AMENDMENT IN THE NATURE OF A SUBSTITUTE

TO H.R. 3561

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting Access to Treatments and Increasing Extremely Needed Transparency Act of 2023'' or the ''PATIENT Act of 2023''.

TITLE I—INCREASING PRICE TRANSPARENCY TO LOWER COSTS

SEC. 101. PRICE TRANSPARENCY REQUIREMENTS.

(a) IN GENERAL.—Section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)) is amended—

(1) by striking ''Each hospital'' and inserting the following:

''(1) IN GENERAL.—Each hospital'';

(2) by inserting '', without subscription and free of charge, in a single machine-readable file,'' after ''a list'';

(3) by inserting ''all'' after ''of the hospital's standard charges for'';

(4) by inserting ''and a list, in plain language and without subscription and free of charge, in a consumer-friendly format, of the hospital's standard charges for as many of the Centers for Medicare & Medicaid Services-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services (or all such additional services, if such hospital provides fewer than 300 shoppable services) as may be necessary for a combined total of at least 300 shoppable services'' after ''Social Security Act''; and

(5) by adding at the end the following: ''Beginning January 1, 2025, each hospital shall include in its lists of standard charges, along with such additional information as the Secretary may require with respect to such charges for purposes of promoting public awareness of hospital pricing in advance of receiving a hospital item or service, the following:

''(A) A plain language description of each item or service included on such list, including, as applicable, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug

Code (NDC), or other payer identifier used or approved by the Centers for Medicare & Medicaid Services for such item or service.

''(B) The gross charge, expressed as a dollar amount, for each such item or service, when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

''(C) Any current payer-specific negotiated charges, clearly associated with the name of the third party payer and plan and expressed as a dollar amount, that applies to each such item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

''(D) The de-identified maximum and minimum negotiated charges for each such item or service.

''(E) The discounted cash price, expressed as a dollar amount, for each such item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. If the discounted cash price is a percentage of another value provided, the calculated value must be entered as a dollar amount. If the discounted cash price equates to

the gross charge, the gross charge shall be re-entered to indicate that no cash discount is available.

''(2) DEEMED COMPLIANCE WITH SHOPPABLE SERVICES REQUIREMENT FOR CERTAIN YEARS.—With respect to a year before 2025, a hospital shall be deemed to meet the requirement of paragraph (1) that such hospital make available a list of standard charges for shoppable services if the hospital maintains an internet-based price estimator tool that meets the following requirements:

''(A) The tool provides estimates for as many of the Centers for Medicare & Medicaid Services specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services (or all such additional services, if such hospital provides fewer than 300 shoppable services) as may be necessary for a combined total of at least 300 shoppable services.

''(B) The tool allows health care consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.

''(C) The tool is prominently displayed on the hospital's website and easily accessible to the public, without subscription, fee, or having to submit personal identifying information, and searchable by service description, billing code, and payer.

The Secretary may not deem the establishment of an internet-based price estimator tool that meets the requirements of this paragraph to constitute compliance with the requirement of paragraph (1) that such hospital make available a list of standard charges for shoppable services for 2025 or a subsequent year.

''(3) UNIFORM METHOD AND FORMAT.—Not later than January 1, 2025, the Secretary shall implement a standard, uniform method and format for hospitals to use in order to satisfy the requirements of this subsection for disclosing directly to the public charge and price information. Such method and format may be similar to any template made available by the Centers for Medicare & Medicaid Services as of the date of the enactment of this paragraph for reporting such information under this subsection and shall meet such standards as determined appropriate by the Secretary.

''(4) MONITORING OF PRICING INFORMATION.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall, through notice and comment rule-making, establish a process to regularly monitor the accuracy of pricing information displayed by each hospital pursuant to paragraph (1).

''(5) DEFINITIONS.—Notwithstanding any other provision of law, for the purpose of paragraphs (1) and (2):

''(A) DE-IDENTIFIED MAXIMUM NEGOTIATED CHARGE.—The term 'de-identified maximum negotiated charge' means the highest charge that a hospital has negotiated with all third party payers for an item or service.

''(B) DE-IDENTIFIED MINIMUM NEGOTIATED CHARGE.—The term 'de-identified minimum negotiated charge' means the lowest charge that a hospital has negotiated with all third party payers for an item or service.

''(C) DISCOUNTED CASH PRICE.—The term 'discounted cash price' means the charge that applies to an individual who pays cash, or cash equivalent, for a hospital item or service. Hospitals that do not offer self-pay discounts

may display the hospital's undiscounted gross charges as found in the hospital chargemaster.

''(D) GROSS CHARGE.—The term 'gross charge' means the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts.

''(E) PAYER-SPECIFIC NEGOTIATED CHARGE.—The term 'payer-specific negotiated charge' means the charge that a hospital has negotiated with a third party payer for an item or service.

''(F) SHOPPABLE SERVICE.—The term 'shoppable service' means a service that can be scheduled by a health care consumer in advance.

''(G) THIRD PARTY PAYER.—The term 'third party payer' means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.

''(6) ENFORCEMENT.—

''(A) IN GENERAL.—In the case of a hospital that fails to comply with this subsection—

''(i) the Secretary shall notify such hospital of such failure not later than 30

days after the date on which the Secretary determines such failure exists; and

''(ii) not later than 45 days after the date of such notification, the hospital shall complete a corrective action plan to comply with such requirements.

''(B) CIVIL MONETARY PENALTY.—

''(i) IN GENERAL.—In addition to any other enforcement actions or penalties that may apply under subsection (b)(3) or another provision of law, a hospital that has received a notification under subparagraph (A)(i) and fails to satisfy the requirement under subparagraph (A)(ii) or otherwise comply with the requirements of this subsection by the date that is 90 days after such notification shall be subject to a civil monetary penalty of an amount—

''(I) in the case of a hospital with not more than 30 beds (as determined under section 180.90(c)(2)(ii)(D) of title 45, Code of Federal Regulations, as in effect on the date of the enactment of this paragraph), not to exceed $300 per day that the violation is on-

going as determined by the Secretary; and

''(II) in the case of a hospital with more than 30 beds (as so determined), equal to—

''(aa) subject to item (bb), $10 per bed per day that the violation is ongoing as determined by the Secretary, but for violations occurring before January 1, 2024, not to exceed $5,500 per each such day; or

''(bb) in the case such hospital has failed to satisfy the requirement under subparagraph (A)(ii) or otherwise comply with the requirements of this subsection for any 1-year period (as determined by the Secretary) beginning on or after January 1, 2024, and the amount otherwise imposed under item (aa) for such failure for such period would be less than $5,000,000, an amount not less than $5,000,000.

''(ii) INCREASE AUTHORITY.—In applying this subparagraph with respect to violations occurring in 2025 or a subsequent year, the Secretary may through notice and comment rulemaking increase any dollar amount applied under this subparagraph by an amount specified by the Secretary.

''(iii) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under clause (i) in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.''.

(b) PUBLICATION OF LIST OF HOSPITALS.—

(1) LIST OF HOSPITALS.—Beginning not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish and maintain a publicly available list on the website of the Centers for Medicare & Medicaid Services of each hospital that the Secretary has

found to be noncompliant with the provisions of section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)). Such list shall include, with respect to each such hospital, a specification as to whether such hospital—

(A) has been issued a civil monetary penalty;

(B) has received a warning notice; or

(C) has submitted a corrective action plan.

(2) ADDITIONS AND UPDATES.—In the case of a hospital not included on the list described in paragraph (1) as of the date of the establishment of such list and that is subject to a review of such hospital's compliance with the provisions described in such paragraph after such date, the Secretary shall add such hospital to such list, along with the specifications described in such paragraph, not later than 1 business day after such review occurs. The Secretary shall update such specifications with respect to any hospital included on such list—

(A) not later than 1 business day after any subsequent review of such hospital's compliance with such provisions; and

(B) not later than 1 business day after any penalty, notice, or request described in paragraph (1) is made with respect to such hospital.

(3) FOIA REQUESTS.—Any penalty, notice, or request described in paragraph (1) shall be subject to public disclosure, in full and without redaction, under section 552 of title 21, United States Code, notwithstanding any exemptions or exclusions otherwise available under such section 552.

