

"(B) the Secretary shall be treated as the issuer of such plan.

"(h) Consultation.—In promulgating regulations to implement this section, the Secretary shall consult with interested parties, including groups representing beneficiaries, health care providers, employers, and insurance companies."

(f) Patient protections during Medicare for All transition period.—

(1) Definitions.—In this subsection, the terms "health insurance coverage", "health insurance issuer", and "group health plan" have the meanings given such terms in section 2791 of the Public Health Service Act ([42 U.S.C. 300gg–91](#)).

(2) Minimizing disruptions to patient care.—The Secretary shall ensure that all individuals enrolled in, or who seek to enroll in, a group health plan, health insurance coverage offered by a health insurance issuer, or the plan established under section 329(d) during the transition period of this subtitle are protected from disruptions in their care during the transition period.

(3) Public consultation.—The Secretary shall consult with communities and advocacy organizations of individuals living with disabilities and other patient advocacy organizations to ensure the transition described in paragraph (2) takes into account the safety and continuity of care for individuals with disabilities, complex medical needs, or chronic conditions.

(g) Transitional health coverage disregard.—Notwithstanding any other provision of law, for purposes of determining eligibility for or the amount of health coverage, medical assistance, child health assistance, premium assistance, a premium tax credit, a cost-sharing reduction, or other financial assistance for any month before January 1, 2029, a payment received under the American Union Jobs Program (42 U.S.C. 1398a et seq.) shall be disregarded in determining income, household income, modified adjusted gross income, or resources under—

(1) title XIX of the Social Security Act ([42 U.S.C. 1396 et seq.](#));

(2) title XXI of such Act ([42 U.S.C. 1397aa et seq.](#));

(3) section 36B of the Internal Revenue Code of 1986 ([26 U.S.C. 36B](#));

(4) sections 1402 and 1412 of the Patient Protection and Affordable Care Act ([42 U.S.C. 18071](#), [18082](#)); and

(5) the Medicare Transition plan established under subsection (d).

(h) Clerical amendment.—The table of contents in part E of title XVIII of the Social Security Act ([42 U.S.C. 1395x et seq.](#)) is amended by adding at the end the following new sections:

"Sec. 1899E. Protection Against High Out-of-Pocket Expenditures.

"Sec. 1899F. Temporary Medicare Buy-In Option for Certain Individuals."

Subtitle C—Addressing Drug Prices

SEC. 331. ACCELERATION OF PBM ACCOUNTABILITY REQUIREMENTS.

(a) Acceleration of effective date for Medicare Part D and MA-PD plans.—Section 1860D-12(h) of the Social Security Act ([42 U.S.C. 1395w-112\(h\)](#)) is amended—

(1) in the matter preceding paragraph (1), by striking "For plan years beginning on or after January 1, 2028" and inserting "For plan years beginning on or after January 1, 2027"; and

(2) in paragraph (5)(A), by striking "June 1, 2027" and inserting "January 1, 2027".

(b) Conforming amendment for Medicare Advantage prescription drug plans.—Section 1857(f)(3)(G) of the Social Security Act ([42 U.S.C. 1395w-27\(f\)\(3\)\(G\)](#)) is amended by striking "January 1, 2028" and inserting "January 1, 2027".

SEC. 332. PROHIBITING PAY-FOR-DELAY AGREEMENTS.

(a) Amendment to definitions.—Section 1111 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ([Public Law 108–173](#)) is amended by adding at the end the following:

"(9) REVERSE PAYMENT AGREEMENT.—

"(A) In general.—The term 'reverse payment agreement' means any agreement, settlement, or understanding, whether oral or written, in which a brand name drug company provides anything of value to a generic drug applicant in exchange for non-competition with respect to a generic drug.

"(B) Exception.—The term 'reverse payment agreement' does not include compensation that is strictly limited to—

"(i) reimbursement of documented and reasonable litigation costs actually incurred by the generic drug applicant in connection with patent litigation; or

"(ii) payment for bona fide services provided by the generic drug applicant, if such payment reflects fair market value and is not conditioned on, linked to, or accompanied by non-competition.

"(10) ANYTHING OF VALUE.—The term 'anything of value' includes money, forgiveness of debt, exclusive licenses, supply agreements, distribution agreements, side deals, promises not to market a generic drug, or any other form of consideration, whether direct or indirect.

"(11) NON-COMPETITION.—The term 'non-competition' means delayed market entry, abandonment or withdrawal of a patent challenge, agreement not to market a generic drug, or any restriction that has the effect of limiting or delaying competition with a brand name drug."

(b) Prohibition.—The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is amended by inserting after section 1114 the following:

"Sec. 1114A. Prohibition on reverse payment agreements.

"(a) In general.—It is unlawful for a brand name drug company and a generic drug applicant to enter into a reverse payment agreement.

"(b) Enforcement.—A violation of this section shall be treated as a violation of a rule defining an unfair, deceptive, or abusive act or practice under the Federal Trade Commission Act ([15 U.S.C. 41 et seq.](#)), and all powers and authorities of the Commission under that Act shall be available to enforce this section as if this section were incorporated into and made a part of that Act."

(c) Enforcement amendments.—Section 1115 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 is amended—

(1) in subsection (a), by striking "\$11,000" and inserting "\$25,000"; and

(2) by adding at the end the following:

"(c) Additional remedies.—

"(1) Disgorgement.—In addition to any other remedy available under this subtitle, the Commission or the Assistant Attorney General may seek disgorgement of any consideration exchanged in violation of section 1114A.

"(2) Monetary penalty in lieu of disgorgement.—In the alternative to disgorgement under paragraph (1), the Commission or the Assistant Attorney General may seek an additional civil penalty in an amount equal to the monetary value of any consideration exchanged in violation of section 1114A."

SEC. 333. CODIFYING THE ANTI-KICKBACK RULE.

(a) Incorporation of specified regulations.—The provisions of the final rule promulgated by the Health and Human Services Department, entitled "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees", as published in the Federal Register on November 30, 2020 ([85 Fed. Reg. 76666](#)), are incorporated into this Act and shall be treated as though such provisions are set forth in this subsection.

(b) Effect of incorporation.—The regulations incorporated under subsection (a) may be altered only by means of an Act of Congress. To the extent that any provision of such regulations does not conform with this Act, the provisions of this Act shall govern.

(c) Definition of regulation.—In this section, the term "regulation" means any rule, regulation, guideline, interpretation, order, or requirement of general applicability prescribed by any officer or employee of the executive branch.

