Union Calendar No. 786

118TH CONGRESS
2D SESSION

H. R. 8261

[Report No. 118–891, Part I]

To amend title XVIII of the Social Security Act to extend certain flexibilities and payment adjustments under the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 7, 2024

Mr. SCHWEIKERT (for himself and Mr. THOMPSON of California) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

DECEMBER 17, 2024

Reported from the Committee on Ways and Means with an amendment

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

DECEMBER 17, 2024

Referral to the Committee on Energy and Commerce extended for a period ending not later than December 19, 2024

DECEMBER 19, 2024

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on May 7, 2024]

A BILL

To amend title XVIII of the Social Security Act to extend certain flexibilities and payment adjustments under the Medicare program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Preserving Telehealth, Hospital, and Ambulance Access Act".

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)(A) of the Social Security Act (42 U.S.C. 1395m(m)(8)(A)) is amended by striking "ending on December 31, 2024" and inserting "ending on December 31, 2026".

(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) EXTENDING USE OF TELEHEALTH TO CONDUCT FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION OF ELIGIBILITY FOR HOSPICE CARE.—Section 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)) is amended—

(1) by striking "ending on December 31, 2024" and inserting "ending on December 31, 2026"; and

(2) by inserting ", except that this subclause shall not apply in the case of such an encounter with an individual occurring on or after January 1, 2025, if such individual is located in an area that is subject to a moratorium on the enrollment of hospice programs under this title pursuant to section 1866(j)(7), if such individual is receiving hospice care from a

provider that is subject to enhanced oversight under this title pursuant to section 1866(j)(3), or if such encounter is performed by a hospice physician or nurse practitioner who is not enrolled under section 1866(j) and is not an opt-out physician or practitioner (as defined in section 1802(b)(6)(D))" before the semicolon.

(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. 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 purposes 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. 103. ESTABLISHMENT OF MODIFIER FOR RECERTIFICATIONS OF HOSPICE CARE ELIGIBILITY CONDUCTED THROUGH TELEHEALTH.

Section 1814(a)(7)(D)(i)(II) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)(II)), as amended by section 101(f), is further amended by inserting ", provided that, in the case of such an encounter occurring on or after the date that is 2 years after the date of the enactment of the 'Preserving Telehealth, Hospital, and Ambulance Access

Act', such physician or nurse practitioner includes in any claim for such encounter one or more modifiers or codes specified by the Secretary to indicate that such encounter was furnished through telehealth" after "as determined appropriate by the Secretary".

SEC. 104. 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 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 department 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. 105. REPORT ON WEARABLE MEDICAL DEVICES.

Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a technology assessment of, and submit to Congress a report on, the capabilities and limitations of wearable medical devices used to support clinical decision-making. Such report shall include a description of—

(1) the potential for such devices to accurately prescribe treatments;

(2) an examination of the benefits and challenges of artificial intelligence to augment such capabilities; and

(3) policy options to enhance the benefits and mitigate potential challenges of developing or using such devices.

SEC. 106. 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 subparagraph (A) 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.

TITLE II—SUSTAINING ACCESS TO HOSPITAL AND EMERGENCY SERVICES

SEC. 201. EXTENSION OF INCREASED INPATIENT HOSPITAL PAYMENT ADJUSTMENT FOR CERTAIN LOW-VOLUME HOSPITALS.

(a) IN GENERAL.—Section 1886(d)(12) of the Social Security Act (42 U.S.C. 1395ww(d)(12)) is amended—

(1) in subparagraph (B), by striking "during the portion of fiscal year 2025 beginning on January 1, 2025, and ending on September 30, 2025, and";

(2) in subparagraph (C)(i)—

(A) in the matter preceding subclause (I)—

(i) by striking "or portion of a fiscal year"; and

(ii) by striking "2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on December 31, 2024" and inserting "2025";

(B) in subclause (III), by striking "2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on December 31, 2024" and inserting "2025"; and

(C) in subclause (IV), by striking "the portion of fiscal year 2025 beginning on January 1,

2025, and ending on September 30, 2025, and"; and

(3) in subparagraph (D)—

(A) in the matter preceding clause (i), by striking "2024 or during the portion of fiscal year 2025 beginning on October 1, 2024, and ending on December 31, 2024" and inserting "2025"; and

(B) in clause (ii), by striking " 2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on December 31, 2024" and inserting "2025".

(b) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, including the amendments made by, this section by program instruction or otherwise.

SEC. 202. EXTENSION OF THE MEDICARE-DEPENDENT HOSPITAL PROGRAM.

(a) IN GENERAL.—Section 1886(d)(5)(G) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)) is amended—

(1) in clause (i), by striking "January 1, 2025" and inserting "October 1, 2025"; and

(2) in clause (ii)(II), by striking "January 1, 2025" and inserting "October 1, 2025".

