

119TH CONGRESS  
1ST SESSION

# H. R. 6703

To ensure access to affordable health insurance.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 15, 2025

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Education and Workforce, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To ensure access to affordable health insurance.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Health Care  
5 Premiums for All Americans Act”.

6 **TITLE I—IMPROVING HEALTH**  
7 **CARE OPTIONS FOR WORKERS**

8 **SEC. 101. ASSOCIATION HEALTH PLANS.**

9 (a) TREATMENT OF GROUP OR ASSOCIATION OF EM-  
10 PLOYERS.—Section 3(5) of the Employee Retirement In-

1 come Security Act of 1974 (29 U.S.C. 1002(5)) is amend-  
2 ed by inserting after “capacity” the following: “(including,  
3 for the purpose of establishing or maintaining a group  
4 health plan, a group or association of employers that satis-  
5 fies the requirements of section 736(a))”.

6 (b) RULES APPLICABLE TO GROUP HEALTH PLANS  
7 ESTABLISHED AND MAINTAINED BY A GROUP OR ASSO-  
8 CIATION OF EMPLOYERS.—

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

13 **“SEC. 736. RULES APPLICABLE TO GROUP HEALTH PLANS**  
14 **ESTABLISHED AND MAINTAINED BY A GROUP**  
15 **OR ASSOCIATION OF EMPLOYERS.**

16 “(a) ASSOCIATION HEALTH PLANS.—A group or as-  
17 sociation of employers may maintain a group health plan,  
18 regardless of whether the employers composing such group  
19 or association are in the same industry, trade, or profes-  
20 sion, if such group or association satisfies the following  
21 requirements:

22 “(1) GROUP OR ASSOCIATION REQUIRE-  
23 MENTS.—The group or association of employers—  
24 “(A) shall—

1           “(i) have been formed and maintained  
2           in good faith for purposes other than pro-  
3           viding health insurance coverage through a  
4           group health plan;

5           “(ii) establish a governing board or  
6           another indicator of formality as described  
7           in paragraph (2); and

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

12          “(iv) make health insurance coverage  
13          under the group health plan offered by  
14          such group or association available—

15                  “(I) to at least 51 employees;  
16                  and

17                  “(II) to all employees of the em-  
18                  ployer members, and any dependents  
19                  of such employees;

20          “(B) may only provide health insurance  
21          coverage through the group health plan of the  
22          group or association—

23                  “(i) to an employee of an employer  
24                  member of the group or association or a  
25                  dependent of such an employee; or

1 “(ii) as necessary to comply with part  
2 6;

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

6 “(i) be a health insurance issuer; or

7 “(ii) be controlled or owned by a  
8 health insurance issuer (or a subsidiary or  
9 affiliate of a health insurance issuer).

10 “(D) may not condition the membership of  
11 an employer in the group or association on any  
12 health status-related factor (as described in sec-  
13 tion 702(a)(1)) relating to any employee or de-  
14 pendent of any employee of any employer mem-  
15 ber.

16 “(2) ORGANIZATIONAL REQUIREMENTS.—

17 “(A) GOVERNING BOARD OR FORMAL OR-  
18 GANIZATION OF THE GROUP OR ASSOCIATION.—

19 “(i) IN GENERAL.—The group or as-  
20 sociation shall have—

21 “(I) a formal organizational  
22 structure with a governing board and  
23 by-laws; or

24 “(II) another structure or indi-  
25 cator of formality.

1           “(ii) REQUIREMENT.—Both struc-  
2           tures described in subclauses (I) and (II)  
3           of clause (i) shall comply with the require-  
4           ments described in subparagraph (B).

5           “(B) FORMAL ORGANIZATION STRUCTURE  
6           OF GROUP OR ASSOCIATION.—

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

11          “(ii) CONTROL.—The control de-  
12          scribed in clause (i) shall be satisfied so  
13          long as at least 75 percent of the positions  
14          on the board or other formal organiza-  
15          tional structure are held by employer mem-  
16          bers.

17          “(iii) ELECTIONS.—Each position of  
18          the governing board or other formal orga-  
19          nizational structure shall be subject to  
20          scheduled elections, as determined by the  
21          group or association, and each employer-  
22          member shall be able to cast only one vote  
23          in each such election.

24          “(C) GROUP HEALTH PLAN REQUIRE-  
25          MENTS.—

1           “(i) CONTROL.—The group health  
2 plan shall be controlled in substance and in  
3 fact by employer members participating in  
4 the group health plan.

5           “(ii) ELIGIBILITY VERIFICATION.—A  
6 plan fiduciary shall verify, on a regular  
7 basis and pursuant to reasonable moni-  
8 toring procedures as established by the  
9 plan fiduciary, whether an individual is a  
10 self-employed individual if such individual  
11 (or a beneficiary thereof) participates in  
12 the group health plan on the basis that  
13 such individual is a self-employed indi-  
14 vidual.

15           “(iii) INELIGIBLE SELF-EMPLOYED  
16 INDIVIDUALS.—

17           “(I) IN GENERAL.—Subject to  
18 subclause (II) and except as required  
19 under part 6, in the case that the  
20 plan fiduciary determines that an in-  
21 dividual who participates in the group  
22 health plan no longer meets the re-  
23 quirements under a self-employed in-  
24 dividual during a plan year, the group  
25 health plan shall not make health in-

1                   surance coverage available to such in-  
2                   dividual for any plan year following  
3                   the plan year in which such deter-  
4                   mination was made.

5                   “(II) REMEDIAL ACTION.—If,  
6                   after the plan fiduciary determines  
7                   that an individual described in clause  
8                   (i) is not a self-employed individual,  
9                   the individual furnishes to the plan fi-  
10                  duciary evidence proving that such in-  
11                  dividual is a self-employed individual,  
12                  such individual shall be eligible to par-  
13                  ticipate in the group health plan.

14                  “(3) DISCRIMINATION AND PRE-EXISTING CON-  
15                  DITION PROTECTIONS.—A group health plan estab-  
16                  lished and maintained by the group or association of  
17                  employers under this section may not—

18                  “(A) establish any rule for eligibility (in-  
19                  cluding continued eligibility) of any individual  
20                  (including an employee of an employer member  
21                  or a self-employed individual, or a dependent of  
22                  such employee or self-employed individual) to  
23                  enroll for benefits under the terms of the plan  
24                  that discriminates based on any health status-  
25                  related factor that relates to such individual

1 (consistent with the rules under section  
2 702(a)(1));

3 “(B) require an individual (including an  
4 employee of an employer member or a self-em-  
5 ployed individual, or a dependent of such em-  
6 ployee or self-employed individual), as a condi-  
7 tion of enrollment or continued enrollment  
8 under the plan, to pay a premium or contribu-  
9 tion that is greater than the premium or con-  
10 tribution for a similarly situated individual en-  
11 rolled in the plan based on any health status-  
12 related factor that relates to such individual  
13 (consistent with the rules under section  
14 702(b)(1)); and

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

19 “(b) PREMIUM RATES FOR A GROUP OR ASSOCIA-  
20 TION OF EMPLOYERS.—

21 “(1) IN GENERAL.—A group health plan estab-  
22 lished and maintained by a group or association of  
23 employers that meets that requirements of this sec-  
24 tion may, to the extent not prohibited under State  
25 law—

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

5           “(B) utilize the specific risk profile of each  
6           employer member of such group or association  
7           to determine contribution rates for each such  
8           employer member’s share of a premium by ac-  
9           tuarily adjusting the established base pre-  
10          mium rates.

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

15                 “(A) treat all such self-employed individ-  
16                 uals as a single risk pool;

17                 “(B) pool all plan participant claims; and

18                 “(C) charge each plan participant the  
19                 same premium rate.