(4) REPORTS TO CONGRESS.—Not later than 1 year after the date of enactment of this Act and each year thereafter, the Secretary of Health and Human Services shall submit to Congress, and make publicly available, a report that contains information regarding complaints of alleged violations of law and enforcement activities by the Secretary under the hospital price transparency rule implementing section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)). Such report shall be made available to the public on the website of the Centers for Medicare & Medicaid Services. Each such report shall include, with respect to the year involved—

(A) the number of compliance and enforcement inquiries opened by the Secretary pursuant to such section;

(B) the number of notices of noncompliance issued by the Secretary based on such inquiries;

(C) the identity of each hospital entity that received a notice of noncompliance and the nature of the failure giving rise to the Secretary's determination of noncompliance;

(D) the amount of civil monetary penalty assessed against the hospital entity;

(E) whether the hospital entity subsequently corrected the noncompliance; and

(F) an analysis of factors contributing to increasing health care costs.

(5) GAO REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the compliance and enforcement with the hospital price transparency rule implementing section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)). The report shall include recommendations related to—

(A) improving price transparency to patients, employers, and the public; and

(B) increased civil monetary penalty amounts to ensure compliance.

(6) REQUEST FOR INFORMATION.—Not later than January 1, 2025, the Secretary of Health and Human Services shall issue a public request for information as to the best method through which hospitals may be required to publish quality data (such as data required to be reported under the Medicare Hospital Compare program) alongside data required to be reported under section 2718(e) of the Public Health Service Act (42 U.S.C. 300gg–18(e)).

(c) ENSURING ACCESSIBILITY THROUGH IMPLEMENTATION.—In implementing the amendments made by this section, the Secretary of Health and Human Services shall through rulemaking ensure that a hospital submitting charges and information pursuant to such amendments takes reasonable steps (as specified by the Secretary) to ensure the accessibility of such charges and information to individuals with limited English proficiency. Such steps may include the hospital's provision of interpretation services or the hospital's provision of translations of charges and information.

SEC. 102. STRENGTHENING HEALTH INSURER TRANSPARENCY REQUIREMENTS.

(a) TRANSPARENCY IN COVERAGE.—Section 1311(e)(3)(C) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(e)(3)(C)) is amended—

(1) by striking ''The Exchange'' and inserting the following:

''(i) IN GENERAL.—The Exchange'';

(2) in clause (i), as inserted by paragraph (1)—

(A) by striking ''participating provider'' and inserting ''provider'';

(B) by inserting ''shall include the information specified in clause (ii) and'' after ''such information'';

(C) by striking ''an Internet website'' and inserting ''a self-service tool that meets the requirements of clause (iii)''; and

(D) by striking ''and such other'' and all that follows through the period and inserting ''or, at the option such individual, through a paper or phone disclosure (as selected by such individual and provided at no cost to such individual) that meets such requirements as the Secretary may specify.''; and

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

''(ii) SPECIFIED INFORMATION.—For purposes of clause (i), the information specified in this clause is, with respect to an item or service for which benefits are available under a health plan furnished by a health care provider, the following:

''(I) If such provider is a participating provider with respect to such item or service, the in-network rate (as defined in subparagraph (F)) for such item or service.

''(II) If such provider is not described in subclause (I), the maximum allowed amount for such item or service.

''(III) The amount of cost sharing (including deductibles, copayments, and coinsurance) that the individual will incur for such item or service (which, in the case such item or service is to be furnished by a provider described in subclause (II), shall be calculated using the maximum amount described in such subclause).

''(IV) The amount the individual has already accumulated with respect to any deductible or out of pocket maximum under the plan (broken down, in the case separate deductibles or maximums apply to separate individuals enrolled in the plan, by such separate deductibles or maximums, in addition to any cumulative deductible or maximum).

''(V) In the case such plan imposes any frequency or volume limitations with respect to such item or service (excluding medical necessity determinations), the amount that such individual has accrued towards such limitation with respect to such item or service.

''(VI) Any prior authorization, concurrent review, step therapy, fail first, or similar requirements applicable to coverage of such item or service under such plan.

''(iii) SELF-SERVICE TOOL.—For purposes of clause (i), a self-service tool estab-

lished by a health plan meets the requirements of this clause if such tool—

"(I) is based on an Internet website;

"(II) provides for real-time responses to requests described in such clause;

"(III) is updated in a manner such that information provided through such tool is timely and accurate;

"(IV) allows such a request to be made with respect to an item or service furnished by—

"(aa) a specific provider that is a participating provider with respect to such item or service;

"(bb) all providers that are participating providers with respect to such plan and such item or service; or

"(cc) a provider that is not described in item (bb); and

''(V) provides that such a request may be made with respect to an item or service through use of the billing code for such item or service or through use of a descriptive term for such item or service.

The Secretary may require such tool, as a condition of complying with subclause (V), to link multiple billing codes to a single descriptive term if the Secretary determines that the billing codes to be so linked correspond to items and services.''.

(b) DISCLOSURE OF ADDITIONAL INFORMATION.—Section 1311(e)(3) of the Patient Protection and Affordable Care Act (42 U.S.C. 18031(e)(3)) is amended by adding at the end the following new subparagraphs:

''(E) RATE AND PAYMENT INFORMATION.—

''(i) IN GENERAL.—Not later than January 1, 2025, and every 3 months thereafter, each health plan shall submit to the Secretary (or otherwise make available to the Secretary through an Internet link provided to the Secretary), and make available to the public, the rate and payment

information described in clause (ii) in accordance with clause (iii).

''(ii) RATE AND PAYMENT INFORMATION DESCRIBED.—For purposes of clause (i), the rate and payment information described in this clause is, with respect to a health plan, the following:

''(I) With respect to each item or service for which benefits are available under such plan, the in-network rate in effect as of the date of the submission of such information with each provider (identified by national provider identifier) that is a participating provider with respect to such item or service, other than such a rate in effect with a provider that, during the 1-year period ending on such date, did not submit any claim for such item or service to such plan.

''(II) With respect to each drug (identified by national drug code) for which benefits are available under such plan, the average amount paid by such plan (net of rebates, dis-

counts, and price concessions) for such drug dispensed or administered during the 90-day period beginning 180 days before such date of submission to each provider that was a participating provider with respect to such drug, broken down by each such provider (identified by national provider identifier), other than such an amount paid to a provider that, during such period, submitted fewer than 20 claims for such drug to such plan.

''(III) With respect to each item or service for which benefits are available under such plan, the amount billed, and the amount allowed by the plan, for each such item or service furnished during the 90-day period specified in subclause (II) by a provider that was not a participating provider with respect to such item or service, broken down by each such provider (identified by national provider identifier), other than items and services with respect to which fewer

than 20 claims for such item or service were submitted to such plan during such period.

''(iii) MANNER OF SUBMISSION.—Rate and payment information required to be submitted and made available under this subparagraph shall be so submitted and so made available in dollar amounts through 3 separate machine-readable files corresponding to the information described in each of subclauses (I) through (III) of clause (ii) that meet such requirements as specified by the Secretary through rulemaking. Such requirements shall ensure that such files are limited to an appropriate size, are made available in a widely-available format that allows for information contained in such files to be compared across health plans, and are accessible to individuals at no cost and without the need to establish a user account or provide other credentials.

''(iv) USER GUIDE.—Each health plan shall make available to the public instructions written in plain language explaining

how individuals may search for information described in clause (ii) in files submitted in accordance with clause (iii).

''(F) DEFINITIONS.—In this paragraph:

''(i) PARTICIPATING PROVIDER.—The term 'participating provider' has the meaning given such term in section 2799A–1 of the Public Health Service Act.

''(ii) IN-NETWORK RATE.—The term 'in-network rate' means, with respect to a health plan and an item or service furnished by a provider that is a participating provider with respect to such plan and item or service, the contracted rate in effect between such plan and such provider for such item or service.''.