SEC. 334. REDUCTION IN MEDICARE PART B PAYMENT PERCENTAGE.

(a) In general.—Section 1847A(b)(1) of the Social Security Act ([42 U.S.C. 1395w-3a\(b\)\(1\)](#)) is amended by striking "106 percent" each place it appears and inserting "94 percent".

(b) Effective date.—The amendment made by subsection (a) shall apply to drugs and biologicals furnished on or after January 1, 2027.

SEC. 335. DRUG PRICES, PHARMACY BENEFIT MANAGERS, AND COMPETITION.

(a) Increasing transparency in generic drug applications.—

(1) In general.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 355\(j\)\(3\)](#)) is amended by adding at the end the following:

"(H) (i) Upon request (in controlled correspondence or an analogous process) by a person that has submitted or intends to submit an abbreviated application under this subsection for a drug that is required by regulation to contain 1 or more of the same inactive ingredients in the same concentrations as the listed drug referred to, or for which the Secretary determines there is a scientific justification for an approach that is in vitro in whole or in part to be used to demonstrate bioequivalence for a drug if such a drug contains 1 or more of the same inactive ingredients in the same concentrations as the listed drug, the Secretary shall inform the person whether such drug is qualitatively and quantitatively the same as the listed drug. The Secretary may also provide such information to such a person on the Secretary's own initiative during the review of an abbreviated application under this subsection for such drug.

"(ii) Notwithstanding section 301(j), if the Secretary determines that such drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

"(I) the ingredient or ingredients that cause such drug not to be qualitatively or quantitatively the same as the listed drug; and

"(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

"(iii) If the Secretary determines that such drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such drug under this subsection unless—

"(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

"(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

"(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

"(v) The disclosures required by this subparagraph are disclosures authorized by law, including for purposes of [section 1905 of title 18](#), United States Code."

(2) Guidance.—

(A) In general.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1)), including with respect to assessing pH adjusters.

(B) Process.—In issuing guidance under this paragraph, the Secretary of Health and Human Services shall—

- (i) publish draft guidance;
- (ii) provide a period of at least 60 days for comment on the draft guidance; and
- (iii) after considering any comments received and not later than 1 year after the close of the comment period on the draft guidance, publish final guidance.

(3) Applicability.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by paragraph (2) is finalized.

(b) Improving transparency and preventing the use of abusive spread pricing and related practices in Medicaid.—

(1) Spread pricing.—

(A) In general.—Section 1927(e) of the Social Security Act ([42 U.S.C. 1396r-8\(e\)](#)) is amended by adding at the end the following:

"(6) Pharmacy price reimbursement required.—

"(A) In general.—A contract between the State and a pharmacy benefit manager (in this paragraph referred to as a 'PBM'), or a contract between the State and a designated entity (as defined in subparagraph (C)) that includes provisions making the designated entity responsible for the administration of medical assistance consisting of covered outpatient drugs for individuals enrolled with the designated entity, shall require that payment for such drugs and related administrative services (as applicable), including payments made by a PBM on behalf of the State or designated entity, is based on a pharmacy price reimbursement model under which—

"(i) any payment made by the designated entity or the PBM (as applicable) for such a drug—

"(I) is limited to—

"(aa) ingredient cost; and

"(bb) a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay if the plan or waiver was making the payment directly;

"(II) is passed through in its entirety by the designated entity or PBM to the pharmacy or provider that dispenses the drug and is not retroactively denied or reduced except as permitted or required under Federal or State law or regulation; and

"(III) is made in a manner that is consistent with [sections 447.502, 447.512, 447.514, and 447.518 of title 42](#), Code of Federal Regulations (or any successor regulation) as if such requirements applied directly to the designated entity or the

PBM, except that any payment by the designated entity or the PBM for the ingredient cost of such a drug purchased by a covered entity (as defined in subsection (a)(5)(B)) may exceed the actual acquisition cost (as defined in [section 447.502 of title 42](#), Code of Federal Regulations (or any successor regulation)) for such drug if—

"(aa) such drug was subject to an agreement under section 340B of the Public Health Service Act ([42 U.S.C. 256b](#));

"(bb) such payment for such cost of such drug does not exceed the maximum payment that would have been made by the designated entity or the PBM for the ingredient cost of such drug had such drug not been purchased by such a covered entity; and

"(cc) such covered entity reports to the Secretary, on an annual basis (in a form and manner specified by the Secretary) and with respect to payments for such costs of such drugs so purchased by such covered entity that are in excess of the actual acquisition costs for such drugs, the aggregate amount of such excess;

"(ii) payment to the designated entity or the PBM (as applicable) for administrative services performed by the designated entity or PBM is limited to an administrative fee that reflects the fair market value of providing such services;

"(iii) the designated entity or the PBM (as applicable) makes available to the State, and the Secretary upon request, all costs and payments related to covered outpatient drugs and accompanying administrative services incurred, received, or made by the designated entity or the PBM, including ingredient costs, professional dispensing fees, administrative fees, post-sale and post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees, and any and all other remuneration; and

"(iv) any form of spread pricing whereby any amount charged or claimed by the designated entity or the PBM (as applicable) is in excess of the amount paid to the pharmacies by the designated entity or the PBM, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for a fair market administrative fee as described in clause (ii)), is not allowable for purposes of claiming Federal matching payments under this title.

"(B) Making certain information available.—The Secretary shall publish, not less frequently than on an annual basis, information received by the Secretary pursuant to subparagraph (A)(i)(III)(cc). Such information shall be so published in an electronic and searchable format, such as through the 340B Office of Pharmacy Affairs Information System (or a successor system).

"(C) Definitions.—In this paragraph:

"(i) Designated entity.—The term 'designated entity' means a managed care entity or other specified entity.

"(ii) Managed care entity; other specified entity.—The terms 'managed care entity' and 'other specified entity' have the meaning given such terms in section 1903(m)(9)(D).".