20          “(c) TREATMENT OF SELF-EMPLOYED INDIVID-  
21          UALS.—For purposes of this section, an individual who is  
22          a self-employed individual shall be treated as—

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

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

4           “(3) a participant of the group health plan in  
5           which the individual participates, subject to the eligi-  
6           bility determination and monitoring requirements set  
7           forth in subsection (a)(2)(C)(i).

8           “(d) DETERMINATION OF EMPLOYER OR JOINT EM-  
9           PLOYER STATUS.—The provision of health insurance cov-  
10          erage by a group or association of employers may not be  
11          construed as evidence for establishing an employer or joint  
12          employer relationship under any Federal or State law.

13          “(e) RULES OF CONSTRUCTION.—

14                 “(1) NO EXEMPTION FROM PHSA.—Nothing in  
15                 this section shall be construed to exempt a group  
16                 health plan (as defined in section 733(a)(1)) offered  
17                 through a group or association of employers from  
18                 the requirements of this part or from the provisions  
19                 of part A of title XXVII of the Public Health Serv-  
20                 ice Act as incorporated by reference into this Act  
21                 through section 715.

22                 “(2) PRIOR OR FUTURE GUIDANCE.—Nothing  
23                 in this section may be construed to limit or other-  
24                 wise affect the ability of a group or association of  
25                 employers from establishing a single plan multiple

1 employer welfare arrangement as specified in any  
2 prior or future guidance issued by the Secretary of  
3 Labor that provides alternative pathways to quali-  
4 fying as a group or association of employer for pur-  
5 poses of section 3(5).

6 “(f) DEFINITIONS.—In this section—

7 “(1) EMPLOYER MEMBER.—The term ‘employer  
8 member’ means—

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

12 “(B) a group made up solely of self-em-  
13 ployed individuals, within which all of the self-  
14 employed individual members of such group or  
15 association are aggregated together as a single  
16 employer member group, provided that such  
17 group includes at least 20 self-employed indi-  
18 vidual members.

19 “(2) SELF-EMPLOYED INDIVIDUAL.—The term  
20 ‘self-employed individual’ means an individual who—

21 “(A) does not have any common law em-  
22 ployees;

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

1 trade or business is incorporated or unincor-  
 2 porated;

3 “(C) earns a wage (as defined in section  
 4 3121(a) of the Internal Revenue Code of 1986)  
 5 or self-employment income (as defined in sec-  
 6 tion 1402(b) of such Code) from such trade or  
 7 business; and

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

11 (2) CLERICAL AMENDMENT.—The table of con-  
 12 tents is amended by inserting after the item relating  
 13 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.”.

14 **SEC. 102. CERTAIN MEDICAL STOP-LOSS INSURANCE OB-**  
 15 **TAINED BY CERTAIN PLAN SPONSORS OF**  
 16 **GROUP HEALTH PLANS NOT INCLUDED**  
 17 **UNDER THE DEFINITION OF HEALTH INSUR-**  
 18 **ANCE COVERAGE.**

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

1 the health risks of its plan participants to reimburse the  
 2 plan or sponsor for losses that the plan or sponsor incurs  
 3 in providing health or medical benefits to such plan par-  
 4 ticipants in excess of a predetermined level set forth in  
 5 the stop-loss policy obtained by such plan or sponsor.”.

6 (b) EFFECT ON OTHER LAWS.—Section 514(b) of  
 7 the Employee Retirement Income Security Act of 1974  
 8 (29 U.S.C. 1144(b)) is amended by adding at the end the  
 9 following:

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

16 **SEC. 103. TREATMENT OF HEALTH REIMBURSEMENT AR-**  
 17 **RANGEMENTS INTEGRATED WITH INDI-**  
 18 **VIDUAL MARKET COVERAGE.**

19 (a) IN GENERAL.—

20 (1) TREATMENT.—Section 9815(b) of the In-  
 21 ternal Revenue Code of 1986 is amended—

22 (A) by striking “EXCEPTION.—Notwith-  
 23 standing subsection (a)” and inserting the fol-  
 24 lowing: “EXCEPTIONS.—

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

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

5           “(2) CUSTOM HEALTH OPTION AND INDIVIDUAL  
6       CARE EXPENSE ARRANGEMENTS.—

7           “(A) IN GENERAL.—For purposes of this  
8       subchapter, a custom health option and indi-  
9       vidual care expense arrangement shall be treat-  
10      ed as meeting the requirements of section 9802  
11      and sections 2705, 2711, 2713, and 2715 of  
12      title XXVII of the Public Health Service Act.

13          “(B) CUSTOM HEALTH OPTION AND INDI-  
14      VIDUAL CARE EXPENSE ARRANGEMENTS DE-  
15      FINED.—For purposes of this section, the term  
16      ‘custom health option and individual care ex-  
17      pense arrangement’ means a health reimburse-  
18      ment arrangement—

19           “(i) which is an employer-provided  
20      group health plan funded solely by em-  
21      ployer contributions to provide payments  
22      or reimbursements for medical care subject  
23      to a maximum fixed dollar amount for a  
24      period,

1           “(ii) under which such payments or  
2 reimbursements may only be made for  
3 medical care provided during periods dur-  
4 ing which the individual is covered—

5           “(I) under individual health in-  
6 surance coverage (other than coverage  
7 that consists solely of excepted bene-  
8 fits), or

9           “(II) under part A and B of title  
10 XVIII of the Social Security Act or  
11 part C of such title,

12           “(iii) which meets the nondiscrimina-  
13 tion requirements of subparagraph (C),

14           “(iv) which meets the substantiation  
15 requirements of subparagraph (D), and

16           “(v) which meets the notice require-  
17 ments of subparagraph (E).

18           “(C) NONDISCRIMINATION.—

19           “(i) IN GENERAL.—An arrangement  
20 meets the requirements of this subpara-  
21 graph if an employer offering such ar-  
22 rangement to an employee within a speci-  
23 fied class of employee—

1           “(I) offers such arrangement to  
2 all employees within such specified  
3 class on the same terms, and

4           “(II) does not offer any other  
5 group health plan (other than an ac-  
6 count-based group health plan or a  
7 group health plan that consists solely  
8 of excepted benefits) to any employees  
9 within such specified class.

10           In the case of an employer who offers a  
11 group health plan provided through health  
12 insurance coverage in the small group mar-  
13 ket (that is subject to section 2701 of the  
14 Public Health Service Act) to all employees  
15 within such specified class, subclause (II)  
16 shall not apply to such group health plan.

17           “(ii) SPECIFIED CLASS OF EM-  
18 PLOYEE.—For purposes of this subpara-  
19 graph, any of the following may be des-  
20 ignated as a specified class of employee:

21                   “(I) Full-time employees.

22                   “(II) Part-time employees.

23                   “(III) Salaried employees.

24                   “(IV) Non-salaried employees.

1           “(V) Employees whose primary  
2 site of employment is in the same rat-  
3 ing area.

4           “(VI) Employees who are in-  
5 cluded in a unit of employees covered  
6 under a collective bargaining agree-  
7 ment to which the employer is subject  
8 (determined under rules similar to the  
9 rules of section 105(h)).

10           “(VII) Employees who have not  
11 met a group health plan, or health in-  
12 surance issuer offering group health  
13 insurance coverage, waiting period re-  
14 quirement that satisfies section 2708  
15 of the Public Health Service Act.

16           “(VIII) Seasonal employees.

17           “(IX) Employees who are non-  
18 resident aliens and who receive no  
19 earned income (within the meaning of  
20 section 911(d)(2)) from the employer  
21 which constitutes income from sources  
22 within the United States (within the  
23 meaning of section 861(a)(3)).