(b) CONFORMING AMENDMENTS.—

(1) EXTENSION OF TARGET AMOUNT.—Section 1886(b)(3)(D) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(D)) is amended—

(A) in the matter preceding clause (i), by striking "January 1, 2025" and inserting "October 1, 2025"; and

(B) in clause (iv), by striking "2024 and the portion of fiscal year 2025 beginning on October 1, 2024, and ending on December 31, 2024" and inserting "2025".

(2) PERMITTING HOSPITALS TO DECLINE RECLASSIFICATION.—Section 13501(e)(2) of the Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. 1395ww note) is amended by striking "2024, or the portion of fiscal year 2025 beginning on October 1, 2024, and ending on December 31, 2024" and inserting "2025".

SEC. 203. EXTENSION OF ADD-ON PAYMENTS FOR AMBULANCE SERVICES.

(a) IN GENERAL.—Section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)) is amended—

(1) in paragraph (12)(A), by striking "January 1, 2025" and inserting "October 1, 2025"; and

(2) in paragraph (13), by striking "January 1, 2025" in each place it appears and inserting "October 1, 2025" in each such place.

(b) PROGRAM INSTRUCTION AUTHORITY.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, including amendments made by, this section through program instruction or otherwise.

TITLE III—OFFSETS

SEC. 301. 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 ESTABLISHMENT

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

(a) IN GENERAL.—

(1) 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 RELATING TO 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, and any affiliates of such pharmacy benefit manager, as applicable, agree to meet the following requirements:

"(A) 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 on behalf of any entity or individual, in connection with the utilization of covered part D drugs, from any such entity or individual other than bona fide service fees, subject to clauses (ii) and (iii).

"(ii) INCENTIVE PAYMENTS.—For the purposes of this subsection, 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'(even if such payment does not otherwise meet the definition of such term under paragraph (7)(B))

if such payment is a flat dollar amount, is consistent with fair market value (as specified by the Secretary), is related to services actually performed by the pharmacy benefit manager or affiliate of such pharmacy benefit manager, on behalf of the entity making such payment, in connection with the utilization of covered part D drugs, and meets additional requirements, if any, as determined appropriate by the Secretary.

"(iii) CLARIFICATION ON REBATES AND DISCOUNTS USED TO LOWER COSTS FOR COVERED PART D DRUGS.—Rebates, discounts, and other price concessions received by a pharmacy benefit manager or an affiliate of a pharmacy benefit manager 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 are compliant with all regulatory and subregulatory requirements related to direct and indirect remuneration for manufacturer rebates 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.—Components of subsets of remuneration arrangements (such as fees or other forms of compensation paid to or retained by the pharmacy benefit manager or affiliate of such pharmacy benefit manager), as determined appropriate by the Secretary, 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, in consultation with the Office of the Inspector General of the Department of Health and Human Services, as determined appropriate by the Secretary. The Secretary, in consultation with the Office of the Inspector General, shall review whether remuneration

under such arrangements is consistent with fair market value (as specified by the Secretary) through reviews and assessments of such remuneration, as determined appropriate.

"(v) DISGORGEMENT.—The pharmacy benefit manager shall disgorge any remuneration paid to such pharmacy benefit manager or an affiliate of such pharmacy benefit manager in violation of this subparagraph to the PDP sponsor.

"(vi) ADDITIONAL REQUIREMENTS.—The pharmacy benefit manager shall—

"(I) enter into a written agreement with any affiliate of such pharmacy benefit manager, under which the affiliate shall identify and disgorge any remuneration described in clause (v) to the pharmacy benefit manager; and

"(II) attest, subject to any requirements determined appropriate by the Secretary, that the pharmacy benefit manager has entered into a written agreement described in subclause (I)

with any relevant affiliate of the pharmacy benefit manager.

"(B) 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.

"(C) 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 (5). Each such report shall in-

clude, 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 co-payments, 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); and

"(kk) total manufacturer-derived revenue, inclusive of bona fide service fees, attributable to the drug and retained by the pharmacy benefit manager and any affiliate of such pharmacy benefit manager.

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

"(ff) A list inclusive of the brand name, generic or non-proprietary name, and National Drug Code 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 formulary 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 covered part D 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) The following information:

"(aa) 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.

"(bb) The amount of compensation provided by such pharmacy benefit manager or affiliate to each such broker, consultant, advisor, and auditor.

"(cc) The methodology for calculating the amount of compensation provided by such pharmacy benefit manager or affiliate, for each such broker, consultant, advisor, and auditor.