(B) Conforming amendments.—Section 1903(m) of such Act ([42 U.S.C. 1396b\(m\)](#)) is amended—

(i) in paragraph (2)(A)(xiii)—

(I) by striking "and (III)" and inserting "(III)";

(II) by inserting before the period at the end the following: ", and (IV) with respect to covered outpatient drugs and related administrative services (as applicable) provided by the entity (or by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement with the entity), that payment for such drugs and related administrative services is based on a pharmacy price reimbursement model described in section 1927(e)(6)(A)"; and

(III) by moving the margin 2 ems to the left; and

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

"(10) No payment shall be made under this title to a State with respect to expenditures incurred by it for payment for services provided by an other specified entity (as defined in paragraph (9)(D)) unless the contract between the State and the entity for the provision of such services provides, with respect to covered outpatient drugs and related administrative services (as applicable) provided by the entity (or by a pharmacy benefit manager on behalf of the entity under a contract or other arrangement with the entity), that payment for such drugs and related administrative services is based on a pharmacy price reimbursement model described in section 1927(e)(6)(A).".

(C) Effective date.—The amendments made by this paragraph shall take effect on January 1, 2027, and shall apply to contracts, arrangements, items, and services furnished on or after that date, without regard to the effective date of any contract. No contract, arrangement, amendment, renewal, option, administrative delay, or guidance delay may delay, limit, extinguish, or reduce the application of the amendments made by this paragraph.

SEC. 336. PHARMACY PAYMENT AND REIMBURSEMENT.

(a) Definitions.—In this section:

(1) Affiliate.—The term "affiliate" means an entity, including a pharmacy, that directly or indirectly through 1 or more intermediaries—

(A) owns, controls, or has an investment interest in a pharmacy benefits manager;

(B) is owned or controlled by, or has an investment interest held by, a pharmacy benefits manager; or

(C) is under common ownership or corporate control of a pharmacy benefits manager.

(2) Beneficiary.—The term "beneficiary" means a person who receives prescription drug benefits pursuant to a Federal health care program.

(3) Bona fide service fee.—The term "bona fide service fee" has the meaning given that term in section 1860D–12(h)(7)(B) of the Social Security Act ([42 U.S.C. 1395w–112\(h\)\(7\)\(B\)](#)).

(4) Cost sharing requirement.—The term "cost sharing requirement" means any coinsurance or deductible imposed on a beneficiary for a prescription drug furnished under a Federal health care program.

(5) Federal health care program.—The term 'Federal health care program' means—

(A) a prescription drug plan under part D of title XVIII of the Social Security Act;

(B) an MA–PD plan under part C of such title;

(C) a managed care entity (as defined in section 1932(a)(1)(B) of such Act ([42 U.S.C. 1396u–2\(a\)\(1\)\(B\)](#)));

(D) an other specified entity (as defined in section 1903(m)(9)(D)(iii) of the Social Security Act ([42 U.S.C. 1396b\(m\)\(9\)\(D\)\(iii\)](#)));

(E) the Federal Employees Health Benefits Program under [chapter 89 of title 5](#), United States Code; or

(F) the TRICARE program (as defined in [section 1072 of title 10](#), United States Code).

(6) In-network pharmacy.—The term "in-network pharmacy" means a pharmacy that is licensed by the State board of pharmacy in the State in which such pharmacy is located, that fills or seeks to fill a prescription for a prescription drug for a beneficiary, and is not an excluded entity and does not have an owner or employee who is on a list of excluded individuals or entities maintained by the Office of Inspector General pursuant to section 1128 of the Social Security Act ([42 U.S.C. 1320a–7](#)).

(7) Pharmacy benefits management services.—The term "pharmacy benefits management services"—

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

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

(8) Pharmacy benefits manager.—The term "pharmacy benefits manager" means a person, business entity, affiliate, or other entity that performs pharmacy benefits management services.

(9) Prescription drug.—The term "prescription drug" means a prescription drug covered by a Federal health care program that is dispensed to a beneficiary for self-administration.

(10) Rebate.—The term "rebate" means any payments and concessions that accrue to a pharmacy benefits manager or the plan sponsor client of such pharmacy benefits manager, directly or indirectly, including through an affiliate, subsidiary, third party, or intermediary,

including an offshore entity or group purchasing organization, from a pharmaceutical manufacturer, its affiliate, subsidiary, third party, or intermediary, including payments, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered by such pharmacy benefits manager on behalf of a Federal health care program.

(11) Spread pricing.—The term "spread pricing" means the practice of a pharmacy benefits manager charging a Federal health care program an amount for a prescription drug claim that exceeds the sum of the amount such pharmacy benefits manager pays the dispensing pharmacy for that same prescription drug claim and a bona fide service fee, including any post-sale or post-adjudication fees, discounts, or adjustments, provided that nothing herein shall be construed to allow post-sale or post-adjudication fees, discounts, or adjustments where otherwise prohibited by law.

(12) Steering.—The term "steering" means—

(A) directing, ordering, or requiring a beneficiary to use a specific pharmacy or pharmacies, including an affiliate pharmacy, for the purpose of filling a prescription or receiving services or other care from a pharmacist;

(B) offering or implementing health insurance plan designs that require a beneficiary to utilize a pharmacy or pharmacies, including an affiliate pharmacy, or that increases costs to a Federal health care program or a beneficiary, including requiring a beneficiary to pay the full cost for a prescription drug when such beneficiary chooses not to use a pharmacy benefits manager affiliate pharmacy;

(C) advertising, marketing, or promoting a pharmacy, including an affiliate pharmacy, over another in-network pharmacy;

(D) creating any network or engaging in any practice, including accreditation or credentialing standards, day supply limitations, or delivery method limitations, that exclude an in-network pharmacy or restrict an in-network pharmacy from filling a prescription for a prescription drug; or

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

(b) In general.—A pharmacy benefits manager administering prescription drug benefits on behalf of a Federal health care program, either directly or through an affiliate of such pharmacy benefits manager, shall, on behalf of such program—

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

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

(B) an amount equal to 2 percent of the amount described in subparagraph (A), or \$25, whichever is less;

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

(3) (A) subject to subparagraph (B), calculate a beneficiary's cost sharing requirement for a prescription drug at the point of sale based on a price that is reduced by an amount equal to at least 80 percent of all rebates received in connection with the dispensing of the prescription drug; or

(B) in the case of a prescription drug for which the rebate cannot be determined at the point of sale, calculate a beneficiary's cost sharing requirement for a prescription drug at the point of sale based on a price that is reduced by an amount equal to 80 percent of the lesser of the average aggregate rebate for such drug in the previous calendar year, or the highest possible rebate that can be received for such drug.