24           “(X) Under such rules as the  
25 Secretary may prescribe, employees

1           who are hired for temporary place-  
2           ment with an unrelated person that is  
3           not the common law employer.

4           “(XI) Such other classes of em-  
5           ployees as the Secretary may des-  
6           ignate.

7           An employer may designate (in such man-  
8           ner as is prescribed by the Secretary) two  
9           or more of the classes described in the pre-  
10          ceding subclauses as the specified class of  
11          employees to which the arrangement is of-  
12          fered for purposes of applying this sub-  
13          paragraph.

14          “(iii) SPECIAL RULE FOR NEW  
15          HIRES.—An employer may designate pro-  
16          spectively so much of a specified class of  
17          employees as are hired after a date set by  
18          the employer. Such subclass of employees  
19          shall be treated as the specified class for  
20          purposes of applying clause (i).

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

1 section 105(h) or 4980H, whichever the  
2 employer elects for the plan year. Such  
3 election shall apply with respect to all em-  
4 ployees of the employer for the plan year.

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

14 “(I) increases as additional de-  
15 pendants of the employee are covered  
16 under the arrangement, and

17 “(II) increases with respect to a  
18 participant as the age of the partici-  
19 pant increases, but not in excess of an  
20 amount equal to 300 percent of the  
21 lowest maximum dollar amount with  
22 respect to such a participant deter-  
23 mined without regard to age.

24 “(D) SUBSTANTIATION REQUIREMENTS.—

25 An arrangement meets the requirements of this

1           subparagraph if the arrangement has reason-  
2           able procedures to substantiate—

3                   “(i) that the participant and any de-  
4                   pendents are, or will be, enrolled in cov-  
5                   erage described in subparagraph (B)(ii) as  
6                   of the beginning of the plan year of the ar-  
7                   rangement (or as of the beginning of cov-  
8                   erage under the arrangement in the case of  
9                   an employee who first becomes eligible to  
10                  participate in the arrangement after the  
11                  date notice is given with respect to the  
12                  plan under subparagraph (E) (determined  
13                  without regard to clause (iii) thereof), and

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

18                  “(E) NOTICE.—

19                   “(i) IN GENERAL.—Except as pro-  
20                   vided in clause (iii), an arrangement meets  
21                   the requirements of this subparagraph if,  
22                   under the arrangement, each employee eli-  
23                   gible to participate is, not later than 60  
24                   days before the beginning of the plan year,  
25                   given written notice of the employee’s

1 rights and obligations under the arrange-  
2 ment which—

3 “(I) is sufficiently accurate and  
4 comprehensive to apprise the employee  
5 of such rights and obligations, and

6 “(II) is written in a manner cal-  
7 culated to be understood by the aver-  
8 age employee eligible to participate.

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

12 “(iii) NOTICE DEADLINE FOR CER-  
13 TAIN EMPLOYEES.—In the case of an em-  
14 ployee—

15 “(I) who first becomes eligible to  
16 participate in the arrangement after  
17 the date notice is given with respect  
18 to the plan under clause (i) (deter-  
19 mined without regard to this clause),  
20 or

21 “(II) whose employer is first es-  
22 tablished fewer than 120 days before  
23 the beginning of the first plan year of  
24 the arrangement,

1           the requirements of this subparagraph  
2           shall be treated as met if the notice re-  
3           quired under clause (i) is provided not  
4           later than the date the arrangement may  
5           take effect with respect to such em-  
6           ployee.”.

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

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

12           (i) no inference shall be made from  
13           such amendments with respect to the rules  
14           prescribed in the Federal Register on June  
15           20, 2019, (84 Fed. Reg. 28888) relating to  
16           health reimbursement arrangements and  
17           other account-based group health plans,  
18           and

19           (ii) any reference to custom health op-  
20           tion and individual care expense arrange-  
21           ments shall for purposes of such rules be  
22           treated as including a reference to indi-  
23           vidual coverage health reimbursement ar-  
24           rangements.

1 (B) OTHER CONFORMING OF RULES.—The  
2 Secretary of the Treasury, the Secretary of  
3 Health and Human Services, and the Secretary  
4 of Labor shall modify such rules as may be nec-  
5 essary to conform to the amendments made by  
6 this subsection.

7 (3) PARTICIPANTS IN CHOICE ARRANGEMENT  
8 ELIGIBLE FOR PURCHASE OF EXCHANGE INSURANCE  
9 UNDER CAFETERIA PLAN.—Section 125(f)(3) of  
10 such Code is amended by adding at the end the fol-  
11 lowing new subparagraph:

12 “(C) EXCEPTION FOR PARTICIPANTS IN  
13 CHOICE ARRANGEMENT.—Subparagraph (A)  
14 shall not apply in the case of an employee par-  
15 ticipating in a custom health option and indi-  
16 vidual care expense arrangement (within the  
17 meaning of section 9815(b)(2)) offered by the  
18 employee’s employer.”.

19 (4) EFFECTIVE DATE.—The amendments made  
20 by this subsection shall apply to plan years begin-  
21 ning after December 31, 2025.

22 (b) INCLUSION OF CHOICE ARRANGEMENT PER-  
23 MITTED BENEFITS ON W-2.—

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

1 paragraph (18), by striking the period at the end of  
2 paragraph (19) and inserting “, and”, and by insert-  
3 ing after paragraph (19) the following new para-  
4 graph:

5 “(20) the total amount of permitted benefits for  
6 enrolled individuals under a custom health option  
7 and individual care expense arrangement (as defined  
8 in section 9815(b)(2)) with respect to such em-  
9 ployee.”.

10 (2) EFFECTIVE DATE.—The amendment made  
11 by this subsection shall apply to taxable years begin-  
12 ning after December 31, 2025.

13 **TITLE II—LOWERING HEALTH**  
14 **CARE PREMIUMS FOR EVERY-**  
15 **ONE**

16 **SEC. 201. OVERSIGHT OF PHARMACY BENEFIT MANAGE-**  
17 **MENT SERVICES.**

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

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

1 **“SEC. 2799A-11. OVERSIGHT OF ENTITIES THAT PROVIDE**  
2 **PHARMACY BENEFIT MANAGEMENT SERV-**  
3 **ICES.**

4 “(a) IN GENERAL.—For plan years beginning on or  
5 after the date that is 30 months after the date of enact-  
6 ment of this section (referred to in this subsection and  
7 subsection (b) as the ‘effective date’), a group health plan  
8 or a health insurance issuer offering group health insur-  
9 ance coverage, or an entity providing pharmacy benefit  
10 management services on behalf of such a plan or issuer,  
11 shall not enter into a contract, including an extension or  
12 renewal of a contract, entered into on or after the effective  
13 date, with an applicable entity unless such applicable enti-  
14 ty agrees to—

15 “(1) not limit or delay the disclosure of infor-  
16 mation to the group health plan (including such a  
17 plan offered through a health insurance issuer) in  
18 such a manner that prevents an entity providing  
19 pharmacy benefit management services on behalf of  
20 a group health plan or health insurance issuer offer-  
21 ing group health insurance coverage from making  
22 the reports described in subsection (b); and

23 “(2) provide the entity providing pharmacy ben-  
24 efit management services on behalf of a group health  
25 plan or health insurance issuer relevant information

1 necessary to make the reports described in sub-  
2 section (b).

