Marianette J. Miller Meeks

(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To ensure access to affordable health insurance.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on _____

A BILL

To ensure access to affordable health insurance.

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 ''Lower Health Care Premiums for All Americans Act''.

TITLE I—IMPROVING HEALTH CARE OPTIONS FOR WORKERS

SEC. 101. ASSOCIATION HEALTH PLANS.

(a) TREATMENT OF GROUP OR ASSOCIATION OF EMPLOYERS.—Section 3(5) of the Employee Retirement In-

come Security Act of 1974 (29 U.S.C. 1002(5)) is amended by inserting after ''capacity'' the following: ''(including, for the purpose of establishing or maintaining a group health plan, a group or association of employers that satisfies the requirements of section 736(a))''.

(b) RULES APPLICABLE TO GROUP HEALTH PLANS ESTABLISHED AND MAINTAINED BY A GROUP OR ASSOCIATION OF EMPLOYERS.—

(1) IN GENERAL.—Part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181, et seq.) is amended by adding at the end the following:

''SEC. 736. RULES APPLICABLE TO GROUP HEALTH PLANS ESTABLISHED AND MAINTAINED BY A GROUP OR ASSOCIATION OF EMPLOYERS.

''(a) ASSOCIATION HEALTH PLANS.—A group or association of employers may maintain a group health plan, regardless of whether the employers composing such group or association are in the same industry, trade, or profession, if such group or association satisfies the following requirements:

''(1) GROUP OR ASSOCIATION REQUIREMENTS.—The group or association of employers—

''(A) shall—

''(i) have been formed and maintained in good faith for purposes other than providing health insurance coverage through a group health plan;

''(ii) establish a governing board or another indicator of formality as described in paragraph (2); and

''(iii) have existed for at least 2 years prior to offering a group health plan to the employees of such group or association; and

''(iv) make health insurance coverage under the group health plan offered by such group or association available—

''(I) to at least 51 employees; and

''(II) to all employees of the employer members, and any dependents of such employees;

''(B) may only provide health insurance coverage through the group health plan of the group or association—

''(i) to an employee of an employer member of the group or association or a dependent of such an employee; or

''(ii) as necessary to comply with part 6;

''(C) may include a health insurance issuer as an employer member, except that the group or association may not—

''(i) be a health insurance issuer; or

''(ii) be controlled or owned by a health insurance issuer (or a subsidiary or affiliate of a health insurance issuer).

''(D) may not condition the membership of an employer in the group or association on any health status-related factor (as described in section 702(a)(1)) relating to any employee or dependent of any employee of any employer member.

''(2) ORGANIZATIONAL REQUIREMENTS.—

''(A) GOVERNING BOARD OR FORMAL ORGANIZATION OF THE GROUP OR ASSOCIATION.—

''(i) IN GENERAL.—The group or association shall have—

''(I) a formal organizational structure with a governing board and by-laws; or

''(II) another structure or indicator of formality.

"(ii) REQUIREMENT.—Both structures described in subclauses (I) and (II) of clause (i) shall comply with the requirements described in subparagraph (B).

"(B) FORMAL ORGANIZATION STRUCTURE OF GROUP OR ASSOCIATION.—

"(i) IN GENERAL.—The functions and activities of the group or association shall be controlled by the employer members in substance and in fact.

"(ii) CONTROL.—The control described in clause (i) shall be satisfied so long as at least 75 percent of the positions on the board or other formal organizational structure are held by employer members.

"(iii) ELECTIONS.—Each position of the governing board or other formal organizational structure shall be subject to scheduled elections, as determined by the group or association, and each employer-member shall be able to cast only one vote in each such election.

"(C) GROUP HEALTH PLAN REQUIREMENTS.—

''(i) CONTROL.—The group health plan shall be controlled in substance and in fact by employer members participating in the group health plan.

''(ii) ELIGIBILITY VERIFICATION.—A plan fiduciary shall verify, on a regular basis and pursuant to reasonable monitoring procedures as established by the plan fiduciary, whether an individual is a self-employed individual if such individual (or a beneficiary thereof) participates in the group health plan on the basis that such individual is a self-employed individual.

''(iii) INELIGIBLE SELF-EMPLOYED INDIVIDUALS.—

''(I) IN GENERAL.—Subject to subclause (II) and except as required under part 6, in the case that the plan fiduciary determines that an individual who participates in the group health plan no longer meets the requirements under a self-employed individual during a plan year, the group health plan shall not make health in-

surance coverage available to such individual for any plan year following the plan year in which such determination was made.

''(II) REMEDIAL ACTION.—If, after the plan fiduciary determines that an individual described in clause (i) is not a self-employed individual, the individual furnishes to the plan fiduciary evidence proving that such individual is a self-employed individual, such individual shall be eligible to participate in the group health plan.

''(3) DISCRIMINATION AND PRE-EXISTING CONDITION PROTECTIONS.—A group health plan established and maintained by the group or association of employers under this section may not—

''(A) establish any rule for eligibility (including continued eligibility) of any individual (including an employee of an employer member or a self-employed individual, or a dependent of such employee or self-employed individual) to enroll for benefits under the terms of the plan that discriminates based on any health status-related factor that relates to such individual

(consistent with the rules under section 702(a)(1));

''(B) require an individual (including an employee of an employer member or a self-employed individual, or a dependent of such employee or self-employed individual), as a condition of enrollment or continued enrollment under the plan, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual enrolled in the plan based on any health status-related factor that relates to such individual (consistent with the rules under section 702(b)(1)); and

''(C) deny coverage under such plan on the basis of a pre-existing condition (consistent with the rules under section 2704 of the Public Health Service Act).

''(b) PREMIUM RATES FOR A GROUP OR ASSOCIATION OF EMPLOYERS.—

''(1) IN GENERAL.—A group health plan established and maintained by a group or association of employers that meets that requirements of this section may, to the extent not prohibited under State law—

''(A) establish base premium rates formed on an actuarially sound, modified community rating methodology that considers the pooling of all plan participant claims; and

''(B) utilize the specific risk profile of each employer member of such group or association to determine contribution rates for each such employer member's share of a premium by actuarially adjusting the established base premium rates.

''(2) ONLY SELF EMPLOYED INDIVIDUALS.—In the case that a group or association is composed only of self-employed individuals, the group health plan established by such group or association shall—

''(A) treat all such self-employed individuals as a single risk pool;

''(B) pool all plan participant claims; and

''(C) charge each plan participant the same premium rate.

''(c) TREATMENT OF SELF-EMPLOYED INDIVIDUALS.—For purposes of this section, an individual who is a self-employed individual shall be treated as—

''(1) an employer who may be a member of a group or association of employers;

''(2) an employee who may participate in a group health plan established and maintained by such group or association; and

''(3) a participant of the group health plan in which the individual participates, subject to the eligibility determination and monitoring requirements set forth in subsection (a)(2)(C)(i).

''(d) DETERMINATION OF EMPLOYER OR JOINT EMPLOYER STATUS.—The provision of health insurance coverage by a group or association of employers may not be construed as evidence for establishing an employer or joint employer relationship under any Federal or State law.

''(e) RULES OF CONSTRUCTION.—

''(1) NO EXEMPTION FROM PHSA.—Nothing in this section shall be construed to exempt a group health plan (as defined in section 733(a)(1)) offered through a group or association of employers from the requirements of this part or from the provisions of part A of title XXVII of the Public Health Service Act as incorporated by reference into this Act through section 715.

''(2) PRIOR OR FUTURE GUIDANCE.—Nothing in this section may be construed to limit or otherwise affect the ability of a group or association of employers from establishing a single plan multiple

employer welfare arrangement as specified in any prior or future guidance issued by the Secretary of Labor that provides alternative pathways to qualifying as a group or association of employer for purposes of section 3(5).

''(f) DEFINITIONS.—In this section—

''(1) EMPLOYER MEMBER.—The term 'employer member' means—

''(A) an employer who is a member of such group or association of employers and employs at least 1 common law employee; or

''(B) a group made up solely of self-employed individuals, within which all of the self-employed individual members of such group or association are aggregated together as a single employer member group, provided that such group includes at least 20 self-employed individual members.

''(2) SELF-EMPLOYED INDIVIDUAL.—The term 'self-employed individual' means an individual who—

''(A) does not have any common law employees;

''(B) has a bona fide ownership right in a trade or business, regardless of whether such

trade or business is incorporated or unincorporated;

''(C) earns a wage (as defined in section 3121(a) of the Internal Revenue Code of 1986) or self-employment income (as defined in section 1402(b) of such Code) from such trade or business; and

''(D) works at least 10 hours a week, or 40 hours per month, providing personal services to such trade or business.''.

(2) CLERICAL AMENDMENT.—The table of contents is amended by inserting after the item relating to section 734 the following:

''735. Standardized reporting format.
''736. Rules applicable to group health plans established and maintained by a group or association of employers.''.

SEC. 102. CERTAIN MEDICAL STOP-LOSS INSURANCE OBTAINED BY CERTAIN PLAN SPONSORS OF GROUP HEALTH PLANS NOT INCLUDED UNDER THE DEFINITION OF HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Section 733(b)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(b)(1)) is amended by adding at the end the following sentence: ''Such term shall not include a stop-loss policy obtained by a self-insured group health plan or a plan sponsor of a group health plan that self-insures

the health risks of its plan participants to reimburse the plan or sponsor for losses that the plan or sponsor incurs in providing health or medical benefits to such plan participants in excess of a predetermined level set forth in the stop-loss policy obtained by such plan or sponsor.''.

(b) EFFECT ON OTHER LAWS.—Section 514(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)) is amended by adding at the end the following:

''(10) The provisions of this title (including part 7 relating to group health plans) shall preempt State laws insofar as they may now or hereafter prevent an employee benefit plan that is a group health plan from insuring against the risk of excess or unexpected health plan claims losses.''.

SEC. 103. TREATMENT OF HEALTH REIMBURSEMENT ARRANGEMENTS INTEGRATED WITH INDIVIDUAL MARKET COVERAGE.

(a) IN GENERAL.—

(1) TREATMENT.—Section 9815(b) of the Internal Revenue Code of 1986 is amended—

(A) by striking ''EXCEPTION.—Notwithstanding subsection (a)'' and inserting the following: ''EXCEPTIONS.—

''(1) SELF-INSURED GROUP HEALTH PLANS.—Notwithstanding subsection (a)'', and

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

''(2) CUSTOM HEALTH OPTION AND INDIVIDUAL CARE EXPENSE ARRANGEMENTS.—

''(A) IN GENERAL.—For purposes of this subchapter, a custom health option and individual care expense arrangement shall be treated as meeting the requirements of section 9802 and sections 2705, 2711, 2713, and 2715 of title XXVII of the Public Health Service Act.

''(B) CUSTOM HEALTH OPTION AND INDIVIDUAL CARE EXPENSE ARRANGEMENTS DEFINED.—For purposes of this section, the term 'custom health option and individual care expense arrangement' means a health reimbursement arrangement—

''(i) which is an employer-provided group health plan funded solely by employer contributions to provide payments or reimbursements for medical care subject to a maximum fixed dollar amount for a period,

''(ii) under which such payments or reimbursements may only be made for medical care provided during periods during which the individual is covered—

''(I) under individual health insurance coverage (other than coverage that consists solely of excepted benefits), or

''(II) under part A and B of title XVIII of the Social Security Act or part C of such title,

''(iii) which meets the nondiscrimination requirements of subparagraph (C),

''(iv) which meets the substantiation requirements of subparagraph (D), and

''(v) which meets the notice requirements of subparagraph (E).

''(C) NONDISCRIMINATION.—

''(i) IN GENERAL.—An arrangement meets the requirements of this subparagraph if an employer offering such arrangement to an employee within a specified class of employee—

''(I) offers such arrangement to all employees within such specified class on the same terms, and

''(II) does not offer any other group health plan (other than an account-based group health plan or a group health plan that consists solely of excepted benefits) to any employees within such specified class.

In the case of an employer who offers a group health plan provided through health insurance coverage in the small group market (that is subject to section 2701 of the Public Health Service Act) to all employees within such specified class, subclause (II) shall not apply to such group health plan.

''(ii) SPECIFIED CLASS OF EMPLOYEE.—For purposes of this subparagraph, any of the following may be designated as a specified class of employee:

''(I) Full-time employees.

''(II) Part-time employees.

''(III) Salaried employees.

''(IV) Non-salaried employees.

''(V) Employees whose primary site of employment is in the same rating area.

''(VI) Employees who are included in a unit of employees covered under a collective bargaining agreement to which the employer is subject (determined under rules similar to the rules of section 105(h)).

''(VII) Employees who have not met a group health plan, or health insurance issuer offering group health insurance coverage, waiting period requirement that satisfies section 2708 of the Public Health Service Act.

''(VIII) Seasonal employees.

''(IX) Employees who are nonresident aliens and who receive no earned income (within the meaning of section 911(d)(2)) from the employer which constitutes income from sources within the United States (within the meaning of section 861(a)(3)).

''(X) Under such rules as the Secretary may prescribe, employees

who are hired for temporary placement with an unrelated person that is not the common law employer.

''(XI) Such other classes of employees as the Secretary may designate.

An employer may designate (in such manner as is prescribed by the Secretary) two or more of the classes described in the preceding subclauses as the specified class of employees to which the arrangement is offered for purposes of applying this subparagraph.

''(iii) SPECIAL RULE FOR NEW HIRES.—An employer may designate prospectively so much of a specified class of employees as are hired after a date set by the employer. Such subclass of employees shall be treated as the specified class for purposes of applying clause (i).

''(iv) RULES FOR DETERMINING TYPE OF EMPLOYEE.—For purposes for clause (ii), any determination of full-time, part-time, or seasonal employment status shall be made under rules similar to the rules of

section 105(h) or 4980H, whichever the employer elects for the plan year. Such election shall apply with respect to all employees of the employer for the plan year.

''(v) PERMITTED VARIATION.—For purposes of clause (i)(I), an arrangement shall not fail to be treated as provided on the same terms within a specified class merely because the maximum dollar amount of payments and reimbursements which may be made under the terms of the arrangement for the year with respect to each employee within such class—

''(I) increases as additional dependents of the employee are covered under the arrangement, and

''(II) increases with respect to a participant as the age of the participant increases, but not in excess of an amount equal to 300 percent of the lowest maximum dollar amount with respect to such a participant determined without regard to age.

''(D) SUBSTANTIATION REQUIREMENTS.—An arrangement meets the requirements of this

subparagraph if the arrangement has reasonable procedures to substantiate—

''(i) that the participant and any dependents are, or will be, enrolled in coverage described in subparagraph (B)(ii) as of the beginning of the plan year of the arrangement (or as of the beginning of coverage under the arrangement in the case of an employee who first becomes eligible to participate in the arrangement after the date notice is given with respect to the plan under subparagraph (E) (determined without regard to clause (iii) thereof), and

''(ii) any requests made for payment or reimbursement of medical care under the arrangement and that the participant and any dependents remain so enrolled.

''(E) NOTICE.—

''(i) IN GENERAL.—Except as provided in clause (iii), an arrangement meets the requirements of this subparagraph if, under the arrangement, each employee eligible to participate is, not later than 60 days before the beginning of the plan year, given written notice of the employee's

rights and obligations under the arrangement which—

''(I) is sufficiently accurate and comprehensive to apprise the employee of such rights and obligations, and

''(II) is written in a manner calculated to be understood by the average employee eligible to participate.

''(ii) NOTICE REQUIREMENTS.—Such notice shall include such information as the Secretary may by regulation prescribe.

''(iii) NOTICE DEADLINE FOR CERTAIN EMPLOYEES.—In the case of an employee—

''(I) who first becomes eligible to participate in the arrangement after the date notice is given with respect to the plan under clause (i) (determined without regard to this clause), or

''(II) whose employer is first established fewer than 120 days before the beginning of the first plan year of the arrangement,

the requirements of this subparagraph shall be treated as met if the notice required under clause (i) is provided not later than the date the arrangement may take effect with respect to such employee.''.

(2) TREATMENT OF CURRENT RULES RELATING TO CERTAIN ARRANGEMENTS.—

(A) NO INFERENCE.—To the extent not inconsistent with the amendments made by this subsection—

(i) no inference shall be made from such amendments with respect to the rules prescribed in the Federal Register on June 20, 2019, (84 Fed. Reg. 28888) relating to health reimbursement arrangements and other account-based group health plans, and

(ii) any reference to custom health option and individual care expense arrangements shall for purposes of such rules be treated as including a reference to individual coverage health reimbursement arrangements.

(B) OTHER CONFORMING OF RULES.—The Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall modify such rules as may be necessary to conform to the amendments made by this subsection.

(3) PARTICIPANTS IN CHOICE ARRANGEMENT ELIGIBLE FOR PURCHASE OF EXCHANGE INSURANCE UNDER CAFETERIA PLAN.—Section 125(f)(3) of such Code is amended by adding at the end the following new subparagraph:

''(C) EXCEPTION FOR PARTICIPANTS IN CHOICE ARRANGEMENT.—Subparagraph (A) shall not apply in the case of an employee participating in a custom health option and individual care expense arrangement (within the meaning of section 9815(b)(2)) offered by the employee's employer.''.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to plan years beginning after December 31, 2025.

(b) INCLUSION OF CHOICE ARRANGEMENT PERMITTED BENEFITS ON W–2.—

(1) IN GENERAL.—Section 6051(a) of such Code is amended by striking ''and'' at the end of

paragraph (18), by striking the period at the end of paragraph (19) and inserting ", and", and by inserting after paragraph (19) the following new paragraph:

"(20) the total amount of permitted benefits for enrolled individuals under a custom health option and individual care expense arrangement (as defined in section 9815(b)(2)) with respect to such employee.".

(2) EFFECTIVE DATE.—The amendment made by this subsection shall apply to taxable years beginning after December 31, 2025.

TITLE II—LOWERING HEALTH CARE PREMIUMS FOR EVERYONE

SEC. 201. 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 be-

half 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 cov-

erage, 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, co-

payment 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 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 man-

agement 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, including the National Drug Code for each such drug;

"(VI) if applicable, a description of the formulary tiers and utilization mechanisms (such as prior authoriza-

tion 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 cov-

erage 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) of the Employee Retirement Income Security Act) 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, 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 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 insurance issuer offering group health insurance cov-

erage 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 seq.), 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 seq.), 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 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;

''(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 seq.), 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.''.

SEC. 202. FUNDING COST SHARING REDUCTION PAYMENTS.

Section 1402 of the Patient Protection and Affordable Care Act (42 U.S.C. 18071) is amended by adding at the end the following new subsection:

''(h) FUNDING.—

''(1) IN GENERAL.—There are appropriated out of any monies in the Treasury not otherwise appropriated such sums as may be necessary for purposes of making payments under this section for plan years beginning on or after January 1, 2027.

''(2) LIMITATION.—

''(A) IN GENERAL.—The amounts appropriated under paragraph (1) may not be used for purposes of making payments under this section for a qualified health plan that provides health benefit coverage that includes coverage of abortion.

''(B) EXCEPTION.—Subparagraph (A) shall not apply to payments for a qualified health plan that provides coverage of abortion only if necessary to save the life of the mother or if the pregnancy is a result of an act of rape or incest.''.