(c) Prohibited actions.—A pharmacy benefits manager administering prescription drug benefits under a Federal health care program shall not—

(1) engage in steering;

(2) engage in any practice that restricts a beneficiary from using any in-network pharmacy to fill a prescription drug;

(3) charge a beneficiary more for a prescription drug than the amount of reimbursement made to the pharmacy that dispenses such drug;

(4) require a beneficiary to obtain a brand name prescription drug when a lower cost, AB-rated generic version of such brand name drug is available;

(5) engage in spread pricing;

(6) charge a Federal health care program, directly or indirectly or through an affiliate, an amount for a prescription drug claim that exceeds the sum of the amount paid to the dispensing pharmacy for that same prescription drug claim and a bona fide service fee;

(7) lower, impose a fee, or otherwise make an adjustment to a prescription drug claim at the time the claim for such drug is adjudicated, or after the claim is adjudicated, that in any way reduces the amount a pharmacy is reimbursed for such drug pursuant to subsection (b), including a fee charged to a pharmacy even if such fee is not tied to a prescription drug claim; or

(8) engage in any practice that bases pharmacy reimbursement for a prescription drug on pharmacy, patient, or any other outcomes, scores, or metrics, provided that nothing shall prohibit pharmacy reimbursement, in addition to reimbursement pursuant to subsection (b), for providing care and services within a pharmacy or a pharmacist's applicable State scope of practice.

(d) Recoupment of funds pursuant to audit.—A pharmacy benefits manager may recoup funds pursuant to an audit in compliance with applicable Federal and State law in which—

(1) an overpayment or misfill was found to have occurred; or

(2) in the case of fraud, provided that all amounts recouped be passed back to the applicable Federal health care program.

(e) Enforcement.—

(1) In general.—A pharmacy benefits manager, or any person acting on behalf of a pharmacy benefits manager, that knowingly and willfully violates this section shall be guilty of a felony and, upon conviction thereof, shall be fined not more than \$1,000,000 for each act in violation, or imprisoned for not more than 10 years, or both.

(2) Civil action.—A person may bring a civil action for violation of this section for the person and the United States Government. The action shall be brought in the name of the United States Government. The action may be dismissed only if the court and the United States Attorney General give written consent to the dismissal and their reasons for consenting. Any such action shall be subject to the same terms, conditions, and provisions set forth in [section 3730 of title 31](#), United States Code, which are hereby incorporated into this section. In such an action, the defendant shall be liable for the civil penalties, damages, and costs provided under [section 3729\(a\) of such title](#).

(f) Improving prescription drug transparency under the Medicaid program.—Section 1927(f) of the Social Security Act ([42 U.S.C. 1396r–8\(f\)](#)) is amended—

(1) in the subsection heading, by striking "retail" and inserting "covered outpatient drug"; and

(2) in paragraph (1)—

(A) in the paragraph heading, by striking "retail" and inserting "covered outpatient drug";

(B) by striking "and" after the semicolon at the end of paragraph (1)(A)(i) and all that precedes it through "(1)" and inserting the following:

"(1) Determining pharmacy actual acquisition costs.—The Secretary shall conduct a survey of pharmacy drug prices to determine the national average drug acquisition cost as follows:

"(A) Use of vendor.—The Secretary may contract services for—

"(i) with respect to a pharmacy that dispenses covered outpatient drugs, including a retail community pharmacy, mail-order pharmacy, specialty pharmacy, nursing home pharmacy, long-term care facility pharmacy, hospital pharmacy, or clinic pharmacy (but not including a charitable pharmacy or a not-for-profit pharmacy), a monthly survey of such pharmacies to determine the national average drug acquisition cost for covered outpatient drugs; and";

(C) in subparagraph (C)—

(i) in clause (i)—

(I) by striking "retail"; and

(II) by striking "prescription" and inserting "covered outpatient"; and

(ii) in clause (ii), by striking "retail community";

(D) in subparagraph (D)(ii), by striking "retail";

(E) in subparagraph (E), by striking the term "retail" each place it appears;

(F) by adding at the end the following new subparagraphs:

"(F) Survey reporting.—Each State shall require any pharmacy in such State to respond to surveys of prices conducted under this subsection if—

"(i) such pharmacy dispenses covered outpatient drugs to individuals receiving benefits under this title; and

"(ii) receives any payment, reimbursement, administrative fee, discount, or rebate related to such dispensing, regardless of whether such payment, reimbursement, administrative fee, discount, or rebate is received from—

"(I) the State;

"(II) a designated entity (as defined in subsection (e)(6)(C)); or

"(III) a pharmacy benefits manager that has a contract with a State or designated entity.

"(G) Survey information.—The Secretary shall make information on national drug acquisition prices obtained under this paragraph publicly available. Such information shall include at least the following:

"(i) The monthly response rate of the surveys conducted pursuant to subparagraph (A), including a list of the pharmacies described in subparagraph (F) that did not respond to such survey.

"(ii) The sampling frame and number of pharmacies sampled monthly.

"(iii) Information on price concessions to each pharmacy, including discounts, rebates, and other price concessions (to the extent that such information is available during the survey period), in aggregate or de-identified form, as determined appropriate by the Secretary.

"(H) Enforcement.—At the discretion of the Secretary, the Secretary, acting through the Inspector General and in collaboration with the Administrator of the Centers for Medicare & Medicaid Services, may enforce noncompliance by a pharmacy with this paragraph by imposing a civil monetary penalty not to exceed \$10,000 for each day of noncompliance. The provisions of section 1128A, other than subsections (a) and (b), shall apply to a penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under subsection (a) of that section.

"(I) Limitation on use of applicable non-retail pharmacy pricing information.—No State or Federal health care program shall use pricing information reported by pharmacies other than retail community pharmacies to develop or inform reimbursement rates for retail community pharmacies.

"(J) Report on specialty pharmacies.—Not later than 1 year after the date that this subparagraph takes effect, the Secretary shall submit to Congress a report examining specialty drug coverage and reimbursement under this title, including—

"(i) a description of how State Medicaid programs define specialty drugs and specialty pharmacies;

"(ii) the amount State Medicaid programs pay for specialty drugs;

"(iii) how States and designated entities (as defined in subsection (e)(6)(C)) determine payment for specialty drugs;

"(iv) the settings in which specialty drugs are dispensed to individuals receiving benefits under this title (such as retail community pharmacies or specialty pharmacies);

"(v) the extent to which specialty drugs (as defined by the respective States) are captured in the national average drug acquisition cost survey (or through another process);

"(vi) examples of specialty drug dispensing fees to support the services associated with dispensing such specialty drugs; and

"(vii) recommendations as to how specialty pharmacies should be defined and how data from specialty pharmacies should be incorporated into, stratified within, or otherwise used in the national average drug acquisition cost survey or any successor survey process."; and

(G) in paragraph (2)—

(i) in subparagraph (A), by inserting "(including payment rates under a designated entity (as defined in subsection (e)(6)(C)))" after "under this title"; and

(ii) in subparagraph (B), by inserting ", and the basis for such dispensing fees" before the semicolon at the end.

(g) Effective date.—This section shall take effect on January 1, 2027.

SEC. 337. PROHIBITION ON UNFAIR PRESCRIPTION DRUG PRICING PRACTICES.

(a) Definitions.—In this section:

(1) Bona fide service fee.—The term "bona fide service fee" has the meaning given that term in section 1860D–12(h)(7)(B) of the Social Security Act ([42 U.S.C. 1395w–112\(h\)\(7\)\(B\)](#)).

(2) Commission.—The term "Commission" means the Federal Trade Commission.

(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 Government or the government of any State, Territory, or subdivision thereof.

(4) 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.

(5) Pharmacy benefit manager.—The term "pharmacy benefit manager" has the meaning given that term in section 311(a)(14).

(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\(i\)](#)).

(b) Prohibition on unfair, deceptive, or abusive prescription drug pricing practices.—

(1) Conduct prohibited.—It shall be unlawful for any pharmacy benefit manager, directly or indirectly, to engage in any of the following activities related to pharmacy benefit management services:

(A) Charge a health plan or payer an amount for a prescription drug claim that exceeds the sum of the amount the pharmacy benefit manager reimburses the dispensing pharmacy for that same prescription drug claim and a bona fide service fee.

(B) 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, unless—

(i) the original claim was submitted fraudulently;

(ii) the original claim payment was inconsistent with the reimbursement terms in the contract; or

(iii) the pharmacist services were not rendered by the pharmacy or pharmacist.

(C) 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.

(2) Safe harbor.—A pharmacy benefit manager shall not be in violation of paragraph (1)(A) if the pharmacy benefit manager:

(A) passes along or returns 100 percent of any price concession to a health plan or payer, including any rebate, discount, or other price concession; and

(B) provides full and complete disclosure of—

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

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

(iii) 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, 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).

(c) Enforcement by the Commission.—

(1) Unfair, deceptive or abusive acts or practices.—A violation of this section shall be treated as a violation of a rule defining an unfair, deceptive or abusive 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 section 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 section.

(B) Privileges and immunities.—Subject to paragraph (3), any person who violates this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act.

(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 section, 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 section shall be liable for a civil penalty of not more than \$1,000,000. Each day of a continuing violation shall be considered a separate violation.

(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\(a\)\(1\)\(B\)](#)).

(d) 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 section, 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.

(A) If an attorney general lacks appropriate jurisdiction to bring a civil action, 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) The attorney general of a State shall provide written notification, including a copy of the complaint to be filed, to the Commission that the attorney general intends to bring such civil action before initiating a civil action. If prior notification is not feasible, the attorney general shall notify the Commission immediately upon instituting the civil action.

(C) The Commission may intervene in any civil action brought by the attorney general of a State under paragraph (1). Upon intervening, the Commission may—

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

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

(2) 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.

(3) No civil action brought pursuant to this subsection shall conflict with the Employee Retirement Income Security Act of 1974 ([29 U.S.C. 1001 et seq.](#)).

(e) Affirmative defense.—In an action brought under this section to enforce subsection (b), it shall be an affirmative defense that the conduct alleged to be a violation of subsection (b) was nonpretextual and reasonably necessary to—

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

(B) protect patient safety; or

(C) protect patient access.

(f) Remedies not exclusive.—Nothing in this section shall be construed to preempt, displace, or supplant any State laws, rules, regulations, or requirements, or the enforcement thereof.

(g) Effective date.—This section shall take effect on January 1, 2027.

SEC. 338. REQUIRING NEGOTIATION OF PRESCRIPTION DRUG PRICES.

(a) Negotiation of drug prices under Medicare part D.—Subsection 1860D–11(i) of the Social Security Act ([42 U.S.C. 1395w–111\(i\)](#)) is amended to read as follows:

"(i) Negotiation of lower drug prices.—

"(1) In general.—Notwithstanding any other provision of law, the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA–PD plan.

"(2) No change in rules for formularies.—

"(A) In general.—Nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary.

"(B) Construction.—Subparagraph (A) shall not be construed as affecting the Secretary's authority to ensure appropriate and adequate access to covered part D drugs under prescription drug plans and under MA–PD plans, including compliance of such plans with formulary requirements under [section 1860D–4\(b\)\(3\)](#).

"(3) Construction.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA–PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1)."

(b) Negotiation of drug prices under Medicare part B.—Section 1842 of the Social Security Act ([42 U.S.C. 1395u](#)) is amended by adding at the end the following new subsection:

"(v) Negotiation Of Prices For Drugs And Biologicals.—

"(1) In general.—Notwithstanding any other provision of law, the Secretary shall negotiate a contract with a manufacturer to establish the amount of payment under this part for any drug or

biological for which the program under this part is the majority purchaser (as determined under paragraph (2)). The Secretary shall negotiate such contracts with the goal of ensuring appropriate and adequate access to necessary drugs and biologicals for individuals enrolled under this part, while minimizing costs to such individuals and to the program under this part to the greatest extent possible.

"(2) Majority purchaser.—For purposes of paragraph (1), the Secretary shall, by regulation, establish a method to identify, based upon drug utilization rates, any drug or biological for which greater than 50 percent of the units sold by the manufacturer of such drug or biological in the preceding calendar year were provided to individuals enrolled under this part.

"(3) Definitions.—In this subsection:

"(A) Drugs and biologicals.—The term 'drug' and the term 'biological' have the same meaning as provided under [section 1861\(t\)](#).

"(B) Manufacturer.—The term 'manufacturer' has the same meaning as provided under [section 1847A\(c\)\(6\)\(A\)](#)."

(c) Payment for least costly alternative for Medicare part B drugs.—Section 1847A(b) of the Social Security Act ([42 U.S.C. 1395w–3a\(b\)](#)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by striking "paragraph (7)" and inserting "paragraphs (7) and (9)"; and

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

"(9) Treatment of functionally equivalent drugs and biologicals.—In the case of a drug or biological furnished on or after January 1, 2027, for which payment is determined under this section, if the drug or biological is functionally equivalent (as defined by the Secretary) to another drug or biological for which payment is determined under this section, the amount of payment for both such drugs or biologicals shall be equal to the payment amount otherwise determined under this section (without regard to the application of this paragraph) for the least costly of such drugs or biologicals."