3 “(b) REPORTS.—

4 “(1) IN GENERAL.—For plan years beginning  
5 on or after the effective date, in the case of any con-  
6 tract between a group health plan or a health insur-  
7 ance issuer offering group health insurance coverage  
8 offered in connection with such a plan and an entity  
9 providing pharmacy benefit management services on  
10 behalf of such plan or issuer, including an extension  
11 or renewal of such a contract, entered into on or  
12 after the effective date, the entity providing phar-  
13 macy benefit management services on behalf of such  
14 a group health plan or health insurance issuer, not  
15 less frequently than every 6 months (or, at the re-  
16 quest of a group health plan, not less frequently  
17 than quarterly, and under the same conditions,  
18 terms, and cost of the semiannual report under this  
19 subsection), shall submit to the group health plan a  
20 report in accordance with this section. Each such re-  
21 port shall be made available to such group health  
22 plan in plain language, in a machine-readable for-  
23 mat, and as the Secretary may determine, other for-  
24 mats. Each such report shall include the information  
25 described in paragraph (2).

1           “(2) INFORMATION DESCRIBED.—For purposes  
2 of paragraph (1), the information described in this  
3 paragraph is, with respect to drugs covered by a  
4 group health plan or group health insurance cov-  
5 erage offered by a health insurance issuer in connec-  
6 tion with a group health plan during each reporting  
7 period—

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

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

18           “(I) the contracted compensation  
19 paid by the group health plan or  
20 health insurance issuer for each cov-  
21 ered drug (identified by the National  
22 Drug Code) to the entity providing  
23 pharmacy benefit management serv-  
24 ices or other applicable entity on be-

1 half of the group health plan or health  
2 insurance issuer;

3 “(II) the contracted compensa-  
4 tion paid to the pharmacy, by any en-  
5 tity providing pharmacy benefit man-  
6 agement services or other applicable  
7 entity on behalf of the group health  
8 plan or health insurance issuer, for  
9 each covered drug (identified by the  
10 National Drug Code);

11 “(III) for each such claim, the  
12 difference between the amount paid  
13 under subclause (I) and the amount  
14 paid under subclause (II);

15 “(IV) the proprietary name, es-  
16 tablished name or proper name, and  
17 National Drug Code;

18 “(V) for each claim for the drug  
19 (including original prescriptions and  
20 refills) and for each dosage unit of the  
21 drug for which a claim was filed, the  
22 type of dispensing channel used to  
23 furnish the drug, including retail, mail  
24 order, or specialty pharmacy;

1           “(VI) with respect to each drug  
2 dispensed, for each type of dispensing  
3 channel (including retail, mail order,  
4 or specialty pharmacy)—

5           “(aa) whether such drug is a  
6 brand name drug or a generic  
7 drug, and—

8           “(AA) in the case of a  
9 brand name drug, the whole-  
10 sale acquisition cost, listed  
11 as cost per days supply and  
12 cost per dosage unit, on the  
13 date such drug was dis-  
14 pensed; and

15           “(BB) in the case of a  
16 generic drug, the average  
17 wholesale price, listed as  
18 cost per days supply and  
19 cost per dosage unit, on the  
20 date such drug was dis-  
21 pensed; and

22           “(bb) the total number of—  
23           “(AA) prescription  
24 claims (including original  
25 prescriptions and refills);

1 “(BB) participants and  
2 beneficiaries for whom a  
3 claim for such drug was  
4 filed through the applicable  
5 dispensing channel;

6 “(CC) dosage units and  
7 dosage units per fill of such  
8 drug; and

9 “(DD) days supply of  
10 such drug per fill;

11 “(VII) the net price per course of  
12 treatment or single fill, such as a 30-  
13 day supply or 90-day supply to the  
14 plan or coverage after rebates, fees,  
15 alternative discounts, or other remun-  
16 eration received from applicable enti-  
17 ties;

18 “(VIII) the total amount of out-  
19 of-pocket spending by participants  
20 and beneficiaries on such drug, in-  
21 cluding spending through copayments,  
22 coinsurance, and deductibles, but not  
23 including any amounts spent by par-  
24 ticipants and beneficiaries on drugs  
25 not covered under the plan or cov-

1 erage, or for which no claim is sub-  
2 mitted under the plan or coverage;

3 “(IX) the total net spending on  
4 the drug;

5 “(X) the total amount received,  
6 or expected to be received, by the plan  
7 or issuer from any applicable entity in  
8 rebates, fees, alternative discounts, or  
9 other remuneration;

10 “(XI) the total amount received,  
11 or expected to be received, by the enti-  
12 ty providing pharmacy benefit man-  
13 agement services, from applicable en-  
14 tities, in rebates, fees, alternative dis-  
15 counts, or other remuneration from  
16 such entities—

17 “(aa) for claims incurred  
18 during the reporting period; and

19 “(bb) that is related to utili-  
20 zation of such drug or spending  
21 on such drug; and

22 “(XII) to the extent feasible, in-  
23 formation on the total amount of re-  
24 muneration for such drug, including  
25 copayment assistance dollars paid, co-

1 payment cards applied, or other dis-  
2 counts provided by each drug manu-  
3 facturer (or entity administering co-  
4 payment assistance on behalf of such  
5 drug manufacturer), to the partici-  
6 pants and beneficiaries enrolled in  
7 such plan or coverage;

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

14 “(I) the total gross spending on  
15 drugs in such class before rebates,  
16 price concessions, alternative dis-  
17 counts, or other remuneration from  
18 applicable entities;

19 “(II) the net spending in such  
20 class after such rebates, price conces-  
21 sions, alternative discounts, or other  
22 remuneration from applicable entities;

23 “(III) the total amount received,  
24 or expected to be received, by the enti-  
25 ty providing pharmacy benefit man-

1           agement services, from applicable en-  
2           tities, in rebates, fees, alternative dis-  
3           counts, or other remuneration from  
4           such entities—

5                   “(aa) for claims incurred  
6                   during the reporting period; and

7                   “(bb) that is related to utili-  
8                   zation of drugs or drug spending;

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

17                  “(V) the number of participants  
18                  and beneficiaries who filled a prescrip-  
19                  tion for a drug in such class, includ-  
20                  ing the National Drug Code for each  
21                  such drug;

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

1                   tion or step therapy) employed for  
2                   drugs in that class; and

3                   “(VII) the total out-of-pocket  
4                   spending under the plan or coverage  
5                   by participants and beneficiaries, in-  
6                   cluding spending through copayments,  
7                   coinsurance, and deductibles, but not  
8                   including any amounts spent by par-  
9                   ticipants and beneficiaries on drugs  
10                  not covered under the plan or cov-  
11                  erage or for which no claim is sub-  
12                  mitted under the plan or coverage;

13                  “(iii) with respect to any drug for  
14                  which gross spending under the group  
15                  health plan or health insurance coverage  
16                  exceeded \$10,000 during the reporting pe-  
17                  riod or, in the case that gross spending  
18                  under the group health plan or coverage  
19                  exceeded \$10,000 during the reporting pe-  
20                  riod with respect to fewer than 50 drugs,  
21                  with respect to the 50 prescription drugs  
22                  with the highest spending during the re-  
23                  porting period—

1                   “(I) a list of all other drugs in  
2                   the same therapeutic class as such  
3                   drug;

4                   “(II) if applicable, the rationale  
5                   for the formulary placement of such  
6                   drug in that therapeutic category or  
7                   class, selected from a list of standard  
8                   rationales established by the Sec-  
9                   retary, in consultation with stake-  
10                  holders; and

11                  “(III) any change in formulary  
12                  placement compared to the prior plan  
13                  year; and

14                  “(iv) in the case that such plan or  
15                  issuer (or an entity providing pharmacy  
16                  benefit management services on behalf of  
17                  such plan or issuer) has an affiliated phar-  
18                  macy or pharmacy under common owner-  
19                  ship, including mandatory mail and spe-  
20                  cialty home delivery programs, retail and  
21                  mail auto-refill programs, and cost-sharing  
22                  assistance incentives funded by an entity  
23                  providing pharmacy benefit services—

24                  “(I) an explanation of any ben-  
25                  efit design parameters that encourage

1 or require participants and bene-  
2 ficiaries in the plan or coverage to fill  
3 prescriptions at mail order, specialty,  
4 or retail pharmacies;

5 “(II) the percentage of total pre-  
6 scriptions dispensed by such phar-  
7 macies to participants or beneficiaries  
8 in such plan or coverage; and

9 “(III) a list of all drugs dis-  
10 pensed by such pharmacies to partici-  
11 pants or beneficiaries enrolled in such  
12 plan or coverage, and, with respect to  
13 each drug dispensed—

14 “(aa) the amount charged,  
15 per dosage unit, per 30-day sup-  
16 ply, or per 90-day supply (as ap-  
17 plicable) to the plan or issuer,  
18 and to participants and bene-  
19 ficiaries;

20 “(bb) the median amount  
21 charged to such plan or issuer,  
22 and the interquartile range of the  
23 costs, per dosage unit, per 30-  
24 day supply, and per 90-day sup-  
25 ply, including amounts paid by

1 the participants and bene-  
2 ficiaries, when the same drug is  
3 dispensed by other pharmacies  
4 that are not affiliated with or  
5 under common ownership with  
6 the entity and that are included  
7 in the pharmacy network of such  
8 plan or coverage;

9 “(cc) the lowest cost per  
10 dosage unit, per 30-day supply  
11 and per 90-day supply, for each  
12 such drug, including amounts  
13 charged to the plan or coverage  
14 and to participants and bene-  
15 ficiaries, that is available from  
16 any pharmacy included in the  
17 network of such plan or coverage;  
18 and

19 “(dd) the net acquisition  
20 cost per dosage unit, per 30-day  
21 supply, and per 90-day supply, if  
22 such drug is subject to a max-  
23 imum price discount; and

24 “(B) with respect to any group health  
25 plan, including group health insurance coverage

1 offered in connection with such a plan, regard-  
2 less of whether the plan or coverage is offered  
3 by a specified large employer or whether it is a  
4 specified large plan—

5 “(i) a summary document for the  
6 group health plan that includes such infor-  
7 mation described in clauses (i) through (iv)  
8 of subparagraph (A), as specified by the  
9 Secretary through guidance, program in-  
10 struction, or otherwise (with no require-  
11 ment of notice and comment rulemaking),  
12 that the Secretary determines useful to  
13 group health plans for purposes of select-  
14 ing pharmacy benefit management serv-  
15 ices, such as an estimated net price to  
16 group health plan and participant or bene-  
17 ficiary, a cost per claim, the fee structure  
18 or reimbursement model, and estimated  
19 cost per participant or beneficiary;

20 “(ii) a summary document for plans  
21 and issuers to provide to participants and  
22 beneficiaries, which shall be made available  
23 to participants or beneficiaries upon re-  
24 quest to their group health plan (including  
25 in the case of group health insurance cov-

1 erage offered in connection with such a  
2 plan), that—

3 “(I) contains such information  
4 described in clauses (iii), (iv), (v), and  
5 (vi), as applicable, as specified by the  
6 Secretary through guidance, program  
7 instruction, or otherwise (with no re-  
8 quirement of notice and comment  
9 rulemaking) that the Secretary deter-  
10 mines useful to participants or bene-  
11 ficiaries in better understanding the  
12 plan or coverage or benefits under  
13 such plan or coverage;

14 “(II) contains only aggregate in-  
15 formation; and

16 “(III) states that participants  
17 and beneficiaries may request specific,  
18 claims-level information required to be  
19 furnished under subsection (c) from  
20 the group health plan or health insur-  
21 ance issuer;

22 “(iii) with respect to drugs covered by  
23 such plan or coverage during such report-  
24 ing period—

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

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

8                   “(III) to the extent feasible, in-  
9                   formation on the total amount of re-  
10                  muneration for such drugs, including  
11                  copayment assistance dollars paid, co-  
12                  payment cards applied, or other dis-  
13                  counts provided by each drug manu-  
14                  facturer (or entity administering co-  
15                  payment assistance on behalf of such  
16                  drug manufacturer) to participants  
17                  and beneficiaries;

18                  “(iv) amounts paid directly or indi-  
19                  rectly in rebates, fees, or any other type of  
20                  compensation (as defined in section  
21                  408(b)(2)(B)(ii)(dd)(AA) of the Employee  
22                  Retirement Income Security Act) to bro-  
23                  kerage firms, brokers, consultants, advi-  
24                  sors, or any other individual or firm, for—

1           “(I) the referral of the group  
2           health plan’s or health insurance  
3           issuer’s business to an entity pro-  
4           viding pharmacy benefit management  
5           services, including the identity of the  
6           recipient of such amounts;

7           “(II) consideration of the entity  
8           providing pharmacy benefit manage-  
9           ment services by the group health  
10          plan or health insurance issuer; or

11          “(III) the retention of the entity  
12          by the group health plan or health in-  
13          surance issuer;

14          “(v) an explanation of any benefit de-  
15          sign parameters that encourage or require  
16          participants and beneficiaries in such plan  
17          or coverage to fill prescriptions at mail  
18          order, specialty, or retail pharmacies that  
19          are affiliated with or under common own-  
20          ership with the entity providing pharmacy  
21          benefit management services under such  
22          plan or coverage, including mandatory mail  
23          and specialty home delivery programs, re-  
24          tail and mail auto-refill programs, and

1 cost-sharing assistance incentives directly  
2 or indirectly funded by such entity; and

3 “(vi) total gross spending on all drugs  
4 under the plan or coverage during the re-  
5 porting period.

6 “(3) OPT-IN FOR GROUP HEALTH INSURANCE  
7 COVERAGE OFFERED BY A SPECIFIED LARGE EM-  
8 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In  
9 the case of group health insurance coverage offered  
10 in connection with a group health plan that is of-  
11 fered by a specified large employer or is a specified  
12 large plan, such group health plan may, on an an-  
13 nual basis, for plan years beginning on or after the  
14 date that is 30 months after the date of enactment  
15 of this section, elect to require an entity providing  
16 pharmacy benefit management services on behalf of  
17 the health insurance issuer to submit to such group  
18 health plan a report that includes all of the informa-  
19 tion described in paragraph (2)(A), in addition to  
20 the information described in paragraph (2)(B).

21 “(4) PRIVACY REQUIREMENTS.—

22 “(A) IN GENERAL.—An entity providing  
23 pharmacy benefit management services on be-  
24 half of a group health plan or a health insur-  
25 ance issuer offering group health insurance cov-

1 erage shall report information under paragraph  
2 (1) in a manner consistent with the privacy reg-  
3 ulations promulgated under section 13402(a) of  
4 the Health Information Technology for Eco-  
5 nomic and Clinical Health Act and consistent  
6 with the privacy regulations promulgated under  
7 the Health Insurance Portability and Account-  
8 ability Act of 1996 in part 160 and subparts A  
9 and E of part 164 of title 45, Code of Federal  
10 Regulations (or successor regulations) (referred  
11 to in this paragraph as the ‘HIPAA privacy  
12 regulations’) and shall restrict the use and dis-  
13 closure of such information according to such  
14 privacy regulations and such HIPAA privacy  
15 regulations.

16 “(B) ADDITIONAL REQUIREMENTS.—

17 “(i) IN GENERAL.—An entity pro-  
18 viding pharmacy benefit management serv-  
19 ices on behalf of a group health plan or  
20 health insurance issuer offering group  
21 health insurance coverage that submits a  
22 report under paragraph (1) shall ensure  
23 that such report contains only summary  
24 health information, as defined in section

1 164.504(a) of title 45, Code of Federal  
2 Regulations (or successor regulations).

3 “(ii) RESTRICTIONS.—In carrying out  
4 this subsection, a group health plan shall  
5 comply with section 164.504(f) of title 45,  
6 Code of Federal Regulations (or a suc-  
7 cessor regulation), and a plan sponsor shall  
8 act in accordance with the terms of the  
9 agreement described in such section.

10 “(C) RULE OF CONSTRUCTION.—

11 “(i) Nothing in this section shall be  
12 construed to modify the requirements for  
13 the creation, receipt, maintenance, or  
14 transmission of protected health informa-  
15 tion under the HIPAA privacy regulations.

16 “(ii) Nothing in this section shall be  
17 construed to affect the application of any  
18 Federal or State privacy or civil rights law,  
19 including the HIPAA privacy regulations,  
20 the Genetic Information Nondiscrimination  
21 Act of 2008 (Public Law 110–233) (in-  
22 cluding the amendments made by such  
23 Act), the Americans with Disabilities Act  
24 of 1990 (42 U.S.C. 12101 et seq.), section  
25 504 of the Rehabilitation Act of 1973 (29

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

7 “(D) WRITTEN NOTICE.—Each plan year,  
8 group health plans, including with respect to  
9 group health insurance coverage offered in con-  
10 nection with a group health plan, shall provide  
11 to each participant or beneficiary written notice  
12 informing the participant or beneficiary of the  
13 requirement for entities providing pharmacy  
14 benefit management services on behalf of the  
15 group health plan or health insurance issuer of-  
16 fering group health insurance coverage to sub-  
17 mit reports to group health plans under para-  
18 graph (1), as applicable, which may include in-  
19 corporating such notification in plan documents  
20 provided to the participant or beneficiary, or  
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-  
23 ATES.—A group health plan receiving a report  
24 under paragraph (1) may disclose such informa-  
25 tion only to the entity from which the report

1 was received or to that entity’s business associ-  
2 ates as defined in section 160.103 of title 45,  
3 Code of Federal Regulations (or successor regu-  
4 lations) or as permitted by the HIPAA privacy  
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC  
7 DISCLOSURE OF INFORMATION.—Nothing in  
8 this section shall prevent an entity providing  
9 pharmacy benefit management services on be-  
10 half of a group health plan or health insurance  
11 issuer offering group health insurance coverage,  
12 from placing reasonable restrictions on the pub-  
13 lic disclosure of the information contained in a  
14 report described in paragraph (1), except that  
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report  
17 to the Department of Health and Human  
18 Services, the Department of Labor, or the  
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-  
21 poses of subsection (c), or any other public  
22 disclosure requirement under this section.

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

1 required with respect to any group health plan  
2 established by a plan sponsor that is, or is af-  
3 filiated with, a drug manufacturer, drug whole-  
4 saler, or other direct participant in the drug  
5 supply chain, in order to prevent anti-competi-  
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18  
9 months after the date of enactment of this sec-  
10 tion, the Secretary shall specify through rule-  
11 making a standard format for entities providing  
12 pharmacy benefit management services on be-  
13 half of group health plans and health insurance  
14 issuers offering group health insurance cov-  
15 erage, to submit reports required under para-  
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not  
18 later than 18 months after the date of enact-  
19 ment of this section, the Secretary shall,  
20 through rulemaking, promulgate any other final  
21 regulations necessary to implement the require-  
22 ments of this section. In promulgating such  
23 regulations, the Secretary shall, to the extent  
24 practicable, align the reporting requirements

1           under this section with the reporting require-  
2           ments under section 2799A-10.

3           “(c) REQUIREMENT TO PROVIDE INFORMATION TO  
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,  
5 including with respect to group health insurance coverage  
6 offered in connection with a group health plan, upon re-  
7 quest of a participant or beneficiary, shall provide to such  
8 participant or beneficiary—

9           “(1) the summary document described in sub-  
10 section (b)(2)(B)(ii); and

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

14           “(d) ENFORCEMENT.—

15           “(1) IN GENERAL.—The Secretary shall enforce  
16 this section. The enforcement authority under this  
17 subsection shall apply only with respect to group  
18 health plans (including group health insurance cov-  
19 erage offered in connection with such a plan) to  
20 which the requirements of subparts I and II of part  
21 A and part D apply in accordance with section 2722,  
22 and with respect to entities providing pharmacy ben-  
23 efit management services on behalf of such plans  
24 and applicable entities providing services on behalf  
25 of such plans.

1           “(2) FAILURE TO PROVIDE INFORMATION.—A  
2           group health plan, a health insurance issuer offering  
3           group health insurance coverage, an entity providing  
4           pharmacy benefit management services on behalf of  
5           such a plan or issuer, or an applicable entity pro-  
6           viding services on behalf of such a plan or issuer  
7           that violates subsection (a); an entity providing  
8           pharmacy benefit management services on behalf of  
9           such a plan or issuer that fails to provide the infor-  
10          mation required under subsection (b); or a group  
11          health plan that fails to provide the information re-  
12          quired under subsection (c), shall be subject to a  
13          civil monetary penalty in the amount of \$10,000 for  
14          each day during which such violation continues or  
15          such information is not disclosed or reported.

16          “(3) FALSE INFORMATION.—A health insurance  
17          issuer, an entity providing pharmacy benefit man-  
18          agement services, or a third party administrator pro-  
19          viding services on behalf of such issuer offered by a  
20          health insurance issuer that knowingly provides false  
21          information under this section shall be subject to a  
22          civil monetary penalty in an amount not to exceed  
23          \$100,000 for each item of false information. Such  
24          civil monetary penalty shall be in addition to other  
25          penalties as may be prescribed by law.

1           “(4) PROCEDURE.—The provisions of section  
2           1128A of the Social Security Act, other than sub-  
3           sections (a) and (b) and the first sentence of sub-  
4           section (c)(1) of such section shall apply to civil  
5           monetary penalties under this subsection in the  
6           same manner as such provisions apply to a penalty  
7           or proceeding under such section.

8           “(5) WAIVERS.—The Secretary may waive pen-  
9           alties under paragraph (2), or extend the period of  
10          time for compliance with a requirement of this sec-  
11          tion, for an entity in violation of this section that  
12          has made a good-faith effort to comply with the re-  
13          quirements in this section.

14          “(e) RULE OF CONSTRUCTION.—Nothing in this sec-  
15          tion shall be construed to permit a health insurance issuer,  
16          group health plan, entity providing pharmacy benefit man-  
17          agement services on behalf of a group health plan or  
18          health insurance issuer, or other entity to restrict dislo-  
19          sure to, or otherwise limit the access of, the Secretary to  
20          a report described in subsection (b)(1) or information re-  
21          lated to compliance with subsections (a), (b), (c), or (d)  
22          by such issuer, plan, or entity.

23          “(f) DEFINITIONS.—In this section:

24                  “(1) APPLICABLE ENTITY.—The term ‘applica-  
25                  ble entity’ means—

1           “(A) an applicable group purchasing orga-  
2           nization, drug manufacturer, distributor, whole-  
3           saler, rebate aggregator (or other purchasing  
4           entity designed to aggregate rebates), or associ-  
5           ated third party;

6           “(B) any subsidiary, parent, affiliate, or  
7           subcontractor of a group health plan, health in-  
8           surance issuer, entity that provides pharmacy  
9           benefit management services on behalf of such  
10          a plan or issuer, or any entity described in sub-  
11          paragraph (A); or

12          “(C) such other entity as the Secretary  
13          may specify through rulemaking.

14          “(2) APPLICABLE GROUP PURCHASING ORGANI-  
15          ZATION.—The term ‘applicable group purchasing or-  
16          ganization’ means a group purchasing organization  
17          that is affiliated with or under common ownership  
18          with an entity providing pharmacy benefit manage-  
19          ment services.

20          “(3) CONTRACTED COMPENSATION.—The term  
21          ‘contracted compensation’ means the sum of any in-  
22          gredient cost and dispensing fee for a drug (inclusive  
23          of the out-of-pocket costs to the participant or bene-  
24          ficiary), or another analogous compensation struc-

1       ture that the Secretary may specify through regula-  
2       tions.

3           “(4) GROSS SPENDING.—The term ‘gross  
4       spending’, with respect to prescription drug benefits  
5       under a group health plan or health insurance cov-  
6       erage, means the amount spent by a group health  
7       plan or health insurance issuer on prescription drug  
8       benefits, calculated before the application of rebates,  
9       fees, alternative discounts, or other remuneration.

10          “(5) NET SPENDING.—The term ‘net spending’,  
11       with respect to prescription drug benefits under a  
12       group health plan or health insurance coverage,  
13       means the amount spent by a group health plan or  
14       health insurance issuer on prescription drug bene-  
15       fits, calculated after the application of rebates, fees,  
16       alternative discounts, or other remuneration.

17          “(6) PLAN SPONSOR.—The term ‘plan sponsor’  
18       has the meaning given such term in section 3(16)(B)  
19       of the Employee Retirement Income Security Act of  
20       1974.

21          “(7) REMUNERATION.—The term ‘remunera-  
22       tion’ has the meaning given such term by the Sec-  
23       retary through rulemaking, which shall be reeval-  
24       ated by the Secretary every 5 years.

1           “(8) SPECIFIED LARGE EMPLOYER.—The term  
2           ‘specified large employer’ means, in connection with  
3           a group health plan (including group health insur-  
4           ance coverage offered in connection with such a  
5           plan) established or maintained by a single em-  
6           ployer, with respect to a calendar year or a plan  
7           year, as applicable, an employer who employed an  
8           average of at least 100 employees on business days  
9           during the preceding calendar year or plan year and  
10          who employs at least 1 employee on the first day of  
11          the calendar year or plan year.

12          “(9) SPECIFIED LARGE PLAN.—The term ‘spec-  
13          ified large plan’ means a group health plan (includ-  
14          ing group health insurance coverage offered in con-  
15          nection with such a plan) established or maintained  
16          by a plan sponsor described in clause (ii) or (iii) of  
17          section 3(16)(B) of the Employee Retirement In-  
18          come Security Act of 1974 that had an average of  
19          at least 100 participants on business days during  
20          the preceding calendar year or plan year, as applica-  
21          ble.

22          “(10) WHOLESALE ACQUISITION COST.—The  
23          term ‘wholesale acquisition cost’ has the meaning  
24          given such term in section 1847A(c)(6)(B) of the  
25          Social Security Act.”; and

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

2 (A) in subsection (a)—

3 (i) in paragraph (1), by inserting  
4 “(other than section 2799A-11)” after  
5 “part D”; and

6 (ii) in paragraph (2), by inserting  
7 “(other than section 2799A-11)” after  
8 “part D”; and

9 (B) in subsection (b)—

10 (i) in paragraph (1), by inserting  
11 “(other than section 2799A-11)” after  
12 “part D”;

13 (ii) in paragraph (2)(A), by inserting  
14 “(other than section 2799A-11)” after  
15 “part D”; and

16 (iii) in paragraph (2)(C)(ii), by insert-  
17 ing “(other than section 2799A-11)” after  
18 “part D”.

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

21 (1) IN GENERAL.—Subtitle B of title I of the  
22 Employee Retirement Income Security Act of 1974  
23 (29 U.S.C. 1021 et seq.) is amended—

1 (A) in subpart B of part 7 (29 U.S.C.  
2 1185 et seq.), by adding at the end the fol-  
3 lowing:

4 **“SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
5 **MACY BENEFIT MANAGEMENT SERVICES.**

6 “(a) IN GENERAL.—For plan years beginning on or  
7 after the date that is 30 months after the date of enact-  
8 ment of this section (referred to in this subsection and  
9 subsection (b) as the ‘effective date’), a group health plan  
10 or a health insurance issuer offering group health insur-  
11 ance coverage, or an entity providing pharmacy benefit  
12 management services on behalf of such a plan or issuer,  
13 shall not enter into a contract, including an extension or  
14 renewal of a contract, entered into on or after the effective  
15 date, with an applicable entity unless such applicable enti-  
16 ty agrees to—

17 “(1) not limit or delay the disclosure of infor-  
18 mation to the group health plan (including such a  
19 plan offered through a health insurance issuer) in  
20 such a manner that prevents an entity providing  
21 pharmacy benefit management services on behalf of  
22 a group health plan or health insurance issuer offer-  
23 ing group health insurance coverage from making  
24 the reports described in subsection (b); and

1           “(2) provide the entity providing pharmacy ben-  
2           efit management services on behalf of a group health  
3           plan or health insurance issuer relevant information  
4           necessary to make the reports described in sub-  
5           section (b).

6           “(b) REPORTS.—

7           “(1) IN GENERAL.—For plan years beginning  
8           on or after the effective date, in the case of any con-  
9           tract between a group health plan or a health insur-  
10          ance issuer offering group health insurance coverage  
11          offered in connection with such a plan and an entity  
12          providing pharmacy benefit management services on  
13          behalf of such plan or issuer, including an extension  
14          or renewal of such a contract, entered into on or  
15          after the effective date, the entity providing phar-  
16          macy benefit management services on behalf of such  
17          a group health plan or health insurance issuer, not  
18          less frequently than every 6 months (or, at the re-  
19          quest of a group health plan, not less frequently  
20          than quarterly, and under the same conditions,  
21          terms, and cost of the semiannual report under this  
22          subsection), shall submit to the group health plan a  
23          report in accordance with this section. Each such re-  
24          port shall be made available to such group health  
25          plan in plain language, in a machine-readable for-

1 mat, and as the Secretary may determine, other for-  
2 mats. Each such report shall include the information  
3 described in paragraph (2).

4 “(2) INFORMATION DESCRIBED.—For purposes  
5 of paragraph (1), the information described in this  
6 paragraph is, with respect to drugs covered by a  
7 group health plan or group health insurance cov-  
8 erage offered by a health insurance issuer in connec-  
9 tion with a group health plan during each reporting  
10 period—

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

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

21 “(I) the contracted compensation  
22 paid by the group health plan or  
23 health insurance issuer for each cov-  
24 ered drug (identified by the National  
25 Drug Code) to the entity providing

1 pharmacy benefit management serv-  
2 ices or other applicable entity on be-  
3 half of the group health plan or health  
4 insurance issuer;

5 “(II) the contracted compensa-  
6 tion paid to the pharmacy, by any en-  
7 tity providing pharmacy benefit man-  
8 agement services or other applicable  
9 entity on behalf of the group health  
10 plan or health insurance issuer, for  
11 each covered drug (identified by the  
12 National Drug Code);

13 “(III) for each such claim, the  
14 difference between the amount paid  
15 under subclause (I) and the amount  
16 paid under subclause (II);

17 “(IV) the proprietary name, es-  
18 tablished name or proper name, and  
19 National Drug Code;

20 “(V) for each claim for the drug  
21 (including original prescriptions and  
22 refills) and for each dosage unit of the  
23 drug for which a claim was filed, the  
24 type of dispensing channel used to