(c) REPORTS.—

(1) COMPLIANCE.—Not later than January 1, 2025, the Comptroller General of the United States shall submit to Congress a report containing—

(A) an analysis of health plan compliance with the amendments made by this section;

(B) an analysis of enforcement of such amendments by the Secretaries of Health and Human Services, Labor, and the Treasury;

(C) recommendations relating to improving such enforcement; and

(D) recommendations relating to improving public disclosure, and public awareness, of information required to be made available by such plans pursuant to such amendments.

(2) PRICES.—Not later than January 1, 2028, the Comptroller General of the United States shall submit to Congress a report containing an assessment of differences in negotiated prices (and any trends in such prices) in the private market between—

(A) rural and urban areas;

(B) the individual, small group, and large group markets;

(C) consolidated and nonconsolidated health care provider areas (as specified by the Secretary);

(D) nonprofit and for-profit hospitals;

(E) nonprofit and for-profit insurers; and

(F) insurers serving local or regional areas and insurers serving multistate or national areas.

(d) ENSURING ACCESSIBILITY THROUGH IMPLEMENTATION.—In implementing the amendments made by this

section, the Secretary shall through rulemaking ensure that any entity making available information pursuant to such amendments takes reasonable steps (as specified by the Secretary) to ensure the accessibility of such to individuals with limited English proficiency. Such steps may include the entity's provision of interpretation services or of translations of such information.

(e) GAO REPORT.—Not later than January 1, 2025, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(1) an analysis of existing efforts amongst ambulatory surgical centers to make pricing information available to patients, employers, and the public; and

(2) recommendations, if any—

(A) to improve ambulatory surgical center price transparency to help patients, employers, and the public better understand pricing information and make more informed care decisions using existing authorities under current law;

(B) to improve current law to promote ambulatory surgical center price transparency for

the purposes described in subparagraph (A); and

(C) to ensure that efforts to improve ambulatory surgical center price transparency have a positive impact without significantly increasing administrative costs and potentially contributing to increased consolidation.

(f) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by subsection (a) shall apply beginning January 1, 2025.

(2) CONTINUED APPLICABILITY OF RULES FOR PREVIOUS YEARS.—Nothing in the amendments made by this section may be construed as affecting the applicability of the rule entitled ''Transparency in Coverage'' published by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services on November 12, 2020 (85 Fed. Reg. 72158) before January 1, 2025.

SEC. 103. REQUIRING A SEPARATE IDENTIFICATION NUMBER AND AN ATTESTATION FOR EACH OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.

Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended by adding at the end the following new paragraph:

''(23) USE OF UNIQUE HEALTH IDENTIFIERS; ATTESTATION.—

''(A) IN GENERAL.—No payment may be made under this subsection (or under an applicable payment system pursuant to paragraph (21)) for items and services furnished on or after January 1, 2026, by an off-campus outpatient department of a provider (as defined in subparagraph (C)) unless—

''(i) such department has obtained, and such items and services are billed under, a standard unique health identifier for health care providers (as described in section 1173(b)) that is separate from such identifier for such provider; and

''(ii) such provider has submitted to the Secretary, during the 2-year period ending on the date such items and services are so furnished, an attestation that such

department is compliant with the requirements described in section 413.65 of title 42, Code of Federal Regulations (or a successor regulation).

''(B) PROCESS FOR SUBMISSION AND REVIEW.—Not later than 1 year after the date of enactment of this paragraph, the Secretary shall, through notice and comment rulemaking, establish a process for each provider with an off-campus outpatient department of a provider to submit an attestation pursuant to subparagraph (A)(ii), and for the Secretary to review each such attestation and determine, through site visits, remote audits, or other means (as determined appropriate by the Secretary), whether such department is compliant with the requirements described in such subparagraph.

''(C) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER DEFINED.—For purposes of this paragraph, the term 'off-campus outpatient department of a provider' means a department of a provider (as defined in section 413.65 of title 42, Code of Federal Regulations, or any successor regulation) that is not located—

''(i) on the campus (as defined in such section) of such provider; or

''(ii) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section).''.

SEC. 104. MANDATORY REPORTING WITH RESPECT TO CERTAIN HEALTH-RELATED OWNERSHIP INFORMATION.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new section:

''SEC. 1150D. MANDATORY REPORTING WITH RESPECT TO CERTAIN HEALTH-RELATED OWNERSHIP INFORMATION.

''(a) MANDATORY REPORTING WITH RESPECT CERTAIN HEALTH-RELATED OWNERSHIP INFORMATION.—

''(1) INITIAL REPORT.—Not later than January 1, 2025 (or in the case of a specified entity formed after January 1, 2025, within 60 days of becoming a specified entity), each specified entity (as defined in subsection (g)(5)) shall submit to the Secretary, in a form and manner specified by the Secretary, a report containing the following information:

''(A) The business structure of the specified entity, including the business type and the tax status of such entity.

''(B) Data on mergers, acquisitions, and changes in ownership with respect to such specified entity for the previous 1-year period.

''(C) In the case that a specified entity is, or includes, a hospital, the additional information described in subsection (b).

''(D) As applicable, the name, address, and business structure of the parent company of such specified entity (including the tax status of such parent company), and the name, address, and business structure of any beneficial owners of the parent company of such specified entity (including the tax status of such beneficial owner) who control (or own a controlling interest in) the parent company, as of the date of the submission of this report.

''(E) Any other information with respect to ownership of a specified entity, as determined by the Secretary.

''(2) SUBSEQUENT REPORTS.—Not later than 1 year after submitting the report under paragraph (1), and annually thereafter, each specified entity

shall submit to the Secretary an updated report, including—

''(A)(i) data on mergers, acquisitions, and changes in ownership with respect to such entities for the previous 1-year period; and

''(ii) any other information with respect to ownership of a specified entity, as determined by the Secretary; and

''(B) in the case that a specified entity is, or includes, a hospital, the additional information described in subsection (b).

''(b) ADDITIONAL INFORMATION SUBMITTED BY CERTAIN SPECIFIED ENTITIES.—For purposes of paragraphs (1)(C) and (2)(B) of subsection (a), with respect to a specified entity that is, or includes, a hospital, the information described in this subsection is the following information with respect to the previous 1-year period:

''(1) The average debt-to-earnings ratio of the specified entity.

''(2) The average amount of debt incurred—

''(A) by the hospital; and

''(B) by the entire specified entity.

''(3) Information with respect to real estate leases and purchases for property used, or intended

to be used, to furnish or otherwise support the provision of health care services.

''(4) In the case of a non-profit hospital, a subsidiary of a non-profit hospital, or a 501(c)(3) entity that shares common ownership with a non-profit hospital, capital gains investments (disaggregated by the type of investment) and any taxes paid on such gains from such investments.

''(5) As applicable, information with respect to the parent company of such specified entity.

''(c) PUBLIC REPORTING.—

''(1) Not later than January 1, 2027, and annually thereafter, the Secretary shall post on a publicly available website of the Department of Health and Human Services a report with respect to the previous 1-year period, including—

''(A) the number of specified entities reporting for such year, disaggregated by the business structure of each specified entity in accordance with paragraph (2);

''(B) the number of owners of each specified entity;

''(C) any change in ownership for each specified entity;

''(D) any change in the tax status of a specified entity;

''(E) an analysis of trends in horizontal and vertical consolidation, disaggregated by business structure and provider type; and

''(F) as applicable, the name, address, and business structure of the parent company of such specified entity (including the business type and the tax status of such parent company).

''(2) In disaggregating the business structure of a specified entity under paragraph (1)(A), or a parent company under subparagraph (F) of such paragraph, the Secretary shall use the following business structures, if applicable, and identify such structures as privately held or publicly traded:

''(A) Hospitals.

''(B) Health plans.

''(C) Private equity companies.

''(D) Venture capital funds.

''(E) Unincorporated business entities.

''(F) S-corporations.

''(G) Real estate investment trusts.

''(H) Hedge funds.

''(I) Exchange-traded funds.

''(J) Sovereign wealth funds.

''(K) Public pension fund direct ownership investments.

''(L) Physician-owned practices with non-physician minority owners.

''(M) Other business structures as identified by the Secretary.

''(d) AUDITS.—The Secretary shall conduct an annual audit consisting of a random sample of specified entities to verify compliance with the requirements of this section and the accuracy of information submitted pursuant to this section.