(d) Enforcement, backstops, and savings provisions.—

(1) Good-faith negotiation; penalties for process abuse.—

(A) Duty to negotiate in good faith.—A manufacturer of a drug or biological subject to negotiation under this section shall engage in negotiations with the Secretary in good faith and shall not engage in any act or omission the primary purpose or effect of which is to delay, obstruct, evade, or frustrate the negotiation of an agreement on price.

(B) Process abuse defined.—For purposes of this paragraph, process abuse includes—

(i) refusal to meet or communicate with the Secretary after receipt of a written request to negotiate;

(ii) repeated failure to provide pricing, cost, utilization, or other information reasonably requested by the Secretary within the timeframes specified by the Secretary;

- (iii) submission of materially incomplete, misleading, or false information;
- (iv) withdrawal from negotiations without good cause after negotiations have commenced;
- (v) conditioning agreement on terms unrelated to price or access; or
- (vi) any other conduct the Secretary determines, by regulation, constitutes bad-faith negotiation.

(C) Civil monetary penalties.—If the Secretary determines that a manufacturer has engaged in process abuse or has violated a requirement of an agreement or information-submission obligation under this section, the Secretary shall impose—

- (i) a civil monetary penalty of \$1,000,000 for each day during which such violation continues; and

- (ii) in the case of knowingly false information, a civil monetary penalty of \$100,000,000 for each item of false information.

(D) Additional remedies.—The penalties under this paragraph are in addition to, and shall not limit, any other remedies or authorities available to the Secretary under this title or any other provision of law.

(2) Fallback price.—If negotiations under subsection (a) or (b) do not result in an agreed-upon price within a reasonable period as determined by the Secretary, the Secretary shall establish a rate for the drug or biological at an amount equal to the lesser of—

- (A) the price paid by the Secretary of Veterans Affairs to procure the drug under the laws administered by the Secretary of Veterans Affairs;

- (B) the price paid to procure the drug under [section 8126 of title 38](#), United States Code; or

- (C) the best price determined under section 1927(c)(1)(C) of the Social Security Act ([42 U.S.C. 1396r-8\(c\)\(1\)\(C\)](#)) for the drug.

(3) Manufacturer agreements and access to negotiated rates.—As a condition of participation in negotiations under subsection (a) or subsection (b), the Secretary shall enter into an agreement with the manufacturer under which the manufacturer shall—

- (A) provide access to the negotiated rate established under this section—

- (i) in the case of a drug furnished under part D, to pharmacies, mail order services, and other dispensers at the point of sale for individuals enrolled under a prescription drug plan or MA–PD plan; and

- (ii) in the case of a drug or biological furnished under part B, to hospitals, physicians, other providers of services, and suppliers for individuals for whom payment may be made under part B; and

(B) comply with such reporting, access, rebate, and other requirements as the Secretary determines necessary to carry out this section.

(4) Administrative duties.—The Secretary shall establish procedures—

(A) to ensure that the negotiated rate established under this section is applied before any coverage or financial assistance under any other health benefit plan or program and before any other discount;

(B) to compute and apply the negotiated rate across different strengths and dosage forms of a drug or biological and not based solely on formulation, package size, or package type; and

(C) to carry out this section with respect to drugs and biologicals furnished under part D, MA–PD plans, and part B.

(5) Information submission.—The Secretary shall establish a process under which a manufacturer of a drug or biological subject to negotiation under subsection (a) or subsection (b) shall submit pricing, cost, utilization, revenue, and such other information as the Secretary determines reasonably necessary to conduct negotiations and administer this section.

(6) Anti-evasion.—The Secretary may promulgate regulations to prevent evasion of this section, including through product hopping, minor reformulations, changes in dosage form, relabeling, or other strategies intended to avoid negotiation, pricing limits, or enforcement under this section.

(7) Savings clause.—Nothing in this section shall be construed to limit the application of the antitrust laws, consumer protection laws, or any other provision of Federal or State law.

(e) Supersession and transition.—

(1) Continuation of existing cycle.—Nothing in this section shall be construed to disturb or invalidate any selection, negotiation, agreement, maximum fair price, or other determination under part E of title XI of the Social Security Act ([42 U.S.C. 1320f et seq.](#)) with respect to a drug or biological selected under such part before February 1, 2027.

(2) No new selections or negotiations under part E.—On or after February 1, 2027, the Secretary may not under part E of such Act—

(A) publish a list of selected drugs for an initial price applicability year after 2028;

(B) enter into a new agreement with a manufacturer with respect to a drug or biological not selected before February 1, 2027; or

(C) establish a new maximum fair price for a drug or biological not selected before February 1, 2027.

(3) Existing agreements and determinations.—Any agreement, maximum fair price, or other determination in effect under part E of such Act with respect to a drug or biological selected before February 1, 2027, shall remain in effect until superseded by a price or agreement established under this section.

(4) Drug-specific supersession.—Upon the establishment under this section of a price or agreement for a drug or biological that is subject to an agreement, maximum fair price, or other determination under part E of such Act, such part shall cease to apply with respect to that drug or biological.

(5) Conforming rule of construction.—On and after the date of enactment of this Act, this section, including section 1860D–11(i) of the Social Security Act ([42 U.S.C. 1395w–111\(i\)](#)), as amended by this section, shall supersede any contrary provision of part E of such Act to the extent necessary to carry out this section.

(6) Repeal.—Effective on the date on which the Secretary certifies that no agreement, maximum fair price, or other determination remains in effect under part E of title XI of the Social Security Act with respect to any drug or biological, such part is repealed.

SEC. 339. DOMESTIC SOURCING PREFERENCE FOR TARGET MEDICINES.

(a) Definitions.—In this section:

(1) Adequate domestic supply.—The term "adequate domestic supply" means, with respect to a target medicine, a supply of 1 or more domestically produced target medicines that the Secretary determines is sufficient to meet reasonably anticipated demand under eligible Federal health programs without materially increasing the risk of a shortage, delaying medically necessary care, impairing patient access, or undermining clinical appropriateness.

(2) Domestically produced target medicine.—The term "domestically produced target medicine" means a target medicine that satisfies domestic production, domestic location, supply-chain resilience, quality-management, and traceability standards established by the Secretary under subsection (g).

