENERAL.—In an action brought under
5 this section to enforce section 2, it shall be an af-
6 firmative defense, on which the defendant has the
7 burden of persuasion by a preponderance of the evi-
8 dence, that the conduct alleged to be a violation of
9 section 2 was nonpretextual and reasonably nec-
10 essary to—

11 (A) prevent a violation of, or comply with,
12 Federal or State law;

13 (B) protect patient safety; or

14 (C) protect patient access.

15 (2) CLARIFICATION.—Nothing in this sub-
16 section shall be construed to prohibit a defendant
17 from raising any other affirmative defense available.

18 **SEC. 7. PROTECTION OF PERSONAL HEALTH INFORMA-**
19 **TION.**

20 In making any disclosure or report required by this
21 Act, a pharmacy benefit manager (including their affili-
22 ates, subsidiaries, and agents) shall not include any infor-
23 mation that would identify a patient or a provider that
24 issued a prescription.

1 **SEC. 8. EFFECT ON STATE LAWS.**

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

5 **SEC. 9. DEFINITIONS.**

6 In this Act:

7 (1) COMMISSION.—The term “Commission”
8 means the Federal Trade Commission.

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

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

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

1 (5) PHARMACY BENEFIT MANAGEMENT SERV-
2 ICES.—The term “pharmacy benefit management
3 services” means, pursuant to a written agreement
4 with a payer or health plan offering group or indi-
5 vidual health insurance coverage, directly or through
6 an intermediary, the service of—

7 (A) negotiating terms and conditions, in-
8 cluding rebates and price concessions, with re-
9 spect to a prescription drug on behalf of the
10 health plan, coverage, or payer; or

11 (B) managing the prescription drug bene-
12 fits provided by the health plan, coverage, or
13 payer, which may include formulary manage-
14 ment the processing and payment of claims for
15 prescription drugs, the performance of drug uti-
16 lization review, the processing of drug prior au-
17 thorization requests, the adjudication of appeals
18 or grievances related to the prescription drug
19 benefit, contracting with network pharmacies,
20 or the provision of related services.

21 (6) PRESCRIPTION DRUG.—The term “prescrip-
22 tion drug” means—

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

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

4 (ii) subject to the requirements of sec-
5 tion 503(b)(1) of such Act (21 U.S.C.
6 353(b)(1));

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

10 (C) a product that is biosimilar to, or
11 interchangeable with, a biologic product under
12 section 351 of the Public Health Service Act
13 (42 U.S.C. 262(i)).

○