"(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 covered part D drugs or other prescription drugs, as applicable, of the manufacturer directly or indirectly contingent upon coverage, formulary placement, or utilization management conditions on any other covered part D drugs or other prescription drugs, as applicable, 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 covered part D drugs and other prescription drugs, as applicable, subject to the contract or agreement and the manufacturers of such drugs, and a high-level description of the terms of such contract or agree-

ment 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, or affiliate of such pharmacy benefit manager, as applicable, or an individual delegated with the authority to sign on behalf of one of these officers, who reports directly to the officer.

"(III) DEFINITION OF OTHER PRESCRIPTION DRUGS.—For purposes of this clause, the term 'other prescription drugs' means prescription drugs covered as supplemental benefits under this part or prescription drugs paid outside of this part.

"(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 (C).

"(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 (C), 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 with-

in 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 (C) that is owned or held by an affiliate of such pharmacy benefit manager.

"(2) ENFORCEMENT.—

"(A) IN GENERAL.—Each PDP sponsor shall—

"(i) disgorge to the Secretary any amounts disgorged to the PDP sponsor by a pharmacy benefit manager under paragraph (1)(A)(v);

"(ii) require, in a written agreement with any pharmacy benefit manager acting on behalf of such sponsor or affiliate of such pharmacy benefit manager, that such pharmacy benefit manager or affiliate 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 or affiliate to meet the require-

ments of paragraph (1) that are applicable to the pharmacy benefit manager or affiliate under the agreement; and

"(iii) require, in a written agreement with any such pharmacy benefit manager acting on behalf of such sponsor or affiliate of such pharmacy benefit manager, that such pharmacy benefit manager or affiliate be subject to punitive remedies for breach of contract for failure to comply with the requirements applicable under paragraph (1).

"(B) REPORTING OF ALLEGED VIOLATIONS.—The Secretary shall make available and maintain a mechanism for manufacturers, PDP sponsors, pharmacies, and other entities that have contractual relationships with pharmacy benefit managers or affiliates of such pharmacy benefit managers to report, on a confidential basis, alleged violations of paragraph (1)(A) or subparagraph (C).

"(C) ANTI-RETALIATION AND ANTI-COERCION.—Consistent with applicable Federal or State law, a PDP sponsor shall not—

"(i) retaliate against an individual or entity for reporting an alleged violation under subparagraph (B); or

"(ii) coerce, intimidate, threaten, or interfere with the ability of an individual or entity to report any such alleged violations.

"(3) CERTIFICATION OF COMPLIANCE.—

"(A) IN GENERAL.—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.

"(B) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

"(4) 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.

"(5) STANDARD FORMATS.—

"(A) IN GENERAL.—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)(C)(i).

"(B) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

"(6) CONFIDENTIALITY.—

"(A) IN GENERAL.—Information disclosed by a pharmacy benefit manager, an affiliate of a pharmacy benefit manager, a PDP sponsor, or a pharmacy 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 (A) to the public in a manner that would identify—

"(i) a specific pharmacy benefit manager, affiliate, pharmacy, manufacturer, wholesaler, PDP sponsor, or plan; or

"(ii) contract prices, rebates, discounts, or other remuneration for specific drugs in a manner that may allow the identification of specific contracting parties or of such specific drugs.

"(7) 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 (as specified by the Secretary) 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 is 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) the amount of discounts, rebates, fees, or other direct or indirect remuneration with respect to covered part D drugs dispensed to enrollees in a prescription drug plan, except as permitted pursuant to paragraph (1)(A)(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 payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, 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'.".

(2) 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).".

(3) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this subsection.

(4) FUNDING.—

(A) SECRETARY.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services Program Management Account, out of any money in the Treasury not otherwise appropriated, $113,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

(B) OIG.—In addition to amounts otherwise available, there is appropriated to the Inspector General of the Department of Health and Human Services, out of any money in the Treasury not otherwise appropriated, $20,000,000 for fiscal year 2025, to remain available until expended, to carry out this subsection.

(b) 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 Fed-

eral 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)(C) of the Social Security Act, as added by subsection (a)(1), 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).

(c) 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, 2028, 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, 2030, a report describing any changes with respect to the information described in paragraph (1) over time, together with any recommendations the Commission determines appropriate.

SEC. 303. EXTENDING THE ADJUSTMENT TO THE CALCULATION OF HOSPICE CAP AMOUNTS UNDER THE MEDICARE PROGRAM.

Section 1814(i)(2)(B) of the Social Security Act (42 U.S.C. 1395f(i)(2)(B)) is amended—

(1) in clause (ii), by striking "2033" and inserting "2034"; and

(2) in clause (iii), by striking "2033" and inserting "2034".

Union Calendar No. 786

118TH CONGRESS
2D SESSION

H. R. 8261

[Report No. 118–891, Part I]

A BILL

To amend title XVIII of the Social Security Act to extend certain flexibilities and payment adjustments under the Medicare program, and for other purposes.

DECEMBER 19, 2024

Committee on Energy and Commerce discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed