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119TH CONGRESS
1ST SESSION

H. R. 2450

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefit management services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 27, 2025

Ms. MCDONALD RIVET (for herself, Mr. CARTER of Georgia, Mr. MENENDEZ, and Mr. JAMES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Workforce, and Ways and Means, 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

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A BILL

To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1984 to increase oversight of pharmacy benefit management services, 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 ''Prescription Drug Transparency and Affordability Act''.

SEC. 2. OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT SERVICES.

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

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

"SEC. 2799A–11. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of this section (referred to in this subsection and subsection (b) as the 'effective date'), a group health plan or a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

''(1) not limit or delay the disclosure of information to the group health plan (including such a plan offered through a health insurance issuer) in such a manner that prevents an entity providing pharmacy benefit management services on behalf of

a group health plan or health insurance issuer offering group health insurance coverage from making the reports described in subsection (b); and

''(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer relevant information necessary to make the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after the effective date, in the case of any contract between a group health plan or a health insurance issuer offering group health insurance coverage offered in connection with such a plan and an entity providing pharmacy benefit management services on behalf of such plan or issuer, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan or health insurance issuer, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a

report in accordance with this section. Each such report shall be made available to such group health plan in plain language, in a machine-readable format, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan or group health insurance coverage offered by a health insurance issuer in connection with a group health plan during each reporting period—

''(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

''(I) the contracted compensation paid by the group health plan or

health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer;

''(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code);

''(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

''(IV) the proprietary name, established name or proper name, and National Drug Code;

''(V) for each claim for the drug (including original prescriptions and refills) and for each dosage unit of the

drug for which a claim was filed, the type of dispensing channel used to furnish the drug, including retail, mail order, or specialty pharmacy;

''(VI) with respect to each drug dispensed, for each type of dispensing channel (including retail, mail order, or specialty pharmacy)—

''(aa) whether such drug is a brand name drug or a generic drug, and—

''(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

"(bb) the total number of—

"(AA) prescription claims (including original prescriptions and refills);

"(BB) participants and beneficiaries for whom a claim for such drug was filed through the applicable dispensing channel;

"(CC) dosage units and dosage units per fill of such drug; and

"(DD) days supply of such drug per fill;

"(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan or coverage after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

"(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments,

coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage, or for which no claim is submitted under the plan or coverage;

''(IX) the total net spending on the drug;

''(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

''(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of such drug or spending on such drug; and

''(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

''(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class—

''(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(II) the net spending in such class after such rebates, price conces-

sions, alternative discounts, or other remuneration from applicable entities;

''(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of drugs or drug spending;

''(IV) the average net spending per 30-day supply and per 90-day supply by the plan or by the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

''(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, includ-

ing the National Drug Code for each such drug;

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

''(VII) the total out-of-pocket spending under the plan or coverage by participants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted under the plan or coverage;

''(iii) with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs,

with respect to the 50 prescription drugs with the highest spending during the reporting period—

"(I) a list of all other drugs in the same therapeutic class as such drug;

"(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year; and

"(iv) in the case that such plan or issuer (or an entity providing pharmacy benefit management services on behalf of such plan or issuer) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing

assistance incentives funded by an entity providing pharmacy benefit services—

"(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies;

"(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan or coverage; and

"(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan or coverage, and, with respect to each drug dispensed—

"(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan or issuer, and to participants and beneficiaries;

"(bb) the median amount charged to such plan or issuer,

and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan or coverage;

''(cc) the lowest cost per dosage unit, per 30-day supply and per 90-day supply, for each such drug, including amounts charged to the plan or coverage and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan or coverage; and

''(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if

such drug is subject to a maximum price discount; and

"(B) with respect to any group health plan, including group health insurance coverage offered in connection with such a plan, regardless of whether the plan or coverage is offered by a specified large employer or whether it is a specified large plan—

"(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

"(ii) a summary document for plans and issuers to provide to participants and

beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan (including in the case of group health insurance coverage offered in connection with such a plan), that—

"(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or coverage or benefits under such plan or coverage;

"(II) contains only aggregate information; and

"(III) states that participants and beneficiaries may request specific, claims-level information required to be furnished under subsection (c) from the group health plan or health insurance issuer; and

''(iii) with respect to drugs covered by such plan or coverage during such reporting period—

''(I) the total net spending by the plan or coverage for all such drugs;

''(II) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

''(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

''(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act) to bro-

kerage firms, brokers, consultants, advisors, or any other individual or firm, for—

"(I) the referral of the group health plan's or health insurance issuer's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

"(II) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

"(III) the retention of the entity by the group health plan or health insurance issuer;

"(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, re-

tail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

''(vi) total gross spending on all drugs under the plan or coverage during the reporting period.

''(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

''(4) PRIVACY REQUIREMENTS.—

''(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or a health insur-

ance issuer offering group health insurance coverage shall report information under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the 'HIPAA privacy regulations') and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section

164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(ii) RESTRICTIONS.—In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

''(C) RULE OF CONSTRUCTION.—

''(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

''(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et sec), section 504 of the Rehabilitation Act of 1973 (29

U.S.C. 794), section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116), title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

''(D) WRITTEN NOTICE.—Each plan year, group health plans, including with respect to group health insurance coverage offered in connection with a group health plan, shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan or health insurance issuer offering group health insurance coverage to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

''(E) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report

was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

''(F) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan, issuer, or entity may not—

''(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

''(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

''(G) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1)

required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

''(5) STANDARD FORMAT AND REGULATIONS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans and health insurance issuers offering group health insurance coverage, to submit reports required under paragraph (1).

''(B) ADDITIONAL REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements

under this section with the reporting requirements under section 2799A–10.

''(c) REQUIREMENT TO PROVIDE INFORMATION TO PARTICIPANTS OR BENEFICIARIES.—A group health plan, including with respect to group health insurance coverage offered in connection with a group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

''(1) the summary document described in subsection (b)(2)(B)(ii); and

''(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

''(d) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary shall enforce this section. The enforcement authority under this subsection shall apply only with respect to group health plans (including group health insurance coverage offered in connection with such a plan) to which the requirements of subparts I and II of part A and part D apply in accordance with section 2722, and with respect to entities providing pharmacy benefit management services on behalf of such plans and applicable entities providing services on behalf of such plans.

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

''(3) FALSE INFORMATION.—A health insurance issuer, an entity providing pharmacy benefit management services, or a third party administrator providing services on behalf of such issuer offered by a health insurance issuer that knowingly provides false information under this section shall be subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information. Such civil monetary penalty shall be in addition to other penalties as may be prescribed by law.

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

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

''(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), (c), or (d) by such issuer, plan, or entity.

''(f) DEFINITIONS.—In this section:

''(1) APPLICABLE ENTITY.—The term 'applicable entity' means—

"(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

"(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

"(C) such other entity as the Secretary may specify through rulemaking.

"(2) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

"(3) CONTRACTED COMPENSATION.—The term 'contracted compensation' means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or beneficiary), or another analogous compensation struc-

ture that the Secretary may specify through regulations.

''(4) GROSS SPENDING.—The term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

''(5) NET SPENDING.—The term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

''(6) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

''(7) REMUNERATION.—The term 'remuneration' has the meaning given such term by the Secretary through rulemaking, which shall be reevaluated by the Secretary every 5 years.

''(8) SPECIFIED LARGE EMPLOYER.—The term 'specified large employer' means, in connection with a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

''(9) SPECIFIED LARGE PLAN.—The term 'specified large plan' means a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) of the Employee Retirement Income Security Act of 1974 that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

''(10) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act.''; and

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

(A) in subsection (a)—

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

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

(B) in subsection (b)—

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

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

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

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

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

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

"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of this section (referred to in this subsection and subsection (b) as the 'effective date'), a group health plan or a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

''(1) not limit or delay the disclosure of information to the group health plan (including such a plan offered through a health insurance issuer) in such a manner that prevents an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage from making the reports described in subsection (b); and