(3) Eligible Federal health program.—The term "eligible Federal health program" means—

(A) the Medicare program under title XVIII of the Social Security Act ([42 U.S.C. 1395 et seq.](#));

(B) the Medicaid program under title XIX of the Social Security Act ([42 U.S.C. 1396 et seq.](#));

(C) the Children's Health Insurance Program under title XXI of the Social Security Act ([42 U.S.C. 1397aa et seq.](#));

(D) the Medicare Transition plan established under section 329(d);

(E) the Medicare for All Program established under section 321;

(F) the TRICARE program under chapter 55 of title 10, United States Code;

(G) a health program administered by the Department of Veterans Affairs;

(H) a health program administered by the Indian Health Service;

(I) a health program administered by the Public Health Service;

(J) a health program administered by the Coast Guard;

(K) a health program administered by the Bureau of Prisons; and

(L) any other Federal program that directly purchases, reimburses, covers, or pays for prescription drugs, biological products, combination products, active pharmaceutical ingredients, associated devices, or pharmaceutical inputs, as determined by the Secretary.

(4) Office.—The term "Office" means the Office of Drug Manufacturing established under section 310C of the Public Health Service Act, as added by section 849.

(5) Responsible agency head.—The term "responsible agency head" means—

(A) with respect to an eligible Federal health program administered by the Department of Health and Human Services, the Secretary; and

(B) with respect to any other eligible Federal health program, the head of the executive agency that administers such program.

(6) Secretary.—The term "Secretary" means the Secretary of Health and Human Services.

(7) Target medicine.—The term "target medicine" means any of the following that is designated under subsection (b):

(A) A drug, as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 321\(g\)](#)).

(B) A biological product, as defined in section 351(i) of the Public Health Service Act ([42 U.S.C. 262\(i\)](#)).

(C) A combination product, as described in section 503(g) of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 353\(g\)](#)).

(D) An active pharmaceutical ingredient, associated device, or pharmaceutical input, as such terms are defined in section 310C of the Public Health Service Act.

(b) Designation of target medicines.—

(1) In general.—Not later than September 1, 2027, the Secretary, in consultation with the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, the Secretary of Veterans Affairs, the Secretary of Defense, the Director of the Indian Health Service, and the Office, shall publish a list of target medicines for which domestic sourcing preferences under this section shall apply.

(2) Required considerations.—In designating target medicines under paragraph (1), the Secretary shall consider—

(A) whether the medicine is publicly manufactured or prioritized for public manufacturing under section 310C of the Public Health Service Act;

(B) whether the medicine is included on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 356e](#));

(C) whether the medicine is included on a list of essential medicines, critical medicines, or medical countermeasures maintained by the Federal Government or the World Health Organization;

(D) whether the medicine is necessary to respond to a public health emergency, national emergency, shortage, or medical countermeasure need;

(E) whether the medicine depends on a single manufacturing facility, single active pharmaceutical ingredient source, single supplier, foreign entity of concern, or other supply-chain vulnerability;

(F) whether the medicine accounts for substantial expenditures under 1 or more eligible Federal health programs; and

(G) whether domestic sourcing would improve patient access, supply reliability, affordability, public health preparedness, or market competition.

(3) Initial mandatory target medicines.—The list published under paragraph (1) shall include, at a minimum, each product described in section 310C(h)(4) of the Public Health Service Act.

(4) Updates.—The Secretary shall update the list published under paragraph (1) not less frequently than once each year and may update such list more frequently as necessary to respond to shortages, emergencies, supply-chain vulnerabilities, market failures, or changes in public manufacturing capacity.

(c) Federal direct-procurement preference.—

(1) In general.—When directly procuring a target medicine, the responsible agency head shall, to the maximum extent practicable, procure a domestically produced target medicine if—

(A) adequate domestic supply exists;

(B) the domestically produced target medicine is clinically appropriate for the intended use;

(C) procurement of the domestically produced target medicine would not delay medically necessary care or emergency response; and

(D) the price of the domestically produced target medicine does not exceed the amount otherwise authorized under this section or other applicable law for the procurement or payment arrangement at issue.

(2) Publicly manufactured products.—In carrying out paragraph (1), a responsible agency head shall give first preference to a domestically produced target medicine publicly manufactured under section 310C of the Public Health Service Act if such medicine satisfies the conditions described in paragraph (1).

(3) Procurement tools.—A responsible agency head may carry out this subsection through multi-year contracts, requirements contracts, indefinite-delivery contracts, blanket purchase agreements, purchase commitments, minimum-volume commitments, advance-purchase commitments, procurement guarantees, preferred-source arrangements, or other procurement

instruments authorized under the Federal Acquisition Regulation, agency procurement law, or this section.

(d) Reimbursement and payment policy.—

(1) In general.—The responsible agency head shall establish phased reimbursement, coverage, formulary, purchasing, and payment policies under the eligible Federal health program administered by such responsible agency head to increase the use of domestically produced target medicines when adequate domestic supply exists.

(2) Authorized mechanisms.—Policies established under paragraph (1) may include, as applicable—

(A) preferred formulary placement;

(B) negotiated-price preferences;

(C) temporary payment adjustments designed solely to offset documented incremental domestic production or supply-chain resilience costs, subject to annual review and public reporting;

(D) purchase commitments or minimum purchase commitments;

(E) procurement guarantees;

(F) designation or certification programs for domestically produced target medicines;

(G) conditions for participation in Federal purchasing, distribution, or payment arrangements; and

(H) other mechanisms determined appropriate by the responsible agency head to increase domestic sourcing without impairing patient access.

(3) Medicare for All alignment.—In establishing payment policies for prescription drugs, biological products, medical supplies, and medically necessary assistive equipment under section 326(f), the Secretary shall incorporate domestic sourcing preferences for target medicines consistent with this section.

(4) Medicare Transition plan alignment.—In administering the Medicare Transition plan under section 329(d), the Administrator of the Centers for Medicare & Medicaid Services shall incorporate domestic sourcing preferences for target medicines consistent with this section.

(e) Publicly manufactured products.—

(1) Deemed compliance.—A target medicine publicly manufactured under section 310C of the Public Health Service Act shall be deemed to satisfy the domestic sourcing preference under this section if the medicine satisfies the standards established under subsection (g) and is approved, licensed, cleared, authorized, or otherwise lawfully marketed or used under the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 301 et seq.](#)) or section 351 of the Public Health Service Act ([42 U.S.C. 262](#)).