''(e) PENALTY FOR FAILURE TO REPORT.—If a specified entity fails to provide a complete report under subsection (a), or submits a report containing false information, such entity shall be subject to a civil monetary penalty of—

''(1) in the case of a specified entity that is a hospital with more than 30 beds, not more than $5,000,000 for each such report not provided or containing false information; and

''(2) in the case of all other specified entities, not more than $2,000,000 for each such report not provided or containing false information.

Such penalties shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

''(f) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to collections of information made under this section.

''(g) DEFINITIONS.—In this section:

''(1) HEALTH PLAN.—The term 'health plan' has the meaning given such term in section 1128C(c).

''(2) HOSPITAL.—The term 'hospital' has the meaning given such term in section 1861(e).

''(3) INDEPENDENT FREESTANDING EMERGENCY DEPARTMENT.—The term 'independent freestanding emergency department' has the meaning given such term in section 2799A–1(a)(3)(D) of the Public Health Service Act.

''(4) PRIVATE EQUITY COMPANY.—The term 'private equity company' means a publicly-traded or non-publicly traded company that collects capital investments from individuals or entities and purchases an ownership share of a provider of services.

''(5) SPECIFIED ENTITY.—The term 'specified entity' means—

''(A) a hospital;

''(B) a physician-owned physician practice with more than 25 physicians for a year;

''(C) a physician practice owned by a hospital, a health plan, a private equity company, or a venture capital firm;

''(D) an ambulatory surgical center meeting the standards specified under section 1832(a)(2)(F)(i); or

''(E) an independent freestanding emergency department.

''(6) VENTURE CAPITAL FUND.—The term 'venture capital fund' has the meaning given such term in section 275.203(l)–1of title 17, Code of Federal Regulations.''.

SEC. 105. INCREASING PRICE TRANSPARENCY OF CLINICAL DIAGNOSTIC LABORATORY TESTS UNDER THE MEDICARE PROGRAM.

Section 1846 of the Social Security Act (42 U.S.C. 1395w–2) is amended—

(1) in the header, by inserting ''**AND ADDITIONAL REQUIREMENTS**'' after ''**SANCTIONS**''; and

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

''(c) PRICE TRANSPARENCY REQUIREMENT.—

''(1) IN GENERAL.—Beginning January 1, 2025, any applicable laboratory that is available to furnish any specified clinical diagnostic laboratory test under this title shall—

''(A) make publicly available on an Internet website the information described in paragraph (2) with respect to each such specified clinical diagnostic laboratory test that such laboratory is so available to furnish; and

''(B) ensure that such information is updated not less frequently than annually.

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to an applicable laboratory and a specified clinical diagnostic laboratory test, the following:

''(A) The discounted cash price for such test (or, if no such price exists, the gross charge for such test).

''(B) The deidentified minimum negotiated rate in effect between such laboratory and any

group health plan or group or individual health insurance coverage for such test.

''(C) The deidentified maximum negotiated rate in effect between such laboratory and any such plan or coverage for such test.

''(3) INCLUSION OF ANCILLARY SERVICES.—Any price or rate for a specified clinical diagnostic laboratory test available to be furnished by an applicable laboratory made publicly available in accordance with paragraph (1) shall include the price or rate (as applicable) for any ancillary item or service (such as specimen collection services) that would normally be furnished by such laboratory as part of such test, as specified by the Secretary.

''(4) ENFORCEMENT.—

''(A) IN GENERAL.—In the case that the Secretary determines that an applicable laboratory is not in compliance with paragraph (1)—

''(i) not later than 30 days after such determination, the Secretary shall notify such laboratory of such determination; and

''(ii) if such laboratory continues to fail to comply with such paragraph after the date that is 90 days after such notification is sent, the Secretary may impose a

civil monetary penalty in an amount not to exceed $300 for each day (beginning with the date that is 91 days after such notification was sent) during which such failure is ongoing.

''(B) APPLICATION OF CERTAIN PROVISIONS.—The provisions of section 1128A (other than subsections (a) and (b) of such section) shall apply to a civil monetary penalty imposed under this paragraph in the same manner as such provisions apply to a civil monetary penalty imposed under subsection (a) of such section.

''(5) DEFINITIONS.—In this subsection:

''(A) APPLICABLE LABORATORY.—The term 'applicable laboratory' has the meaning given such term in section 414.502, of title 42, Code of Federal Regulations.

''(B) GROUP HEALTH PLAN; GROUP HEALTH INSURANCE COVERAGE; INDIVIDUAL HEALTH INSURANCE COVERAGE.—The terms 'group health plan', 'group health insurance coverage', and 'individual health insurance coverage' have the meaning given such terms in section 2791 of the Public Health Service Act.

''(C) SPECIFIED CLINICAL DIAGNOSTIC LABORATORY TEST.—the term 'specified clinical diagnostic laboratory test' means a clinical diagnostic laboratory test that is included on the list of shoppable services specified by the Centers for Medicare & Medicaid Services (as described in section 2718(e)(1) of the Public Health Service Act), other than such a test that is only available to be furnished by a single provider of services or supplier.''.

SEC. 106. PROMOTING TRANSPARENCY OF COMMON OWNERSHIP INTERESTS UNDER PARTS C AND D OF THE MEDICARE PROGRAM.

(a) MEDICARE ADVANTAGE.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

''(6) REQUIRED DISCLOSURE OF CERTAIN INFORMATION RELATING TO HEALTH CARE PROVIDER OWNERSHIP.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2026, a contract under this section with an MA organization that is an applicable MA organization (as defined in subparagraph (C)) with respect to such plan year shall require the organization to re-

port to the Secretary, not later than 18 months after the last day of such plan year, the information described in subparagraph (B) with respect to such plan year.

''(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, with respect to an MA organization and a plan year, the following:

''(i) The number of items and services furnished during such plan year by each specified provider (as defined in subparagraph (C)) for which payment was made by such organization.

''(ii) The number of items and services furnished during such plan year by providers of services or suppliers not described in clause (i) for which payment was made by such organization.

''(iii) The average per-enrollee number of qualifying diagnoses (as defined in subparagraph (C)) made during such plan year by specified providers (including through chart reviews and health risk assessments) with respect to individuals en-

rolled under an MA plan offered by such organization, broken down by site of service of such providers, as specified by the Secretary.

''(iv) The average per-enrollee number of qualifying diagnoses made during such plan year by providers of services and suppliers not described in clause (iii) (including through such reviews and assessments) with respect to such individuals, broken down by site of service of such providers.

''(v) The average risk score (as calculated under the methodology described in subparagraph (C)(iii)) for such an individual for such plan year who received items and services from a specified provider during such plan year.

''(vi) The average risk score for such an individual for such plan year who did not receive items and services from a specified provider during such plan year.

''(vii) The average risk score for such an individual for such plan year who received a health risk assessment from an

assessment entity that was a specified assessment entity during such plan year.

''(viii) The average risk score for such an individual for such plan year who received a health risk assessment from an assessment entity that was not a specified assessment entity during such plan year.

''(ix) The number of prior authorization requests for an item or service submitted to such organization during such plan year, the number of such requests that were approved by such organization, the number of such requests that were denied by such organization, and the number of such denied requests that were subsequently appealed and then approved at any level of appeal, broken down by whether the entity proposing to furnish such item or service was a specified provider or not a specified provider.

''(x) The total amount of incentive-based payments made to, and the total amount of shared losses recoupments collected from, specified providers during such plan year.

''(xi) The total amount of incentive-based payments made to, and the total amount of shared losses recoupments collected from, providers of services and suppliers not described in clause (x) during such plan year.

''(xii) The allowed amount, and the amount of cost sharing imposed, with respect to each item and service furnished during such plan year by specified providers paid by such organization.

''(xiii) The allowed amount, and the amount of cost sharing imposed, with respect to each item and service furnished during such plan year by providers of services and suppliers not described in clause (xii) paid by such organization.

''(xiv) The taxpayer identification number of each provider of services and supplier that furnished an item or service during such plan year for which payment was made by such organization.