''(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer relevant information necessary to make the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after the effective date, in the case of any contract between a group health plan or a health insurance issuer offering group health insurance coverage offered in connection with such a plan and an entity providing pharmacy benefit management services on behalf of such plan or issuer, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan or health insurance issuer, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a report in accordance with this section. Each such report shall be made available to such group health plan in plain language, in a machine-readable for-

mat, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan or group health insurance coverage offered by a health insurance issuer in connection with a group health plan during each reporting period—

''(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

''(I) the contracted compensation paid by the group health plan or health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing

pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer;

''(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code);

''(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

''(IV) the proprietary name, established name or proper name, and National Drug Code;

''(V) for each claim for the drug (including original prescriptions and refills) and for each dosage unit of the drug for which a claim was filed, the type of dispensing channel used to

furnish the drug, including retail, mail order, or specialty pharmacy;

''(VI) with respect to each drug dispensed, for each type of dispensing channel (including retail, mail order, or specialty pharmacy)—

''(aa) whether such drug is a brand name drug or a generic drug, and—

''(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

''(bb) the total number of—

"(AA) prescription claims (including original prescriptions and refills);

"(BB) participants and beneficiaries for whom a claim for such drug was filed through the applicable dispensing channel;

"(CC) dosage units and dosage units per fill of such drug; and

"(DD) days supply of such drug per fill;

"(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan or coverage after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

"(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments, coinsurance, and deductibles, but not

including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage, or for which no claim is submitted under the plan or coverage;

''(IX) the total net spending on the drug;

''(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

''(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of such drug or spending on such drug; and

''(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

''(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class—

''(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(II) the net spending in such class after such rebates, price conces-

sions, alternative discounts, or other remuneration from applicable entities;

''(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of drugs or drug spending;

''(IV) the average net spending per 30-day supply and per 90-day supply by the plan or by the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

''(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, includ-

ing the National Drug Code for each such drug;

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

''(VII) the total out-of-pocket spending under the plan or coverage by participants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted under the plan or coverage;

''(iii) with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs,

with respect to the 50 prescription drugs with the highest spending during the reporting period—

"(I) a list of all other drugs in the same therapeutic class as such drug;

"(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and

"(III) any change in formulary placement compared to the prior plan year; and

"(iv) in the case that such plan or issuer (or an entity providing pharmacy benefit management services on behalf of such plan or issuer) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing

assistance incentives funded by an entity providing pharmacy benefit services—

"(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies;

"(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan or coverage; and

"(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan or coverage, and, with respect to each drug dispensed—

"(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan or issuer, and to participants and beneficiaries;

"(bb) the median amount charged to such plan or issuer,

and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan or coverage;

''(cc) the lowest cost per dosage unit, per 30-day supply and per 90-day supply, for each such drug, including amounts charged to the plan or coverage and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan or coverage; and

''(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if

such drug is subject to a maximum price discount; and

"(B) with respect to any group health plan, including group health insurance coverage offered in connection with such a plan, regardless of whether the plan or coverage is offered by a specified large employer or whether it is a specified large plan—

"(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

"(ii) a summary document for plans and issuers to provide to participants and

beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan (including in the case of group health insurance coverage offered in connection with such a plan), that—

"(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or coverage or benefits under such plan or coverage;

"(II) contains only aggregate information; and

"(III) states that participants and beneficiaries may request specific, claims-level information required to be furnished under subsection (c) from the group health plan or health insurance issuer;

''(iii) with respect to drugs covered by such plan or coverage during such reporting period—

''(I) the total net spending by the plan or coverage for all such drugs;

''(II) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

''(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

''(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA)) to brokerage

firms, brokers, consultants, advisors, or any other individual or firm, for—

''(I) the referral of the group health plan's or health insurance issuer's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

''(II) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

''(III) the retention of the entity by the group health plan or health insurance issuer;

''(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, re-

tail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

''(vi) total gross spending on all drugs under the plan or coverage during the reporting period.

''(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

''(4) PRIVACY REQUIREMENTS.—

''(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or a health insur-

ance issuer offering group health insurance coverage shall report information under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17932(a)) and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the 'HIPAA privacy regulations') and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section

164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(ii) RESTRICTIONS.—In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

''(C) RULE OF CONSTRUCTION.—

''(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

''(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et sec), section 504 of the Rehabilitation Act of 1973 (29

U.S.C. 794), section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. 18116), title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

''(D) WRITTEN NOTICE.—Each plan year, group health plans, including with respect to group health insurance coverage offered in connection with a group health plan, shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan or health insurance issuer offering group health insurance coverage to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

''(E) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report

was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

''(F) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan, issuer, or entity may not—

''(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

''(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

''(G) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1)

required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

''(5) STANDARD FORMAT AND REGULATIONS.—

''(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans and health insurance issuers offering group health insurance coverage, to submit reports required under paragraph (1).

''(B) ADDITIONAL REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements

under this section with the reporting requirements under section 725.

''(c) REQUIREMENT TO PROVIDE INFORMATION TO PARTICIPANTS OR BENEFICIARIES.—A group health plan, including with respect to group health insurance coverage offered in connection with a group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

''(1) the summary document described in subsection (b)(2)(B)(ii); and

''(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), or (c) of this section or section 502(c)(13) by such issuer, plan, or entity.

''(e) DEFINITIONS.—In this section:

''(1) APPLICABLE ENTITY.—The term 'applicable entity' means—

''(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

''(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

''(C) such other entity as the Secretary may specify through rulemaking.

''(2) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

''(3) CONTRACTED COMPENSATION.—The term 'contracted compensation' means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or bene-

ficiary), or another analogous compensation structure that the Secretary may specify through regulations.

''(4) GROSS SPENDING.—The term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

''(5) NET SPENDING.—The term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

''(6) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term in section 3(16)(B).

''(7) REMUNERATION.—The term 'remuneration' has the meaning given such term by the Secretary through rulemaking, which shall be reevaluated by the Secretary every 5 years.

''(8) SPECIFIED LARGE EMPLOYER.—The term 'specified large employer' means, in connection with a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

''(9) SPECIFIED LARGE PLAN.—The term 'specified large plan' means a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

''(10) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).'';

(B) in section 502 (29 U.S.C. 1132)—

(i) in subsection (a)(6), by striking ''or (9)'' and inserting ''(9), or (13)'';

(ii) in subsection (b)(3), by striking ''under subsection (c)(9)'' and inserting ''under paragraphs (9) and (13) of subsection (c)''; and

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

''(13) SECRETARIAL ENFORCEMENT AUTHORITY RELATING TO OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT SERVICES.—

''(A) FAILURE TO PROVIDE INFORMATION.—The Secretary may impose a penalty against a plan administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, or an applicable entity (as defined in section 726(f)) that violates section 726(a); an entity providing pharmacy benefit management services on behalf of such a plan or issuer that fails to provide the information required under section 726(b); or any person who causes a group health plan to fail to provide the information

required under section 726(c), in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

''(B) FALSE INFORMATION.—The Secretary may impose a penalty against a plan administrator of a group health plan, a health insurance issuer offering group health insurance coverage, an entity providing pharmacy benefit management services, or an applicable entity (as defined in section 726(f)) that knowingly provides false information under section 726, in an amount not to exceed $100,000 for each item of false information. Such penalty shall be in addition to other penalties as may be prescribed by law.

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

(C) in section 732(a) (29 U.S.C. 1191a(a)), by striking ''section 711'' and inserting ''sections 711 and 726''.

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

''Sec. 726. Oversight of entities that provide pharmacy benefit management services.''.

(c) INTERNAL REVENUE CODE OF 1986.—

(1) IN GENERAL.—Chapter 100 of the Internal Revenue Code of 1986 is amended—

(A) by adding at the end of subchapter B the following:

''SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.

''(a) IN GENERAL.—For plan years beginning on or after the date that is 30 months after the date of enactment of this section (referred to in this subsection and subsection (b) as the 'effective date'), a group health plan, or an entity providing pharmacy benefit management services on behalf of such a plan, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

''(1) not limit or delay the disclosure of information to the group health plan in such a manner that prevents an entity providing pharmacy benefit management services on behalf of a group health plan from making the reports described in subsection (b); and

''(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan relevant information necessary to make the reports described in subsection (b).

''(b) REPORTS.—

''(1) IN GENERAL.—For plan years beginning on or after the effective date, in the case of any contract between a group health plan and an entity providing pharmacy benefit management services on behalf of such plan, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a report in accordance with this section.

Each such report shall be made available to such group health plan in plain language, in a machine-readable format, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

''(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan during each reporting period—

''(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

''(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

''(I) the contracted compensation paid by the group health plan for each covered drug (identified by the National Drug Code) to the entity providing pharmacy benefit management

services or other applicable entity on behalf of the group health plan;

''(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan, for each covered drug (identified by the National Drug Code);

''(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

''(IV) the proprietary name, established name or proper name, and National Drug Code;

''(V) for each claim for the drug (including original prescriptions and refills) and for each dosage unit of the drug for which a claim was filed, the type of dispensing channel used to furnish the drug, including retail, mail order, or specialty pharmacy;

''(VI) with respect to each drug dispensed, for each type of dispensing

channel (including retail, mail order, or specialty pharmacy)—

"(aa) whether such drug is a brand name drug or a generic drug, and—

"(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

"(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

"(bb) the total number of—

"(AA) prescription claims (including original prescriptions and refills);

"(BB) participants and beneficiaries for whom a

claim for such drug was filed through the applicable dispensing channel;

"(CC) dosage units and dosage units per fill of such drug; and

"(DD) days supply of such drug per fill;

"(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

"(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan, or for which no claim is submitted under the plan;

''(IX) the total net spending on the drug;

''(X) the total amount received, or expected to be received, by the plan from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

''(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

''(aa) for claims incurred during the reporting period; and

''(bb) that is related to utilization of such drug or spending on such drug; and

''(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manu-

facturer (or entity administering co-payment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan;

''(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan during the reporting period, and, with respect to each such therapeutic class—

''(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(II) the net spending in such class after such rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

''(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative dis-

counts, or other remuneration from such entities—

"(aa) for claims incurred during the reporting period; and

"(bb) that is related to utilization of drugs or drug spending;

"(IV) the average net spending per 30-day supply and per 90-day supply by the plan and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

"(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, including the National Drug Code for each such drug;

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

"(VII) the total out-of-pocket spending under the plan by partici-

pants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or for which no claim is submitted under the plan;

''(iii) with respect to any drug for which gross spending under the group health plan exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan exceeded $10,000 during the reporting period with respect to fewer than 50 drugs, with respect to the 50 prescription drugs with the highest spending during the reporting period—

''(I) a list of all other drugs in the same therapeutic class as such drug;

''(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Sec-

retary, in consultation with stakeholders; and

''(III) any change in formulary placement compared to the prior plan year; and

''(iv) in the case that such plan (or an entity providing pharmacy benefit management services on behalf of such plan) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing assistance incentives funded by an entity providing pharmacy benefit services—

''(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan to fill prescriptions at mail order, specialty, or retail pharmacies;

''(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan; and

"(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan, and, with respect to each drug dispensed—

"(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan, and to participants and beneficiaries;

"(bb) the median amount charged to such plan, and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan;

"(cc) the lowest cost per dosage unit, per 30-day supply

and per 90-day supply, for each such drug, including amounts charged to the plan and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan; and

"(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if such drug is subject to a maximum price discount; and

"(B) with respect to any group health plan, regardless of whether the plan is offered by a specified large employer or whether it is a specified large plan—

"(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of select-

ing pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

''(ii) a summary document for plans to provide to participants and beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan, that—

''(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or benefits under such plan;

''(II) contains only aggregate information; and

''(III) states that participants and beneficiaries may request specific,

claims-level information required to be furnished under subsection (c) from the group health plan; and

''(iii) with respect to drugs covered by such plan during such reporting period—

''(I) the total net spending by the plan for all such drugs;

''(II) the total amount received, or expected to be received, by the plan from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

''(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

''(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section

408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act (29 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to brokerage firms, brokers, consultants, advisors, or any other individual or firm, for—

"(I) the referral of the group health plan's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

"(II) consideration of the entity providing pharmacy benefit management services by the group health plan; or

"(III) the retention of the entity by the group health plan;

"(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan, including mandatory mail and specialty home delivery pro-

grams, retail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

''(vi) total gross spending on all drugs under the plan during the reporting period.

''(3) OPT-IN FOR GROUP HEALTH INSURANCE COVERAGE OFFERED BY A SPECIFIED LARGE EMPLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after the date of enactment of this section, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

''(4) PRIVACY REQUIREMENTS.—

''(A) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan shall report infor-

mation under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 13402(a) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17932(a)) and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the 'HIPAA privacy regulations') and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) IN GENERAL.—An entity providing pharmacy benefit management services on behalf of a group health plan that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

''(ii) RESTRICTIONS.—In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

''(C) RULE OF CONSTRUCTION.—

''(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

''(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et sec), section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), section 1557 of the Patient Protection and Affordable Care Act (42

U.S.C. 18116), title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

''(D) WRITTEN NOTICE.—Each plan year, group health plans shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

''(E) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

''(F) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan or entity may not—

''(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

''(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

''(G) LIMITED FORM OF REPORT.—The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

"(5) STANDARD FORMAT AND REGULATIONS.—

"(A) IN GENERAL.—Not later than 18 months after the date of enactment of this section, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans, to submit reports required under paragraph (1).

"(B) ADDITIONAL REGULATIONS.—Not later than 18 months after the date of enactment of this section, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements under this section with the reporting requirements under section 9825.

"(c) REQUIREMENT TO PROVIDE INFORMATION TO PARTICIPANTS OR BENEFICIARIES.—A group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

"(1) the summary document described in subsection (b)(2)(B)(ii); and

''(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), or (c) of this section or section 4980D(g) by such issuer, plan, or entity.

''(e) DEFINITIONS.—In this section:

''(1) APPLICABLE ENTITY.—The term 'applicable entity' means—

''(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

''(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such

a plan or issuer, or any entity described in subparagraph (A); or

''(C) such other entity as the Secretary may specify through rulemaking.

''(2) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

''(3) CONTRACTED COMPENSATION.—The term 'contracted compensation' means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or beneficiary), or another analogous compensation structure that the Secretary may specify through regulations.

''(4) GROSS SPENDING.—The term 'gross spending', with respect to prescription drug benefits under a group health plan, means the amount spent by a group health plan on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

''(5) NET SPENDING.—The term 'net spending', with respect to prescription drug benefits under a

group health plan, means the amount spent by a group health plan on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

''(6) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(B)).

''(7) REMUNERATION.—The term 'remuneration' has the meaning given such term by the Secretary, through rulemaking, which shall be reevaluated by the Secretary every 5 years.

''(8) SPECIFIED LARGE EMPLOYER.—The term 'specified large employer' means, in connection with a group health plan established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

''(9) SPECIFIED LARGE PLAN.—The term 'specified large plan' means a group health plan established or maintained by a plan sponsor described in clause (ii) or (iii) of section 3(16)(B) of the Em-

ployee Retirement Income Security Act of 1974 (29 U.S.C. 1002(16)(B)) that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

''(10) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)).'';

(2) EXCEPTION FOR CERTAIN GROUP HEALTH PLANS.—Section 9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting ''other than with respect to section 9826,'' before ''any group health plan''.

(3) ENFORCEMENT.—Section 4980D of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

''(g) APPLICATION TO REQUIREMENTS IMPOSED ON CERTAIN ENTITIES PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES.—In the case of any requirement under section 9826 that applies with respect to an entity providing pharmacy benefit management services on behalf of a group health plan, any reference in this section to such group health plan (and the reference in subsection

(e)(1) to the employer) shall be treated as including a reference to such entity.''.

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

''Sec. 9826. Oversight of entities that provide pharmacy benefit management services.''.

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