AMENDMENT IN THE NATURE OF A SUBSTITUTE

TO H.R. 7623

OFFERED BY M__. _____

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Telehealth Modernization Act of 2024''.

TITLE I—PRESERVING PATIENTS' ACCESS TO CARE IN THE HOME

SEC. 101. EXTENSION OF CERTAIN TELEHEALTH FLEXIBILITIES.

(a) REMOVING GEOGRAPHIC REQUIREMENTS AND EXPANDING ORIGINATING SITES FOR TELEHEALTH SERVICES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (2)(B)(iii), by striking ''ending December 31, 2024'' and inserting ''ending December 31, 2026''; and

(2) in paragraph (4)(C)(iii), by striking ''ending on December 31, 2024'' and inserting ''ending on December 31, 2026''.

(b) EXPANDING PRACTITIONERS ELIGIBLE TO FURNISH TELEHEALTH SERVICES.—Section 1834(m)(4)(E) of the Social Security Act (42 U.S.C. 1395m(m)(4)(E)) is amended by striking ''ending on December 31, 2024'' and inserting ''ending on December 31, 2026''.

(c) EXTENDING TELEHEALTH SERVICES FOR FEDERALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.—Section 1834(m)(8) of the Social Security Act (42 U.S.C. 1395m(m)(8)) is amended—

(1) in subparagraph (A), by striking ''ending on December 31, 2024'' and inserting ''ending on December 31, 2026'';

(2) in subparagraph (B)—

(A) in the subparagraph heading, by inserting ''BEFORE 2025'' after ''RULE'';

(B) in clause (i), by striking ''during the periods for which subparagraph (A) applies'' and inserting ''before January 1, 2025''; and

(C) in clause (ii), by inserting ''furnished to an eligible telehealth individual before January 1, 2025'' after ''telehealth services''; and

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

''(C) PAYMENT RULE FOR 2025 AND 2026.—

''(i) IN GENERAL.—A telehealth service furnished to an eligible telehealth individual by a Federally qualified health center or rural health clinic on or after January 1, 2025, and before January 1, 2027, shall be deemed to be so furnished to such individual as an outpatient of such center or clinic (as applicable) for purposes of paragraphs (1) and (3), respectively, of section 1861(aa), and payable as a Federally qualified health center service or rural health clinic service (as applicable) under the prospective payment system established under section 1834(o) or the payment methodology established under section 1833(a)(3), respectively.

''(ii) TREATMENT OF COSTS.—Costs associated with the delivery of telehealth services by a Federally qualified health center or rural health clinic on or after January 1, 2025, and before January 1, 2027, shall be considered allowable costs for purposes of the prospective payment system established under section 1834(o)

and any payment methodology developed under section 1833(a)(3), as applicable.

''(iii) REQUIRED REPORTING.—Notwithstanding any other provision of this paragraph, no payment may be made under this part for a telehealth service furnished to an eligible telehealth individual by a Federally qualified health center or rural health clinic during a year beginning on or after January 1, 2025, and ending before January 1, 2027, unless such center or clinic reports to the Secretary, at a time and in a manner specified by the Secretary, the number of telehealth services so furnished by such center or clinic during such year.''.

(d) DELAYING THE IN-PERSON REQUIREMENTS UNDER MEDICARE FOR MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH AND TELECOMMUNICATIONS TECHNOLOGY.—

(1) DELAY IN REQUIREMENTS FOR MENTAL HEALTH SERVICES FURNISHED THROUGH TELEHEALTH.—Section 1834(m)(7)(B)(i) of the Social Security Act (42 U.S.C. 1395m(m)(7)(B)(i)) is amended, in the matter preceding subclause (I), by

striking ''on or after'' and all that follows through ''described in section 1135(g)(1)(B))'' and inserting ''on or after January 1, 2027''.

(2) MENTAL HEALTH VISITS FURNISHED BY RURAL HEALTH CLINICS.—Section 1834(y)(2) of the Social Security Act (42 U.S.C. 1395m(y)(2)) is amended by striking ''January 1, 2025'' and all that follows through the period at the end and inserting ''January 1, 2027.''.

(3) MENTAL HEALTH VISITS FURNISHED BY FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1834(o)(4)(B) of the Social Security Act (42 U.S.C. 1395m(o)(4)(B)) is amended by striking ''January 1, 2025'' and all that follows through the period at the end and inserting ''January 1, 2027.''.

(e) ALLOWING FOR THE FURNISHING OF AUDIO-ONLY TELEHEALTH SERVICES.—Section 1834(m)(9) of the Social Security Act (42 U.S.C. 1395m(m)(9)) is amended by striking ''ending on December 31, 2024'' and inserting ''ending on December 31, 2026''.

(f) REQUIRING MODIFIERS FOR TELEHEALTH SERVICES IN CERTAIN INSTANCES.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended by adding at the end the following new paragraph:

''(10) REQUIRED USE OF MODIFIERS IN CERTAIN INSTANCES.—Not later than January 1, 2026, the Secretary shall establish requirements to include a code or modifier, as determined appropriate by the Secretary, in the case of—

''(A) claims for telehealth services under this subsection that are provided—

''(i) by a physician or practitioner that contracts with an entity that owns such virtual platform; or

''(ii) for which a physician or practitioner has a payment arrangement with an entity for use of such virtual platform; and

''(B) claims for telehealth services under this subsection that are billed incident to a physician's or practitioner's professional service.''.

(g) PROGRAM INSTRUCTION AUTHORITY.—The Secretary of Health and Human Services may implement the amendments made by this section through program instruction or otherwise.

SEC. 102. EXTENDING ACUTE HOSPITAL CARE AT HOME WAIVER FLEXIBILITIES.

Section 1866G of the Social Security Act (42 U.S.C. 1395cc–7) is amended—

(1) in subsection (a)(1), by striking ''2024'' and inserting ''2029''; and

(2) in subsection (b)—

(A) in the header, by striking ''STUDY AND REPORT'' and inserting ''STUDIES AND REPORTS'';

(B) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by striking ''The Secretary'' and inserting ''Not later than September 30, 2024, and again not later than September 30, 2028, the Secretary'';

(ii) in clause (iv), by striking ''and'' at the end;

(iii) in clause (v), by striking the period at the end and inserting ''; and''; and

(iv) by adding at the end the following new clause:

''(vi) in the case of the second study conducted under this paragraph, the quality of care, outcomes, costs, quantity and intensity of services, and other relevant metrics between individuals who entered into the Acute Hospital Care at Home initiative directly from an emergency depart-

ment compared with individuals who entered into the Acute Hospital Care at Home initiative directly from an existing inpatient stay in a hospital.''; and

(C) in paragraph (2)—

(i) in the header, by striking ''REPORT'' and inserting ''REPORTS''; and

(ii) by inserting ''and again not later than September 30, 2028,'' after ''2024,''; and

(iii) by striking ''on the study conducted under paragraph (1).'' and inserting the following: ''on—

''(A) with respect to the first report submitted under this paragraph, the first study conducted under paragraph (1); and

''(B) with respect to the second report submitted under this paragraph, the second study conducted under paragraph (1).''.

SEC. 103. ENHANCING CERTAIN PROGRAM INTEGRITY REQUIREMENTS FOR DME UNDER MEDICARE.

(a) DURABLE MEDICAL EQUIPMENT.—Section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) is amended by adding at the end the following new paragraph:

''(23) MASTER LIST INCLUSION AND CLAIM REVIEW FOR CERTAIN ITEMS.—

''(A) MASTER LIST INCLUSION.—Beginning January 1, 2027, for purposes of the Master List described in section 414.234(b) of title 42, Code of Federal Regulations (or any successor regulation), an item for which payment may be made under this subsection shall be treated as having aberrant billing patterns (as such term is used for purposes of such section) if the Secretary determines that, without explanatory contributing factors (such as furnishing emergent care services), a substantial number of claims for such items under this subsection are from an ordering physician or practitioner with whom the individual involved does not have a prior relationship, as determined on the basis of claims.

''(B) CLAIM REVIEW.—With respect to items furnished on or after January 1, 2027 that are included on the Master List pursuant to subparagraph (A), if such an item is not subject to a determination of coverage in advance pursuant to paragraph (15)(C), the Secretary

may conduct prepayment review of claims for payment for such item.''.

(b) REPORT ON IDENTIFYING CLINICAL DIAGNOSTIC LABORATORY TESTS AT HIGH RISK FOR FRAUD AND EFFECTIVE MITIGATION MEASURES.—Not later than January 1, 2026, the Inspector General of the Department of Health and Human Services shall submit to Congress a report assessing fraudulent claims for clinical diagnostic laboratory tests for which payment may be made under section 1834A of the Social Security Act (42 U.S.C. 1395m–1) and effective tools for reducing such fraudulent claims. The report shall include—

(1) which, if any, clinical diagnostic laboratory tests are identified as being at high risk of fraudulent claims, and an analysis of the factors that contribute to such risk;

(2) with respect to a clinical diagnostic laboratory test identified under paragraph (1) as being at high risk of fraudulent claims—

(A) the amount payable under such section 1834A with respect to such test;

(B) the number of such tests furnished to individuals enrolled under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.);

(C) whether an order for such a test was more likely to come from a provider with whom the individual involved did not have a prior relationship, as determined on the basis of prior payment experience; and

(D) the frequency with which a claim for payment under such section 1834A included the payment modifier identified by code 59 or 91; and

(3) suggested strategies for reducing the number of fraudulent claims made with respect to tests so identified as being at high risk, including—

(A) an analysis of whether the Centers for Medicare & Medicaid Services can detect aberrant billing patterns with respect to such tests in a timely manner;

(B) any strategies for identifying and monitoring the providers who are outliers with respect to the number of such tests that such providers order; and

(C) targeted education efforts to mitigate improper billing for such tests.

SEC. 104. GUIDANCE ON FURNISHING SERVICES VIA TELEHEALTH TO INDIVIDUALS WITH LIMITED ENGLISH PROFICIENCY.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary of Health and Human Services, in consultation with 1 or more entities from each of the categories described in paragraphs (1) through (7) of subsection (b), shall issue and disseminate, or update and revise as applicable, guidance for the entities described in such subsection on the following:

(1) Best practices on facilitating and integrating use of interpreters during a telemedicine appointment.

(2) Best practices on providing accessible instructions on how to access telecommunications systems (as such term is used for purposes of section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) for individuals with limited English proficiency.

(3) Best practices on improving access to digital patient portals for individuals with limited English proficiency.

(4) Best practices on integrating the use of video platforms that enable multi-person video calls furnished via a telecommunications system for pur-

poses of providing interpretation during a telemedicine appointment for an individual with limited English proficiency.

(5) Best practices for providing patient materials, communications, and instructions in multiple languages, including text message appointment reminders and prescription information.

(b) ENTITIES DESCRIBED.—For purposes of subsection (a), an entity described in this subsection is an entity in 1 or more of the following categories:

(1) Health information technology service providers, including—

(A) electronic medical record companies;

(B) remote patient monitoring companies; and

(C) telehealth or mobile health vendors and companies.

(2) Health care providers, including—

(A) physicians; and

(B) hospitals.

(3) Health insurers.

(4) Language service companies.

(5) Interpreter or translator professional associations.

(6) Health and language services quality certification organizations.

(7) Patient and consumer advocates, including such advocates that work with individuals with limited English proficiency.

SEC. 105. CODIFYING IN-HOME CARDIOPULMONARY REHABILITATION FLEXIBILITIES ESTABLISHED IN RESPONSE TO COVID–19.

Section 1861(eee)(2) of the Social Security Act (42 U.S.C. 1395x(eee)(2)) is amended—

(1) in subparagraph (A)(ii), by inserting ''(including, with respect to items and services furnished through audio-visual real-time communications technology on or after January 1, 2025, and before January 1, 2027, in the home of an individual who is an outpatient of the hospital)'' after ''outpatient basis''; and

(2) in subparagraph (B), by inserting ''(including, with respect to items and services furnished through audio-visual real-time communications technology on or after January 1, 2025, and before January 1, 2027, the virtual presence of such physician, physician assistant, nurse practitioner, or clinical nurse specialist)'' after ''under the program''.

SEC. 106. INCLUSION OF VIRTUAL DIABETES PREVENTION PROGRAM SUPPLIERS IN MDPP EXPANDED MODEL.

(a) IN GENERAL.—Not later than January 1, 2025, the Secretary shall revise the regulations under parts 410 and 424 of title 42, Code of Federal Regulations, to provide that, for the period beginning January 1, 2025, and ending January 1, 2030—

(1) an entity may participate in the MDPP by offering only online or virtual MDPP services via synchronous or asynchronous technology or telecommunications if such entity—

(A) has full CDC DPRP recognition at the time such entity applies to enroll as a MDPP supplier, and maintains such recognition while so enrolled; and

(B) has passed screening requirements upon initial enrollment at a ''high'' categorical risk in accordance with section 424.518(c)(2) of title 42, Code of Federal Regulations (or any successor regulations);

(2) if an entity participates in the MDPP in the manner described in paragraph (1)—

(A) the administrative location of such entity shall be the address of the entity on file

under the Diabetes Prevention Recognition Program; and

(B) in the case of virtual or online MDPP services furnished by such entity to an MDPP beneficiary who was not located in the same State as the entity at the time such services were furnished, the entity shall not be prohibited from submitting a claim for payment for such services solely by reason of the location of such beneficiary at such time; and

(3) no limit is applied on the number of times an individual may enroll in the MDPP.

(b) DEFINITIONS.—In this section:

(1) CDC.—The term ''CDC'' means the Centers for Disease Control and Prevention.

(2) MDPP.—The term ''MDPP'' means the Medicare Diabetes Prevention Program conducted under section 1115A of the Social Security Act (42 U.S.C. 1315a), as described in the final rule published in the Federal Register entitled ''Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Pro-

vider and Supplier Enrollment Policies; and Basic Health Program'' (88 Fed. Reg. 78818 (November 16, 2023)).

(3) REGULATORY TERMS.—The terms ''Diabetes Prevention Recognition Program'', ''full CDC DPRP recognition'', ''MDPP beneficiary'', ''MDPP services'', and ''MDPP supplier'' have the meanings given each such term in section 410.79(b) of title 42, Code of Federal Regulations.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 107. MEDICATION-INDUCED MOVEMENT DISORDER OUTREACH AND EDUCATION.

Not later than June 30, 2025, the Secretary shall use existing communications mechanisms to provide education and outreach to physicians and appropriate non-physician practitioners participating under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) with respect to periodic screening for medication-induced movement disorders that are associated with the treatment of mental health disorders in at-risk patients and best practices to perform screenings in a telehealth setting. Such outreach shall reference the importance of periodic screening for medication-induced movement disorders in people taking antipsychotic medication,

best practices for screening for medication-induced movement disorders via telehealth, and clarification regarding how to account for screening in evaluation and management code selection. The Secretary shall seek input from relevant stakeholders to inform the educational material. The Secretary shall conduct the same education and outreach for best practices for other screenings in a telehealth setting as determined appropriate by the Secretary.

TITLE II—OFFSETS

SEC. 201. REVISING PHASE-IN OF MEDICARE CLINICAL LABORATORY TEST PAYMENT CHANGES.

(a) REVISED PHASE-IN OF REDUCTIONS FROM PRIVATE PAYOR RATE IMPLEMENTATION.—Section 1834A(b)(3) of the Social Security Act (42 U.S.C. 1395m–1(b)(3)) is amended—

(1) in subparagraph (A), by striking ''2027'' and inserting ''2028''; and

(2) in subparagraph (B)—

(A) in clause (ii), by striking ''2024'' and inserting ''2025''; and

(B) in clause (iii), by striking ''2025 through 2027'' and inserting ''2026 through 2028''.

(b) REVISED REPORTING PERIOD FOR REPORTING OF PRIVATE SECTOR PAYMENT RATES FOR ESTABLISH-

MENT OF MEDICARE PAYMENT RATES.—Section 1834A(a)(1)(B) of the Social Security Act (42 U.S.C. 1395m–1(a)(1)(B)) is amended—

(1) in clause (i), by striking ''2024'' and inserting ''2025''; and

(2) in clause (ii), by striking ''2025'' each place it appears and inserting ''2026''.

(c) IMPLEMENTATION.—The Secretary of Health and Human Services may implement the amendments made by this section by program instruction or otherwise.

SEC. 202. ARRANGEMENTS WITH PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) PRESCRIPTION DRUG PLANS.—Section 1860D–12 of the Social Security Act (42 U.S.C. 1395w–112) is amended by adding at the end the following new subsection:

''(h) REQUIREMENTS ON PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2027:

''(1) AGREEMENTS WITH PHARMACY BENEFIT MANAGERS.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that any pharmacy benefit manager acting

on behalf of such sponsor has a written agreement with the PDP sponsor under which the pharmacy benefit manager agrees to meet the following requirements:

''(A) TRANSPARENCY REGARDING GUARANTEES AND COST PERFORMANCE EVALUATIONS.—The pharmacy benefit manager shall—

''(i) define, interpret, and apply, in a fully transparent and consistent manner for purposes of calculating or otherwise evaluating pharmacy benefit manager performance against pricing guarantees or similar cost performance measurements related to rebates, discounts, price concessions, or net costs, terms such as—

''(I) 'generic drug', in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation;

''(II) 'brand name drug', in a manner consistent with the definition of the term under section 423.4 of title 42, Code of Federal Regulations, or a successor regulation;

"(III) 'specialty drug';

"(IV) 'rebate'; and

"(V) 'discount';

"(ii) identify any drugs, claims, or price concessions excluded from any pricing guarantee or other cost performance calculation or evaluation in a clear and consistent manner; and

"(iii) where a pricing guarantee or other cost performance measure is based on a pricing benchmark other than the wholesale acquisition cost (as defined in section 1847A(c)(6)(B)) of a drug, calculate and provide a wholesale acquisition cost-based equivalent to the pricing guarantee or other cost performance measure in the written agreement.

"(B) PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Not later than July 1 of each year, beginning in 2027, the pharmacy benefit manager shall submit to the PDP sponsor, and to the Secretary, a report, in accordance with this subparagraph, and shall make such report available to such sponsor at no cost to such

sponsor in a format specified by the Secretary under paragraph (4). Each such report shall include, with respect to such PDP sponsor and each plan offered by such sponsor, the following information with respect to the previous plan year:

''(I) A list of all drugs covered by the plan that were dispensed including, with respect to each such drug—

''(aa) the brand name, generic or non-proprietary name, and National Drug Code;

''(bb) the number of plan enrollees for whom the drug was dispensed, the total number of prescription claims for the drug (including original prescriptions and refills, counted as separate claims), and the total number of dosage units of the drug dispensed;

''(cc) the number of prescription claims described in item (bb) by each type of dispensing channel through which the drug

was dispensed, including retail, mail order, specialty pharmacy, long term care pharmacy, home infusion pharmacy, or other types of pharmacies or providers;

''(dd) the average wholesale acquisition cost, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

''(ee) the average wholesale price for the drug, listed as cost per day's supply, cost per dosage unit, and cost per typical course of treatment (as applicable);

''(ff) the total out-of-pocket spending by plan enrollees on such drug after application of any benefits under the plan, including plan enrollee spending through copayments, coinsurance, and deductibles;

''(gg) total rebates paid by the manufacturer on the drug as reported under the Detailed DIR

Report (or any successor report) submitted by such sponsor to the Centers for Medicare & Medicaid Services;

''(hh) all other direct or indirect remuneration on the drug as reported under the Detailed DIR Report (or any successor report) submitted by such sponsor to the Centers for Medicare & Medicaid Services;

''(ii) the average pharmacy reimbursement amount paid by the plan for the drug in the aggregate and disaggregated by dispensing channel identified in item (cc);

''(jj) the average National Average Drug Acquisition Cost (NADAC) for retail community pharmacies; and

''(kk) total manufacturer-derived revenue, inclusive of bona fide service fees, retained by the pharmacy benefit manager and

any affiliate of such pharmacy benefit manager attributable to the drug.

''(II) In the case of a pharmacy benefit manager that has an affiliate that is a retail, mail order, or specialty pharmacy, with respect to drugs covered by such plan that were dispensed, the following information:

''(aa) The percentage of total prescriptions that were dispensed by pharmacies that are an affiliate of the pharmacy benefit manager for each drug.

''(bb) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are not an affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

''(cc) The interquartile range of the total combined costs paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply for each drug dispensed by pharmacies that are an affiliate of the pharmacy benefit manager and that are included in the pharmacy network of such plan.

''(dd) The lowest total combined cost paid by the plan and plan enrollees, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for each drug that is available from any pharmacy included in the pharmacy network of such plan.

''(ee) The difference between the average acquisition cost of the affiliate, such as a pharmacy or other entity that acquires prescription drugs, that initially ac-

quires the drug and the amount reported under subclause (I)(jj) for each drug.

''(ff) A list of covered part D drugs subject to an agreement with a covered entity under section 340B of the Public Health Service Act for which the pharmacy benefit manager or an affiliate of the pharmacy benefit manager had a contract or other arrangement with such a covered entity in the service area of such plan.

''(III) Where a drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (referred to in this subclause as the 'listed drug') is covered by the plan, the following information:

''(aa) A list of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an application

that references such listed drug that are not covered by the plan, are covered on the same formulary tier or a formulary tier typically associated with higher cost-sharing than the listed drug, or are subject to utilization management that the listed drug is not subject to.

''(bb) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the listed drug.

''(cc) Where a generic drug listed under item (aa) is on a formulary tier typically associated with higher cost-sharing than the listed drug, the estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the generic drugs described in item (aa), had the plan provided coverage for such drugs on the same formulary tier as the listed drug.

''(dd) A written justification for providing more favorable coverage of the listed drug than the generic drugs described in item (aa).

''(ee) The number of currently marketed generic drugs approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act pursuant to an application that references such listed drug.

''(IV) Where a reference product (as defined in section 351(i) of the Public Health Service Act) is covered by the plan, the following information:

''(aa) A list of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health Service Act pursuant to an application that refers to such reference product that are not covered by the plan, are covered on the same formulary tier or a for-

mulary tier typically associated with higher cost-sharing than the reference product, or are subject to utilization management that the reference product is not subject to.

''(bb) The estimated average beneficiary cost-sharing under the plan for a 30-day supply of the reference product.

''(cc) Where a biosimilar biological product listed under item (aa) is on a formulary tier typically associated with higher cost-sharing than the listed drug, the estimated average cost-sharing that a beneficiary would have paid for a 30-day supply of each of the biosimilar biological products described in item (aa), had the plan provided coverage for such products on the same formulary tier as the reference product.

''(dd) A written justification for providing more favorable coverage of the reference product than the biosimilar biological product described in item (aa).

''(ee) The number of currently marketed biosimilar biological products licensed under section 351(k) of the Public Health Service Act, pursuant to an application that refers to such reference product.

''(V) Total gross spending on covered part D drugs by the plan, not net of rebates, fees, discounts, or other direct or indirect remuneration.

''(VI) The total amount retained by the pharmacy benefit manager or an affiliate of such pharmacy benefit manager in revenue related to utilization of prescription drugs under that plan, inclusive of bona fide service fees.

''(VII) The total spending on covered part D drugs net of rebates, fees,

discounts, or other direct and indirect remuneration by the plan.

''(VIII) An explanation of any benefit design parameters under such plan that encourage plan enrollees to fill prescriptions at pharmacies that are an affiliate of such pharmacy benefit manager, such as mail and specialty home delivery programs, and retail and mail auto-refill programs.

''(IX) A list of all brokers, consultants, advisors, and auditors that receive compensation from the pharmacy benefit manager or an affiliate of such pharmacy benefit manager for referrals, consulting, auditing, or other services offered to PDP sponsors related to pharmacy benefit management services.

''(X) A list of all affiliates of the pharmacy benefit manager.

''(XI) A summary document submitted in a standardized template developed by the Secretary that includes

such information described in subclauses (I) through (X).

''(ii) WRITTEN EXPLANATION OF CONTRACTS OR AGREEMENTS WITH DRUG MANUFACTURERS.—

''(I) IN GENERAL.—The pharmacy benefit manager shall, not later than 30 days after the finalization of any contract or agreement between such pharmacy benefit manager or an affiliate of such pharmacy benefit manager and a drug manufacturer (or subsidiary, agent, or entity affiliated with such drug manufacturer) that makes rebates, discounts, payments, or other financial incentives related to one or more prescription drugs of the manufacturer directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other prescription drugs, submit to the PDP sponsor a written explanation of such contract or agreement.

"(II) REQUIREMENTS.—A written explanation under subclause (I) shall—

"(aa) include the manufacturer subject to the contract or agreement, all prescription drugs subject to the contract or agreement and the manufacturers of such drugs, and a high-level description of the terms of such contract or agreement and how such terms apply to such drugs; and

"(bb) be certified by the Chief Executive Officer, Chief Financial Officer, or General Counsel of such pharmacy benefit manager, affiliate of such pharmacy benefit manager, or an individual delegated with the authority to sign on behalf of one of these officers, who reports directly to the officer.

"(C) NO INCOME OTHER THAN BONA FIDE SERVICE FEES.—

''(i) IN GENERAL.—The pharmacy benefit manager and any affiliate of such pharmacy benefit manager shall not derive any remuneration with respect to any services provided in connection with the utilization of covered part D drugs from any entity or individual other than bona fide service fees, subject to clauses (ii) and (iii).

''(ii) INCENTIVE PAYMENTS.—For the purposes of this subparagraph, an incentive payment paid by a PDP sponsor to a pharmacy benefit manager that is performing services on behalf of such sponsor shall be deemed a 'bona fide service fee' if such payment is a flat dollar amount, is consistent with fair market value, and is related to services actually performed by the pharmacy benefit manager or affiliate of such pharmacy benefit manager in connection with the utilization of covered part D drugs.

''(iii) CLARIFICATION ON REBATES AND DISCOUNTS USED TO LOWER COSTS FOR COVERED PART D DRUGS.—Rebates, discounts, and other price concessions re-

ceived from manufacturers, even if such price concessions are calculated as a percentage of a drug's price, shall not be considered a violation of the requirements of clause (i) if they are fully passed through to a PDP sponsor and exclusively used to lower costs for prescription drugs under this part, including in cases where a PDP sponsor is acting as a pharmacy benefit manager on behalf of a prescription drug plan offered by such PDP sponsor.

''(iv) EVALUATION OF REMUNERATION ARRANGEMENTS.—Remuneration arrangements between pharmacy benefit managers or affiliates of such pharmacy benefit managers, as applicable, and other entities involved in the dispensing or utilization of covered part D drugs (including PDP sponsors, manufacturers, pharmacies, and other entities as determined appropriate by the Secretary) shall be subject to review by the Secretary and the Office of the Inspector General of the Department of Health and Human Services. The Secretary, in consultation with the Office of the Inspec-

tor General, shall evaluate whether remuneration under such arrangements is consistent with fair market value through reviews and assessments of such remuneration, as determined appropriate.

''(D) AUDIT RIGHTS.—

''(i) IN GENERAL.—Not less than once a year, at the request of the PDP sponsor, the pharmacy benefit manager shall allow for an audit of the pharmacy benefit manager to ensure compliance with all terms and conditions under the written agreement and the accuracy of information reported under subparagraph (B).

''(ii) AUDITOR.—The PDP sponsor shall have the right to select an auditor. The pharmacy benefit manager shall not impose any limitations on the selection of such auditor.

''(iii) PROVISION OF INFORMATION.—The pharmacy benefit manager shall make available to such auditor all records, data, contracts, and other information necessary to confirm the accuracy of information provided under subparagraph (B), subject

to reasonable restrictions on how such information must be reported to prevent redisclosure of such information.

''(iv) TIMING.—The pharmacy benefit manager must provide information under clause (iii) and other information, data, and records relevant to the audit to such auditor within 6 months of the initiation of the audit and respond to requests for additional information from such auditor within 30 days after the request for additional information.

''(v) INFORMATION FROM AFFILIATES.—The pharmacy benefit manager shall be responsible for providing to such auditor information required to be reported under subparagraph (B) that is owned or held by an affiliate of such pharmacy benefit manager.

''(E) ENFORCEMENT.—The pharmacy benefit manager shall—

''(i) disgorge to a PDP sponsor (or, in a case where the PDP sponsor is an affiliate of such pharmacy benefit manager, to the Secretary) any payment, remuneration,

or other amount received by the pharmacy benefit manager or an affiliate of such pharmacy benefit manager in violation of subparagraph (A), subparagraph (C), or the written agreement entered into with such sponsor under this part with respect to a prescription drug plan;

''(ii) reimburse the PDP sponsor for any civil money penalty imposed on the PDP sponsor as a result of the failure of the pharmacy benefit manager to meet the requirements of this paragraph that are applicable to the pharmacy benefit manager under the agreement; and

''(iii) be subject to punitive remedies for breach of contract for failure to comply with the requirements applicable under this paragraph.

''(2) CERTIFICATION OF COMPLIANCE.—Each PDP sponsor shall furnish to the Secretary (in a time and manner specified by the Secretary) an annual certification of compliance with this subsection, as well as such information as the Secretary determines necessary to carry out this subsection.

''(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as prohibiting payments related to reimbursement for ingredient costs to any entity that acquires prescription drugs, such as a pharmacy or wholesaler.

''(4) STANDARD FORMATS.—Not later than June 1, 2026, the Secretary shall specify standard, machine-readable formats for pharmacy benefit managers to submit annual reports required under paragraph (1)(B)(i).

''(5) CONFIDENTIALITY.—

''(A) IN GENERAL.—Information disclosed by a pharmacy benefit manager or PDP sponsor under this subsection that is not otherwise publicly available or available for purchase shall not be disclosed by the Secretary or a PDP sponsor receiving the information, except that the Secretary may disclose the information for the following purposes:

''(i) As the Secretary determines necessary to carry out this part.

''(ii) To permit the Comptroller General to review the information provided.

''(iii) To permit the Director of the Congressional Budget Office to review the information provided.

''(iv) To permit the Executive Director of the Medicare Payment Advisory Commission to review the information provided.

''(v) To the Attorney General for the purposes of conducting oversight and enforcement under this title.

''(vi) To the Inspector General of the Department of Health and Human Services in accordance with its authorities under the Inspector General Act of 1978 (section 406 of title 5, United States Code), and other applicable statutes.

''(B) RESTRICTION ON USE OF INFORMATION.—The Secretary, the Comptroller General, the Director of the Congressional Budget Office, and the Executive Director of the Medicare Payment Advisory Commission shall not report on or disclose information disclosed pursuant to subparagraph (B) to the public in a manner that would identify a specific pharmacy benefit manager, affiliate, manufacturer or wholesaler,

PDP sponsor, or plan, or contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties.

''(6) DEFINITIONS.—For purposes of this subsection:

''(A) AFFILIATE.—The term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership structure with a pharmacy benefit manager or PDP sponsor, or that acts as a contractor or agent to such pharmacy benefit manager or PDP sponsor, insofar as such contractor or agent performs any of the functions described under subparagraph (C).

''(B) BONA FIDE SERVICE FEE.—The term 'bona fide service fee' means a fee that is reflective of the fair market value for a bona fide, itemized service actually performed on behalf of an entity, that the entity would otherwise perform (or contract for) in the absence of the service arrangement and that are not passed on in whole or in part to a client or customer, whether or not the entity takes title to the drug. Such fee must be a flat dollar amount

and shall not be directly or indirectly based on, or contingent upon—

''(i) drug price, such as wholesale acquisition cost or drug benchmark price (such as average wholesale price);

''(ii) discounts, rebates, fees, or other direct or indirect remuneration amounts with respect to covered part D drugs dispensed to enrollees in a prescription drug plan, except as permitted pursuant to paragraph (1)(C)(ii);

''(iii) coverage or formulary placement decisions or the volume or value of any referrals or business generated between the parties to the arrangement; or

''(iv) any other amounts or methodologies prohibited by the Secretary.

''(C) PHARMACY BENEFIT MANAGER.—The term 'pharmacy benefit manager' means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a PDP sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan, including the processing and pay-

ment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered part D drugs, or the provision of related services. Such term includes any person or entity that carries out one or more of the activities described in the preceding sentence, irrespective of whether such person or entity calls itself a 'pharmacy benefit manager'.''.

(b) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

''(F) REQUIREMENTS RELATING TO PHARMACY BENEFIT MANAGERS.—For plan years beginning on or after January 1, 2027, section 1860D–12(h).''.

(c) GAO STUDY AND REPORT ON CERTAIN REPORTING REQUIREMENTS.—

(1) STUDY.—The Comptroller General of the United States (in this subsection referred to as the ''Comptroller General'') shall conduct a study on Federal and State reporting requirements for health

plans and pharmacy benefit managers related to the transparency of prescription drug costs and prices. Such study shall include an analysis of the following:

(A) Federal statutory and regulatory reporting requirements for health plans and pharmacy benefit managers related to prescription drug costs and prices.

(B) Selected States' statutory and regulatory reporting requirements for health plans and pharmacy benefit managers related to prescription drug costs and prices.

(C) The extent to which the statutory and regulatory reporting requirements identified in subparagraphs (A) and (B) overlap and conflict.

(D) The resources required by health plans and pharmacy benefit managers to comply with the reporting requirements described in subparagraphs (A) and (B).

(E) Other items determined appropriate by the Comptroller General.

(2) REPORT.—Not later than 2 years after the date on which information is first required to be reported under section 1860D–12(h)(1)(B) of the Social Security Act, as added by subsection (a), the

Comptroller General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for legislation and administrative actions that would streamline and reduce the burden associated with the reporting requirements for health plans and pharmacy benefit managers described in paragraph (1).

(d) MEDPAC REPORTS ON AGREEMENTS WITH PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Medicare Payment Advisory Commission shall submit to Congress the following reports:

(1) Not later than March 31, 2027, a report regarding agreements with pharmacy benefit managers with respect to prescription drug plans and MA–PD plans. Such report shall include—

(A) a description of trends and patterns, including relevant averages, totals, and other figures for each of the types of information submitted;

(B) an analysis of any differences in agreements and their effects on plan enrollee out-of-pocket spending and average pharmacy reimbursement, and any other impacts; and

(C) any recommendations the Commission determines appropriate.

(2) Not later than March 31, 2029, a report describing any changes with respect to the information described in paragraph (1) over time, together with any recommendations the Commission determines appropriate.

(e) FUNDING.—There are appropriated, out of any monies in the Treasury not otherwise obligated, $55,000,000 for fiscal year 2026, to remain available until expended, to the Secretary of Health and Human Services for purposes of carrying out the amendments made by subsections (a) and (b).

SEC. 203. ENHANCING PBM TRANSPARENCY REQUIREMENTS.

(a) IN GENERAL.—Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) by striking subsection (a) and inserting the following:

''(a) PROVISION OF INFORMATION.—

''(1) IN GENERAL.—The following entities shall provide the information described in subsection (b) to the Secretary and, in the case of an entity described in subparagraph (B) or an affiliate of such entity described in subparagraph (C), to the health

benefits plan with which the entity is under contract, at such times, and in such form and manner, as the Secretary shall specify:

"(A) A health benefits plan.

"(B) Any entity that provides pharmacy benefits management services on behalf of a health benefits plan (in this section referred to as a 'PBM') that manages prescription drug coverage under a contract with—

"(i) a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII; or

"(ii) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act.

"(C) Any affiliate of an entity described in subparagraph (B) that acts as a price negotiator or group purchaser on behalf of such PBM, PDP sponsor, MA organization, or qualified health benefits plan.

"(2) AFFILIATE DEFINED.—In this section, the term 'affiliate' means any entity that is owned by, controlled by, or related under a common ownership

structure with a PBM (including an entity owned or controlled by the PDP sponsor of a prescription drug plan, MA organization offering an MA–PD plan, or qualified health benefits plan for which such entity is acting as a price negotiator or group purchaser).'';

(2) in subsection (b)—

(A) in paragraph (2), by inserting ''and percentage'' after ''and the aggregate amount''; and

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

''(4) The amount (in the aggregate and disaggregated by type) of all fees the PBM or an affiliate of the PBM receives from all pharmaceutical manufacturers in connection with patient utilization under the plan, and the amount and percentage (in the aggregate and disaggregated by type) of such fees that are passed through to the plan sponsor or issuer.''; and

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

''(e) ANNUAL REPORT.—The Secretary shall make publicly available on the Internet website of the Centers for Medicare & Medicaid Services an annual report that

summarizes the trends observed with respect to data reported under subsection (b).''.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to plan or contract years beginning on or after January 1, 2027.

(c) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the amendments made by this section by program instruction or otherwise.

(d) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the implementation of the amendments made by this section.

SEC. 204. REQUIRING A SEPARATE IDENTIFICATION NUMBER AND AN ATTESTATION FOR EACH OFF-CAMPUS OUTPATIENT DEPARTMENT OF A PROVIDER.

(a) IN GENERAL.—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 appli-

cable 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).''.

(b) HHS OIG ANALYSIS.—Not later than January 1, 2030, the Inspector General of the Department of Health and Human Services shall submit to Congress—

(1) an analysis of the process established by the Secretary of Health and Human Services to conduct the reviews and determinations described in section 1833(t)(23)(B) of the Social Security Act, as added by subsection (a) of this section; and

(2) recommendations based on such analysis, as the Inspector General determines appropriate.

(c) MEDICAID IMPROVEMENT FUND.—Section 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w–1(b)(1)) is amended by striking ''$0'' and inserting ''$2,203,000,000''.

SEC. 205. MEDICARE COVERAGE OF EXTERNAL INFUSION PUMPS AND NON-SELF-ADMINISTRABLE HOME INFUSION DRUGS.

Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following new sentence: ''Beginning with the first calendar quarter beginning on or after the date that is one year after the date of the enactment of the 'Joe Fiandra Access to Home Infusion Act of 2023', an external infusion pump and associated home infusion drug (as defined in subsection (iii)(3)(C)) or other associated supplies that do not meet the appropriate for use in the home requirement applied to the definition of durable medical equipment under section 414.202 of title 42, Code of Federal Regulations (or

any successor to such regulation) shall be treated as meeting such requirement if each of the following criteria is satisfied:

''(1) The prescribing information approved by the Food and Drug Administration for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

''(2) A qualified home infusion therapy supplier (as defined in subsection (iii)(3)(D)) administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home (as defined in subsection (iii)(3)(B)).

''(3) The prescribing information described in paragraph (1) instructs that the drug should be infused at least 12 times per year—

''(A) intravenously or subcutaneously; or

''(B) at infusion rates that the Secretary determines would require the use of an external infusion pump.''.