''(xv) For each MA plan offered by such organization during such plan year—

''(I) the total amount of payments made under section 1853(a)(1) to such organization for coverage of individuals under such plan, and the total amount of payments made by such individuals to such organization for coverage under such plan (including any premiums, deductibles, coinsurance, and copayments);

''(II) the total amount expended under such plan as payment for items and services furnished by each specified provider during such plan year;

''(III) the total amount expended under such plan as payment for items and services furnished by providers of services or suppliers not described in subclause (II) during such plan year;

''(IV) the medical loss ratio under such plan with respect to individuals furnished an item or service from a specified provider during such plan year; and

''(V) the medical loss ratio under such plan with respect to individuals

not described in subclause (IV) during such plan year.

In calculating average per-enrollee numbers of qualifying diagnoses and average risk scores under clauses (iii) through (viii), a plan shall not take into account qualifying diagnoses made with respect to individuals diagnosed with end-stage renal disease or risk scores for such individuals.

''(C) DEFINITIONS.—In this paragraph:

''(i) APPLICABLE MA ORGANIZATION.—The term 'applicable MA organization' means, with respect to a plan year, an MA organization with at least 25,000 individual enrolled under Medicare Advantage plans offered by such organization during such plan year.

''(ii) ASSESSMENT ENTITY.—The term 'assessment entity' means an entity with a focus on furnishing in-home health risk assessments, as specified by the Secretary.

''(iii) QUALIFYING DIAGNOSIS.—The term 'qualifying diagnosis' means, with respect to an individual, a diagnosis that is taken into account in calculating a risk score for such individual under the risk ad-

justment methodology established by the Secretary pursuant to section 1853(a)(3).

''(iv) SPECIFIED ASSESSMENT ENTITY.—The term 'specified assessment entity' means, with respect to an MA organization and a plan year, an assessment entity with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).

''(v) SPECIFIED PROVIDER.—The term 'specified provider' means, with respect to an MA organization and a plan year, a provider of services or supplier with respect to which such organization (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such organization) is a person with an ownership or control interest (as so defined).

''(D) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44,

United States Code, shall not apply to information collected under this paragraph.''.

(b) PHARMACY BENEFIT MANAGER AND PHARMACY INFORMATION.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraphs:

''(9) PROVISION OF INFORMATION RELATING TO PHARMACY OWNERSHIP.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2026, a contract entered into under this part with a PDP sponsor that is an applicable PDP sponsor (as defined in subparagraph (C)) with respect to such plan year shall require the sponsor to report to the Secretary, not later than 1 year after the last day of such plan year, the information described in subparagraph (B) with respect to such plan year.

''(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, for each prescription drug plan offered by a PDP sponsor for a plan year, the following:

''(i) The average negotiated price for each covered part D drug for which bene-

fits are available under such plan for each network pharmacy during such plan year (including an identification of whether each such pharmacy is a specified pharmacy).

''(ii) The average per-drug amount of direct and indirect remuneration paid by specified pharmacies for such covered part D drugs dispensed during such plan year under such plan.

''(iii) The average per-drug amount of direct and indirect remuneration paid by pharmacies not described in clause (ii) for such covered part D drugs dispensed during such plan year under such plan.

''(C) DEFINITIONS.—In this paragraph:

''(i) APPLICABLE PDP SPONSOR.—The term 'applicable PDP sponsor' means, with respect to a plan year, a PDP sponsor with at least 25,000 individual enrolled under prescription drug plans offered by such sponsor during such plan year.

''(ii) DIRECT AND INDIRECT REMUNERATION.—The term 'direct and indirect remuneration' has the meaning given such

term in section 423.308 of title 42, Code of Federal Regulations (or any successor regulation).

''(iii) NETWORK PHARMACY.—The term 'network pharmacy' has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (or any successor regulation).

''(iv) NEGOTIATED PRICE.—The 'negotiated price' for a covered part D drug shall take into account all negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for such drug, and include any dispensing fee for such drug.

''(v) SPECIFIED PHARMACY.—The term 'specified pharmacy' means, with respect to an PDP sponsor and a plan year, a pharmacy with respect to which such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined).

"(D) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to information collected under this paragraph.

"(10) PROVISION OF INFORMATION BY PHARMACY BENEFIT MANAGERS.—

"(A) IN GENERAL.—For plan years beginning on or after January 1, 2026, a contract entered into under this part with a PDP sponsor shall prohibit such sponsor from entering into a contract with a specified pharmacy benefit manager for purposes of performing any service with respect to covered part D drugs dispensed under any prescription drug plan offered by such sponsor for such plan year unless such manager agrees to report to the Secretary, not later than 1 year after the last day of such plan year, the information described in subparagraph (B) with respect to each prescription drug plan for which such manager is providing any such service during such plan year, regardless of the sponsor of such plan.

"(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is, with respect to

a pharmacy benefit manager performing services under a prescription drug plan for a plan year, the following:

''(i) With respect to the total amount of direct and indirect remuneration (as defined in subparagraph (C)) collected by such manager (or collected on behalf of such plan by any other entity with a contract in effect with such manager for such collection) for all covered part D drugs dispensed under such plan during such plan year—

''(I) the total amount of such remuneration passed through to the PDP sponsor of such plan; and

''(II) the total amount of such remuneration retained by such manager or such other entities.

''(ii) The total amount paid by such manager to pharmacies for drugs dispensed under such plan during such plan year.

''(iii) The total amount of payments made by such sponsor to such manager as

reimbursement for such manager's payments described in clause (ii).

''(iv) The total amount of payments made by such sponsor to such manager as fees for services furnished by such manager with respect to such plan for such plan year (not including payments described in clause (iii)).

''(v) The total amount of administrative costs incurred by such manager for furnishing such services under such plan for such plan year.

''(vi) A specification as to whether such manager is a specified pharmacy benefit manager with respect to the PDP sponsor of such plan.

''(C) DEFINITION.—In this paragraph:

''(i) DIRECT AND INDIRECT REMUNERATION.—The term 'direct and indirect remuneration' has the meaning given such term in section 423.308 of title 42, Code of Federal Regulations (or any successor regulation).

''(ii) SPECIFIED PHARMACY BENEFIT MANAGER.—the term 'specified pharmacy

benefit manager' means, with respect to an PDP sponsor and a plan year, a pharmacy benefit manager with respect to which such sponsor (or any person with an ownership or control interest (as defined in section 1124(a)(3)) in such sponsor) is a person with an ownership or control interest (as so defined).

''(D) NONAPPLICATION OF PAPERWORD REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to information collected under this paragraph.''.

(c) ENCOUNTER DATA.—Section 1859 of the Social Security Act (42 U.S.C. 1395w–28) is amended by adding at the end the following new subsection:

''(j) INCLUSION OF CERTAIN INFORMATION IN ENCOUNTER DATA.—

''(1) IN GENERAL.—In the case of any encounter data submitted by a Medicare Advantage plan with respect to an item or service furnished to an individual under such plan during a plan year beginning on or after January 1, 2026, the Secretary shall require that such data include—

''(A) the allowed amount for such item or service;

''(B) the amount of cost sharing (including deductibles, copayments, and coinsurance) imposed for such item or service;

''(C) in the case such individual was furnished, during such plan year before such item or service was so furnished, an at-home health risk assessment from a specified assessment entity, an indicator that such individual was so furnished such an assessment by such an entity; and

''(D) in the case such individual was furnished, during such plan year before such item or service was so furnished, an at-home health risk assessment from an assessment entity not described in subparagraph (C), an indicator (distinct from the indicator described in such subparagraph) that such individual was so furnished such an assessment by such an entity.

''(2) DEFINITIONS.—For purposes of this subsection, the terms 'assessment entity' and 'specified assessment entity' have the meaning given such terms in section 1857(e)(6).''.

(d) MEDPAC REPORT.—

(1) IN GENERAL.—Not later than June 15, 2029, the Medicare Payment Advisory Commission

shall submit to Congress a report describing the state of vertical integration in the health care sector with respect to entities participating in the Medicare program in 2025. Such report shall include an examination of entities such as health care providers, pharmacies, PDP sponsors, MA organizations, and pharmacy benefit managers.