(2) No special Food and Drug Administration treatment.—Nothing in this subsection shall be construed to require the Food and Drug Administration to give special deference to a target medicine described in paragraph (1).

(f) Patient access and shortage guardrails.—The Secretary or the responsible agency head, as applicable, shall waive, suspend, or modify the application of a preference, requirement, payment policy, or procurement policy under this section to the extent necessary to prevent such application from—

(1) delaying or interrupting medically necessary care;

(2) worsening or materially increasing the risk of a drug shortage;

(3) requiring a patient to switch from a clinically appropriate medicine if the patient's treating clinician determines that the switch would be medically inappropriate;

(4) blocking access to a medicine when adequate domestic supply does not exist;

(5) increasing patient cost-sharing;

(6) preventing an appropriate emergency response;

(7) requiring the use of a target medicine that has not been approved, licensed, cleared, authorized, or otherwise lawfully marketed or used under the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 301 et seq.](#)) or section 351 of the Public Health Service Act ([42 U.S.C. 262](#)); or

(8) violating a binding obligation of the United States under an international agreement after application of any exception, reservation, waiver, or other authority available to preserve the operation of this section.

(g) Interim final rules; phase-in.—

(1) Interim final rules.—Not later than July 1, 2027, the Secretary, in consultation with the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, the Secretary of Veterans Affairs, the Secretary of Defense, the Director of the Indian Health Service, and the Office, shall issue interim final rules to carry out this section, including rules for designation of target medicines and for certification, documentation, and verification of domestically produced target medicines.

(2) Domestic production standards.—The interim final rules issued under paragraph (1) shall establish standards for determining whether a target medicine is a domestically produced target medicine, including standards relating to—

(A) the location of final dosage form manufacturing;

(B) the location of active pharmaceutical ingredient manufacturing;

(C) domestic production of associated devices and pharmaceutical inputs, where practicable;

(D) quality-management maturity, reliability, and inspection history;

(E) supply-chain mapping and traceability;

(F) resilience against shortages, emergencies, and foreign supply disruption; and

(G) exceptions or phased standards for target medicines for which domestic production of an active pharmaceutical ingredient, associated device, or pharmaceutical input is not yet available.

(3) Direct procurement implementation.—Not later than January 1, 2028—

(A) the Federal Acquisition Regulatory Council established under [section 1302\(a\) of title 41](#), United States Code, in consultation with the Secretary, the Director of the Office of Management and Budget, the Secretary of Defense, the Secretary of Veterans Affairs, and the Administrator of General Services, shall revise the Federal Acquisition Regulation and issue guidance as necessary to implement subsection (c); and

(B) each responsible agency head shall begin applying the preference under subsection (c) to solicitations issued and contracts entered into, extended, renewed, or modified.

(4) Reimbursement and payment phase-in.—The responsible agency head shall begin applying policies under subsection (d) as soon as practicable after the issuance of interim final rules under paragraph (1), and not later than July 1, 2028.

(5) Medicare for All phase-in.—The Secretary shall fully integrate the policies required under this section into the Medicare for All Program not later than January 1, 2029.

(6) Final rules.—The Secretary shall issue final rules to carry out this section not later than January 1, 2029.

(h) Supply-gap referrals and reports.—

(1) Supply-gap referrals.—If the Secretary determines that adequate domestic supply does not exist for a target medicine, the Secretary shall refer the target medicine to the Office, the Secretary of Commerce, the Strategic Public Production Corporation established under section 848, the National Infrastructure Bank established under section 642, and any other appropriate Federal official for consideration of public manufacturing, industrial reconstruction financial assistance, strategic public production assets, financing, purchase commitments, or other capacity-building action.

(2) Annual report.—Not later than December 31, 2027, and annually thereafter, the Secretary, in coordination with each responsible agency head, shall submit to Congress and make publicly available a report that includes—

(A) the list of target medicines designated under subsection (b);

(B) an assessment of domestic supply for each target medicine;

(C) a description of direct procurement preferences, reimbursement policies, payment policies, temporary payment adjustments, formulary policies, purchase commitments, and other actions taken under this section;

(D) the number and basis of waivers, suspensions, or modifications under subsection (f);

(E) an assessment of the effect of this section on patient access, drug shortages, prices, Federal health program spending, and domestic manufacturing capacity;

(F) a description of each supply-gap referral made under paragraph (1); and

(G) recommendations for additional legislation or administrative action necessary to secure adequate domestic supply of target medicines.

(i) Certification, audits, and enforcement.—

(1) Certification.—The Secretary may require a manufacturer, distributor, wholesaler, contractor, health plan, provider, or other entity seeking treatment of a target medicine as a domestically produced target medicine to submit certifications, records, supply-chain documentation, and other information necessary to verify compliance with this section.

(2) Audits.—The Secretary and any responsible agency head may audit certifications, records, supply-chain documentation, contracts, and other information submitted or maintained under this section.

(3) False statements and claims.—A knowing material false statement, false certification, or false claim under this section shall be subject to applicable penalties and remedies under sections 287, 1001, and 1035 of title 18, United States Code, [section 3729 of title 31](#), United States Code, and sections 1128, 1128A, and 1128B of the Social Security Act ([42 U.S.C. 1320a-7](#), [1320a-7a](#), [1320a-7b](#)).

(4) Loss of preference.—The Secretary or a responsible agency head may deny, suspend, or revoke eligibility for a preference, payment policy, procurement policy, certification, or designation under this section for knowing or repeated noncompliance with this section.

(j) Rules of construction.—

(1) Food and Drug Administration authority.—Nothing in this section shall be construed to alter, limit, or supersede the authority of the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 301 et seq.](#)) or section 351 of the Public Health Service Act ([42 U.S.C. 262](#)).

(2) Patient access.—Nothing in this section shall be construed to require denial of coverage, reimbursement, or payment for a target medicine when denial would impair patient access, clinical appropriateness, or emergency response.

(3) Public manufacturing.—Nothing in this section shall be construed to limit the authority of the Office under section 310C of the Public Health Service Act.

(4) Negotiated prices and fair prices.—Nothing in this section shall be construed to require the Secretary or any responsible agency head to pay more than the fair price, negotiated price, or other lawful payment amount applicable to a target medicine.

(5) International agreements.—This section shall be applied to the maximum extent consistent with binding obligations of the United States under international agreements.