(2) REPORT ON CHANGES.—Not later than June 15, 2032, and again not later than June 15, 2035, the Medicare Payment Advisory Commission shall submit to Congress a report describing the effects of any changes in the vertical integration in the health care sector on the Medicare program that occurred during the preceding 3 years, with a particular focus on such changes with respect to health care providers, pharmacies, PDP sponsors, MA organizations, and pharmacy benefit managers that were under separate ownership and that, as of the date of the submission of such report, are under common ownership.

(e) PUBLICATION.—Not later than January 1, 2027, the Secretary of Health and Human Services shall establish a process under which information submitted to the Secretary pursuant to the amendments made by subsections (a) and (b) is publicly disclosed. Such process

shall ensure that any information so disclosed does not identify a specific drug manufacturer, provider of services or supplier, pharmacy, pharmacy benefit manager, or any price charged with respect to a particular drug.

SEC. 107. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

(a) PHSA.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) in part D (42 U.S.C. 300gg–111 et seq.), by adding at the end the following new section:

"SEC. 2799A–11. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or health insurance issuer offering group health insurance coverage or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan or an issuer providing group health insurance coverage shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan or health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) as applicable, information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, issuer, or entity providing pharmacy bene-

fits management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of participants and beneficiaries who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

''(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's or health insurance issuer's business to the pharmacy benefits manager.

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under

section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller

General of the United States, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 2(d) of the Pharmacy Benefits Manager Accountability Act.

''(5) STANDARD FORMAT.—Not later than 6 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefits management services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—A health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money

penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Health and Human Services to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such issuer, plan, or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

(2) in section 2723 (42 U.S.C. 300gg–22)—

(A) in subsection (a)—

(i) in paragraph (1), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''; and

(ii) in paragraph (2), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''; and

(B) in subsection (b)—

(i) in paragraph (1), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D'';

(ii) in paragraph (2)(A), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''; and

(iii) in paragraph (2)(C)(ii), by inserting ''(other than subsections (a) and (b) of section 2799A–11)'' after ''part D''.

(b) ERISA.—

(1) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021 et seq.) is amended—

(A) in subpart B of part 7 (29 U.S.C. 1185 et seq.), by adding at the end the following:

"SEC. 726. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan or issuer shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or issuer, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or issuer, from making the reports described in subsection (b).

"(b) REPORTS.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan or an issuer providing

group health insurance coverage shall submit to the plan sponsor (as defined in section 3(16)(B)) of such group health plan or group health insurance coverage a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) as applicable, information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan or coverage;

''(B) a list of each drug covered by such plan, issuer, or entity providing pharmacy benefits management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled

during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan or health insurance coverage exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products

that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of participants and beneficiaries who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by participants and beneficiaries, including

participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan or coverage—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan or health insurance coverage on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan or health insurance coverage and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan or health insurance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

"(F) the total net spending on prescription drugs by the health plan or health insurance coverage during the reporting period; and

"(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's or health insurance issuer's business to the pharmacy benefits manager.

"(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

"(3) DISCLOSURE AND REDISCLOSURE.—

"(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as

defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such issuer or entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 2(d) of the Pharmacy Benefits Manager Accountability Act.

''(5) STANDARD FORMAT.—Not later than 6 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for health insurance issuers and entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Labor

to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such issuer, plan, or entity.

''(d) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

(B) in section 502 (29 U.S.C. 1132)—

(i) in subsection (a)—

(I) in paragraph (6), by striking ''or (9)'' and inserting ''(9), or (13)'';

(II) in paragraph (10), by striking at the end ''or'';

(III) in paragraph (11), at the end by striking the period and inserting ''; or''; and

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

''(12) by the Secretary, in consultation with the Secretary of Health and Human Services, and the Secretary of the Treasury, to enforce section 726.'';

(ii) in subsection (b)(3), by inserting ''and subsections (a)(12) and (c)(13)'' before '', the Secretary is not''; and

(iii) in subsection (c), by adding at the end the following new paragraph:

''(13) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.—

''(A) FAILURE TO PROVIDE TIMELY INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against any health insurance issuer or entity providing pharmacy benefits management services that violates section 726(a) or fails to provide information required under section 726(b) in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(B) FALSE INFORMATION.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, may impose a penalty against a health insurance issuer or entity providing pharmacy benefits management services that knowingly provides false information under section 726 in an amount not to exceed $100,000 for each item of false information. Such penalty shall be in addition to other penalties as may be prescribed by law.

''(C) WAIVERS.—The Secretary may waive penalties under subparagraph (A), or extend the period of time for compliance with a requirement of section 726, for an entity in violation of such section that has made a good-faith effort to comply with such section.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following new item:

''Sec. 726. Oversight of pharmacy benefits manager services.''.

(c) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

''SEC. 9826. OVERSIGHT OF PHARMACY BENEFITS MANAGER SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity or subsidiary providing pharmacy benefits management services on behalf of such a plan shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan,

or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan, from making the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefits management services on behalf of a group health plan shall submit to the plan sponsor (as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974) of such group health plan a report in accordance with this subsection and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan—

''(A) as applicable, information collected from drug manufacturers by such entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the participants and beneficiaries in such plan;

''(B) a list of each drug covered by such plan or entity providing pharmacy benefits

management services that was dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per pill, or in the case of a drug in another form, per dose;

''(iv) the total out-of-pocket spending by participants and beneficiaries on such drug, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for any drug for which gross spending of the group health plan exceeded $10,000 during the reporting period—

''(I) a list of all other drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class as such drug; and

''(II) the rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable;

''(C) a list of each therapeutic category or class of drugs that were dispensed under the health plan during the reporting period, and, with respect to each such therapeutic category or class of drugs, during the reporting period—

''(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

''(ii) the number of participants and beneficiaries who filled a prescription for a drug in that category or class;

''(iii) if applicable to that category or class, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that category or class;

''(iv) the total out-of-pocket spending by participants and beneficiaries, including participant and beneficiary spending through copayments, coinsurance, and deductibles; and

''(v) for each therapeutic category or class under which 3 or more drugs are included on the formulary of such plan—

''(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

''(aa) that has been paid, or is to be paid, by drug manufacturers for claims incurred during the reporting period; or

''(bb) that is related to utilization of drugs, in such therapeutic category or class;

''(II) the total net spending, after deducting rebates, price concessions, alternative discounts or other remuneration from drug manufacturers, by the health plan on that category or class of drugs; and

''(III) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply, incurred by the health plan and its participants and beneficiaries, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

''(D) total gross spending on prescription drugs by the plan during the reporting period, before rebates and other manufacturer fees or remuneration;

''(E) total amount received, or expected to be received, by the health plan in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party, other than the plan sponsor, related to utilization of drug or drug

spending under that health plan during the reporting period;

''(F) the total net spending on prescription drugs by the health plan during the reporting period; and

''(G) amounts paid directly or indirectly in rebates, fees, or any other type of remuneration to brokers, consultants, advisors, or any other individual or firm who referred the group health plan's business to the pharmacy benefits manager.

''(2) PRIVACY REQUIREMENTS.—Entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and shall restrict the use and disclosure of such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such informa-

tion only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such entity may not restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, the Comptroller General of the United States, or applicable State agencies.

''(C) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required of plan sponsors who are drug manufacturers, drug wholesalers, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

''(4) REPORT TO GAO.—An entity providing pharmacy benefits management services on behalf of

a group health plan shall submit to the Comptroller General of the United States each of the first 4 reports submitted to a plan sponsor under paragraph (1) with respect to such plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (2), the disclosure and redisclosure standards under paragraph (3), the standards specified pursuant to paragraph (5), and such other information that the Comptroller General determines necessary to carry out the study under section 2(d) of the Pharmacy Benefits Manager Accountability Act.

''(5) STANDARD FORMAT.—Not later than 6 months after the date of enactment of this section, the Secretary shall specify through rulemaking standards for entities required to submit reports under paragraph (4) to submit such reports in a standard format.

''(c) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Health and Human Services, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—An entity providing pharmacy benefits man-

agement services that violates subsection (a) or fails to provide information required under subsection (b) shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(3) FALSE INFORMATION.—An entity providing pharmacy benefits management services that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

''(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsection (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

''(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this sec-

tion, for an entity in violation of this section that has made a good-faith effort to comply with this section.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a group health plan or other entity to restrict disclosure to, or otherwise limit the access of, the Department of the Treasury to a report described in subsection (b)(1) or information related to compliance with subsection (a) by such plan or entity.

''(e) DEFINITION.—In this section, the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''.

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 9826. Oversight of pharmacy benefits manager services.''.

(d) GAO STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on—

(A) pharmacy networks of group health plans, health insurance issuers, and entities providing pharmacy benefits management services under such group health plan or group or

individual health insurance coverage, including networks that have pharmacies that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefits management services or pharmacy benefits administrative services under group health plan or group or individual health insurance coverage;

(B) as it relates to pharmacy networks that include pharmacies under common ownership described in subparagraph (A)—

(i) whether such networks are designed to encourage enrollees of a plan or coverage to use such pharmacies over other network pharmacies for specific services or drugs, and if so, the reasons the networks give for encouraging use of such pharmacies; and

(ii) whether such pharmacies are used by enrollees disproportionately more in the aggregate or for specific services or drugs compared to other network pharmacies;

(C) whether group health plans and health insurance issuers offering group or individual health insurance coverage have options to elect

different network pricing arrangements in the marketplace with entities that provide pharmacy benefits management services, the prevalence of electing such different network pricing arrangements;

(D) pharmacy network design parameters that encourage enrollees in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity; and

(E) the degree to which mail order, specialty, or retail pharmacies that dispense prescription drugs to an enrollee in a group health plan or health insurance coverage that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefits management services or pharmacy benefits administrative services under group health plan or group or individual health insurance coverage receive reimbursement that is greater than the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to enrollees in the plan or coverage by other pharmacies included in the pharmacy

network of that plan, issuer, or entity that are not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefits management services.

(2) REQUIREMENT.—The Comptroller General of the United States shall ensure that the report under paragraph (1) does not contain information that would allow a reader to identify a specific plan or entity providing pharmacy benefits management services or otherwise contain commercial or financial information that is privileged or confidential.

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

TITLE II—SUPPORTING PATIENTS, HEALTH CARE WORKERS, COMMUNITY HEALTH CENTERS, AND HOSPITALS

SEC. 201. EXTENSION FOR COMMUNITY HEALTH CENTERS, THE NATIONAL HEALTH SERVICE CORPS, AND TEACHING HEALTH CENTERS THAT OPERATE GME PROGRAMS.

(a) TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.—

(1) ADDITION TO CAPPED AMOUNTS FOR FISCAL YEARS 2024 AND 2025.—Paragraph (2) of section 340H(b) of the Public Health Service Act (42 U.S.C. 256h(b)) is amended by adding at the end the following:

''(C) ADDITION.—For each of fiscal years 2024 and 2025, the Secretary may use the amounts made available under subsection (f) for payments described in such subparagraphs (A) and (B) in addition to the total amount of funds appropriated under subsection (g).''.

(3) RECONCILIATION.—Section 340H(f) of the Public Health Service Act (42 U.S.C. 256h(f)) is amended—

(A) by striking ''The Secretary shall determine'' and inserting the following:

''(1) DETERMINATION.—The Secretary shall determine''.; and

(B) by adding at the end the following:

''(2) ANNUAL REPORT TO CONGRESS.—For each fiscal year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report specifying—

''(A) the total amount of funds recouped under paragraph (1);

''(B) the rationale for the funds being recouped; and

''(C) in the case of the reports for each of fiscal years 2024 and 2025, the total amount of funds recouped under paragraph (1) that were used pursuant to subsection (b)(2)(C) to adjust total payment amounts above the total amounts appropriated under subsection (g).''.

(4) FUNDING.—Section 340H(g) of the Public Health Service Act (42 U.S.C. 256h(g)) is amended—

(A) by amending paragraph (1) to read as follows:

''(1) IN GENERAL.—To carry out this section, there are appropriated such sums as may be necessary, not to exceed—

''(A) $230,000,000, for the period of fiscal years 2011 through 2015;

''(B) $60,000,000 for each of fiscal years 2016 and 2017;

''(C) $126,500,000 for each of fiscal years 2018 through 2023;

''(D) $175,000,000 for each of fiscal years 2024 and 2025;

''(E) $225,000,000 for each of fiscal years 2026 and 2027; and

''(F) $275,000,000 for each of fiscal years 2028 and 2029.''; and

(B) by adding at the end the following:

''(3) AVAILABILITY.—The amounts made available under paragraph (1) shall remain available until expended.''.

(b) EXTENSION FOR COMMUNITY HEALTH CENTERS.—Section 10503(b)(1)(F) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(1)(F)) is amended—

(1) by striking ''and'' before ''$4,000,000,000'' and inserting a comma; and

(2) by inserting '', and $4,200,000,000 for each of fiscal years 2024 and 2025'' before the semicolon.

(c) EXTENSION FOR THE NATIONAL HEALTH SERVICE CORPS.—Section 10503(b)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 254b–2(b)(2)) is amended—

(1) in subparagraph (G), by striking ''and'' at the end;

(2) in subparagraph (H), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(I) $350,000,000 for each of fiscal years 2024 and 2025.''.

(d) GOVERNMENT ACCOUNTABILITY OFFICE REPORT.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report assessing the effectiveness of the Na-

tional Health Service Corps at attracting health care professionals to HPSAs, including by—

(A) assessing the metrics used by the Health Resources and Services Administration in evaluating the program;

(B) comparing the retention rates of NHSC participants in the HPSAs where they completed their period of obligated service to the retention rate of non-NHSC participants in the corresponding HPSAs;

(C) comparing the retention rates of NHSC participants in the HPSAs where they completed their period of obligated service to the retention rates of NHSC participants in HPSAs other than those where they completed their period of obligated service;

(D) identifying factors that influence a NHSC participant's decision to practice in a HPSA other than the HPSA where they completed their period of obligated service;

(E) identifying factors other than participation in the National Health Service Corps Scholarship and Loan Repayment Programs that attract health care professionals to a HPSA;

(F) assessing the impact the National Health Service Corps has on wages for health care professionals in a HPSA; and

(G) comparing the distribution of NHSC participants across HPSAs, including a comparison of rural versus non-rural HPSAs.

(2) DEFINITION.—In this section:

(A) The term ''HPSA'' means a health professional shortage area designated under section 332 of the Public Health Service Act (42 U.S.C. 254e).

(B) The term ''NHSC participant'' means a National Health Service Corps member participating in the National Health Service Corps Scholarship or Loan Repayment Program.

(e) APPLICATION OF PROVISIONS.—Amounts appropriated pursuant to the amendments made by this section shall be subject to the requirements contained in Public Law 117–328 for funds for programs authorized under sections 330 through 340 of the Public Health Service Act.

(f) CONFORMING AMENDMENT.—Paragraph (4) of section 3014(h) of title 18, United States Code, is amended by striking ''and section 301(d) of division BB of the Consolidated Appropriations Act, 2021.'' and inserting

''section 301(d) of division BB of the Consolidated Appropriations Act, 2021, and section 201(e) of the PATIENT Act of 2023''.

SEC. 202. EXTENSION OF SPECIAL DIABETES PROGRAMS.

(a) EXTENSION OF SPECIAL DIABETES PROGRAMS FOR TYPE I DIABETES.—Section 330B(b)(2) of the Public Health Service Act (42 U.S.C. 254c–2(b)(2)) is amended—

(1) in subparagraph (C), by striking ''and'' at the end;

(2) in subparagraph (D), by striking the period and inserting ''; and''; and

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

''(E) $170,000,000 for each of fiscal years 2024 and 2025, to remain available until expended.''.

(b) EXTENDING FUNDING FOR SPECIAL DIABETES PROGRAMS FOR INDIANS.—Section 330C(c)(2) of the Public Health Service Act (42 U.S.C. 254c–3(c)(2)) is amended—

(1) in subparagraph (C), by striking ''and'' at the end;

(2) in subparagraph (D), by striking the period and inserting ''; and''; and

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

''(E) $170,000,000 for each of fiscal years 2024 and 2025, to remain available until expended.''.

SEC. 203. DELAYING CERTAIN DISPROPORTIONATE SHARE HOSPITAL PAYMENT REDUCTIONS UNDER THE MEDICAID PROGRAM.

Section 1923(f)(7)(A) of the Social Security Act (42 U.S.C.1396r–4(f)(7)(A)) is amended—

(1) in clause (i), in the matter preceding subclause (I), by striking ''2024'' and inserting ''2026''; and

(2) in clause (ii), by striking ''2024'' and inserting ''2026''.

SEC. 204. MEDICAID IMPROVEMENT FUND.

Section 1941(b)(3)(A) of the Social Security Act (42 U.S.C. 1396w–1(b)(3)(A)) is amended by striking ''$7,000,000,000'' and inserting ''$0''.

TITLE III—REDUCING HEALTH CARE COSTS

SEC. 301. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) 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 one 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 one 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, whether the quantity or proportion of any ingredient in such drug is greater than or less than the quantity or proportion of such ingredient in the listed drug.

''(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.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than one 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 subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance under this subsection, the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

SEC. 302. PARITY IN MEDICARE PAYMENTS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES FURNISHED OFF-CAMPUS.

(a) IN GENERAL.—Section 1833(t)(16) of the Social Security Act (42 U.S.C. 1395l(t)(16)) is amended by adding at the end the following new subparagraph:

''(H) PARITY IN FEE SCHEDULE AMOUNT FOR CERTAIN SERVICES FURNISHED BY AN OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.—

''(i) IN GENERAL.—Subject to clause (iii), in the case of specified OPD services (as defined in clause (iii)) that are furnished during 2025 or a subsequent year by an off-campus outpatient department of a provider (as defined in clause (iv)), there

shall be substituted for the amount otherwise determined under this subsection for such service and year an amount equal to the payment amount that would have been payable under the applicable payment system under this part (other than under this subsection) had such services been furnished by such a department subject to such payment system pursuant to paragraph (21)(C).

''(ii) NOT BUDGET NEUTRAL IMPLEMENTATION.—In making any budget neutrality adjustments under this subsection for 2025 or a subsequent year, the Secretary shall not take into account the reduced expenditures that result from the application of this subparagraph.

''(iii) TRANSITION.—The Secretary shall provide for a 4-year phase-in of the application of clause (i), with clause (i) being fully applicable for specified OPD services beginning with 2028.

''(iv) DEFINITIONS.—For purposes of this subparagraph:

"(I) DESIGNATED AMBULATORY PAYMENT CLASSIFICATION GROUP.—The term 'designated ambulatory payment classification group' means an ambulatory payment classification group for drug administration services.

"(II) SPECIFIED OPD SERVICES DEFINED.—The term 'specified OPD services' means covered OPD services assigned to a designated ambulatory payment classification group.

"(III) OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER DEFINED.—The term 'off-campus outpatient department of a provider' means a department of a provider (as defined in section 413.65(a)(2) of title 42, Code of Federal Regulations) that is not located—

"(aa) on the campus (as such term is defined in such section 413.65(a)(2)) of such provider; or

''(bb) within the distance (described in such definition of campus) from a remote location of a hospital facility (as defined in such section 413.65(a)(2)).''.

(b) IMPLEMENTATION.—Section 1833(t)(12) of the Social Security Act (42 U.S.C. 1395l(t)(12)) is amended—

(1) in subparagraph (D), by striking ''and'' at the end;

(2) in subparagraph (E), by striking the period at the end and inserting ''; and''; and

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

''(F) the determination of any payment amount under paragraph (16)(H), including the transition under clause (iii) of such paragraph.''.

SEC. 303. IMPROVING TRANSPARENCY AND PREVENTING THE USE OF ABUSIVE SPREAD PRICING AND RELATED PRACTICES IN MEDICAID.

(a) PHARMACY PRICE REIMBURSEMENT REQUIREMENTS.—

(1) 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 entity responsible for the administration of medical assistance consisting of covered outpatient drugs for individuals enrolled with the 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 entity, is based on pharmacy price reimbursement model under which—

"(i) any payment made by the 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 entity or PBM to the pharmacy or provider that dispenses the drug; 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 entity or the PBM, except that any payment by the entity or the PBM for the ingredient cost of such a drug furnished by a covered entity (as defined in subsection (a)(5)(B)) may exceed the acquisition cost for such drug if—

"(aa) such drug was subject to agreement under section 340B of the Public Health Service Act;

"(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 furnished by such a covered entity; and

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

"(ii) payment to the 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 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 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 entity or the PBM (as applicable) is in excess of the amount paid to the pharmacies on behalf of the entity, including any post-sale or post-invoice fees, discounts, or related adjustments such as direct and indirect remuneration fees or assessments (after allowing for an 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 'covered entity' means a managed care entity or a specified entity.

''(ii) MANAGED CARE ENTITY; SPECIFIED ENTITY.—The terms 'managed care entity' and 'specified entity' have the meaning given such terms in section 1903(m)(9)(D).''.

(2) CONFORMING AMENDMENTS.—Section 1903(m)(2)(A)(xiii) of such Act (42 U.S.C. 1396b(m)(2)(A)(xiii)) is amended—

(A) by striking ''and (III)'' and inserting ''(III)'';

(B) by inserting before the period at the end the following: ", and (IV) the pharmacy benefit provided by the entity (or pharmacy benefit manager on behalf of the entity under a contract), the other specified entity (as defined in paragraph (9)(D)), or by another arrangement between the entity and the pharmacy benefit manager, shall comply with the requirements of section 1927(e)(6)"; and

(C) by moving the left margin 2 ems to the left.

(3) EFFECTIVE DATE.—The amendments made by this subsection apply to contracts between States and pharmacy benefit managers and covered entities (as defined in section 1927(e)(6) of the Social Security Act, as added by paragraph (1) that have an effective date beginning on or after the date that is 18 months after the date of enactment of this Act.

(b) ENSURING ACCURATE PAYMENTS TO PHARMACIES UNDER MEDICAID.—

(1) IN GENERAL.—Section 1927(f) of the Social Security Act (42 U.S.C. 1396r–8(f)) is amended—

(A) 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 retail community 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 retail community pharmacies, the determination of retail survey prices of the national average drug acquisition cost for covered outpatient drugs based on a monthly survey of such pharmacies; and'';

(B) by adding at the end of paragraph (1) the following:

''(F) SURVEY REPORTING.—A State shall require that any retail community pharmacy in the State that receives any payment, reimbursement, administrative fee, discount, or rebate related to the dispensing of covered outpatient drugs to individuals receiving benefits under this title, regardless of whether such payment, reimbursement, administrative fee, discount, or

rebate is received from the State or a managed care entity directly or from a pharmacy benefit manager or other specified entity (as defined in section 1903(m)(9)(D)) that has a contract with the State or a managed care entity, shall respond to surveys of retail prices conducted under this subsection.

''(G) SURVEY INFORMATION.—Information on national drug acquisition prices obtained under this paragraph shall be made publicly available in a timely manner following the collection of such information and shall include at least the following:

''(i) The monthly response rate to the survey including a list of pharmacies not in compliance with subparagraph (F).

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

''(iii) Information on price concessions to the pharmacy, including discounts, rebates, and other price concessions, to the extent that such information is available during the survey period.

''(H) 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 managed care entities 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 speciality 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 associ-

ated with dispensing such specialty drugs; and

''(vii) recommendations as to whether specialty pharmacies should be included in the survey of retail prices to ensure national average drug acquisition costs capture drugs sold at specialty pharmacies, and how such specialty pharmacies should be defined.

''(I) ENFORCEMENT.—At the discretion of the Secretary, the Secretary may enforce noncompliance with this paragraph by a pharmacy through the establishment of penalties or the suspension of payments under this title, in full or in part, until compliance with this paragraph has been completed.''; and

(C) in paragraph (2)—

(i) in subparagraph (A), by inserting ''(including payment rates under Medicaid managed care plans)'' after ''under this title''; and

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

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on the first day of the first quarter that begins on or after the date that is 18 months after the date of enactment of this Act.

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