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

3 “(VI) with respect to each drug  
4 dispensed, for each type of dispensing  
5 channel (including retail, mail order,  
6 or specialty pharmacy)—

7 “(aa) whether such drug is a  
8 brand name drug or a generic  
9 drug, and—

10 “(AA) in the case of a  
11 brand name drug, the whole-  
12 sale acquisition cost, listed  
13 as cost per days supply and  
14 cost per dosage unit, on the  
15 date such drug was dis-  
16 pensed; and

17 “(BB) in the case of a  
18 generic drug, the average  
19 wholesale price, listed as  
20 cost per days supply and  
21 cost per dosage unit, on the  
22 date such drug was dis-  
23 pensed; and

24 “(bb) the total number of—

1                   “(AA) prescription  
2                   claims (including original  
3                   prescriptions and refills);

4                   “(BB) participants and  
5                   beneficiaries for whom a  
6                   claim for such drug was  
7                   filed through the applicable  
8                   dispensing channel;

9                   “(CC) dosage units and  
10                  dosage units per fill of such  
11                  drug; and

12                  “(DD) days supply of  
13                  such drug per fill;

14                  “(VII) the net price per course of  
15                  treatment or single fill, such as a 30-  
16                  day supply or 90-day supply to the  
17                  plan or coverage after rebates, fees,  
18                  alternative discounts, or other remun-  
19                  eration received from applicable enti-  
20                  ties;

21                  “(VIII) the total amount of out-  
22                  of-pocket spending by participants  
23                  and beneficiaries on such drug, in-  
24                  cluding spending through copayments,  
25                  coinsurance, and deductibles, but not

1 including any amounts spent by par-  
2 ticipants and beneficiaries on drugs  
3 not covered under the plan or cov-  
4 erage, or for which no claim is sub-  
5 mitted under the plan or coverage;

6 “(IX) the total net spending on  
7 the drug;

8 “(X) the total amount received,  
9 or expected to be received, by the plan  
10 or issuer from any applicable entity in  
11 rebates, fees, alternative discounts, or  
12 other remuneration;

13 “(XI) the total amount received,  
14 or expected to be received, by the enti-  
15 ty providing pharmacy benefit man-  
16 agement services, from applicable en-  
17 tities, in rebates, fees, alternative dis-  
18 counts, or other remuneration from  
19 such entities—

20 “(aa) for claims incurred  
21 during the reporting period; and

22 “(bb) that is related to utili-  
23 zation of such drug or spending  
24 on such drug; and

1                   “(XII) to the extent feasible, in-  
2                   formation on the total amount of re-  
3                   muneration for such drug, including  
4                   copayment assistance dollars paid, co-  
5                   payment cards applied, or other dis-  
6                   counts provided by each drug manu-  
7                   facturer (or entity administering co-  
8                   payment assistance on behalf of such  
9                   drug manufacturer), to the partici-  
10                  pants and beneficiaries enrolled in  
11                  such plan or coverage;

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

18                         “(I) the total gross spending on  
19                         drugs in such class before rebates,  
20                         price concessions, alternative dis-  
21                         counts, or other remuneration from  
22                         applicable entities;

23                         “(II) the net spending in such  
24                         class after such rebates, price conces-

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

3 “(III) the total amount received,  
4 or expected to be received, by the enti-  
5 ty providing pharmacy benefit man-  
6 agement services, from applicable en-  
7 tities, in rebates, fees, alternative dis-  
8 counts, or other remuneration from  
9 such entities—

10 “(aa) for claims incurred  
11 during the reporting period; and

12 “(bb) that is related to utili-  
13 zation of drugs or drug spending;

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

22 “(V) the number of participants  
23 and beneficiaries who filled a prescrip-  
24 tion for a drug in such class, includ-

1           ing the National Drug Code for each  
2           such drug;

3                   “(VI) if applicable, a description  
4                   of the formulary tiers and utilization  
5                   mechanisms (such as prior authoriza-  
6                   tion or step therapy) employed for  
7                   drugs in that class; and

8                   “(VII) the total out-of-pocket  
9                   spending under the plan or coverage  
10                  by participants and beneficiaries, in-  
11                  cluding spending through copayments,  
12                  coinsurance, and deductibles, but not  
13                  including any amounts spent by par-  
14                  ticipants and beneficiaries on drugs  
15                  not covered under the plan or cov-  
16                  erage or for which no claim is sub-  
17                  mitted under the plan or coverage;

18                  “(iii) with respect to any drug for  
19                  which gross spending under the group  
20                  health plan or health insurance coverage  
21                  exceeded \$10,000 during the reporting pe-  
22                  riod or, in the case that gross spending  
23                  under the group health plan or coverage  
24                  exceeded \$10,000 during the reporting pe-  
25                  riod with respect to fewer than 50 drugs,

1 with respect to the 50 prescription drugs  
2 with the highest spending during the re-  
3 porting period—

4 “(I) a list of all other drugs in  
5 the same therapeutic class as such  
6 drug;

7 “(II) if applicable, the rationale  
8 for the formulary placement of such  
9 drug in that therapeutic category or  
10 class, selected from a list of standard  
11 rationales established by the Sec-  
12 retary, in consultation with stake-  
13 holders; and

14 “(III) any change in formulary  
15 placement compared to the prior plan  
16 year; and

17 “(iv) in the case that such plan or  
18 issuer (or an entity providing pharmacy  
19 benefit management services on behalf of  
20 such plan or issuer) has an affiliated phar-  
21 macy or pharmacy under common owner-  
22 ship, including mandatory mail and spe-  
23 cialty home delivery programs, retail and  
24 mail auto-refill programs, and cost sharing

1 assistance incentives funded by an entity  
2 providing pharmacy benefit services—

3 “(I) an explanation of any ben-  
4 efit design parameters that encourage  
5 or require participants and bene-  
6 ficiaries in the plan or coverage to fill  
7 prescriptions at mail order, specialty,  
8 or retail pharmacies;

9 “(II) the percentage of total pre-  
10 scriptions dispensed by such phar-  
11 macies to participants or beneficiaries  
12 in such plan or coverage; and

13 “(III) a list of all drugs dis-  
14 pensed by such pharmacies to partici-  
15 pants or beneficiaries enrolled in such  
16 plan or coverage, and, with respect to  
17 each drug dispensed—

18 “(aa) the amount charged,  
19 per dosage unit, per 30-day sup-  
20 ply, or per 90-day supply (as ap-  
21 plicable) to the plan or issuer,  
22 and to participants and bene-  
23 ficiaries;

24 “(bb) the median amount  
25 charged to such plan or issuer,

1 and the interquartile range of the  
2 costs, per dosage unit, per 30-  
3 day supply, and per 90-day sup-  
4 ply, including amounts paid by  
5 the participants and bene-  
6 ficiaries, when the same drug is  
7 dispensed by other pharmacies  
8 that are not affiliated with or  
9 under common ownership with  
10 the entity and that are included  
11 in the pharmacy network of such  
12 plan or coverage;

13 “(cc) the lowest cost per  
14 dosage unit, per 30-day supply  
15 and per 90-day supply, for each  
16 such drug, including amounts  
17 charged to the plan or coverage  
18 and to participants and bene-  
19 ficiaries, that is available from  
20 any pharmacy included in the  
21 network of such plan or coverage;  
22 and

23 “(dd) the net acquisition  
24 cost per dosage unit, per 30-day  
25 supply, and per 90-day supply, if

1                   such drug is subject to a max-  
2                   imum price discount; and

3                   “(B) with respect to any group health  
4                   plan, including group health insurance coverage  
5                   offered in connection with such a plan, regard-  
6                   less of whether the plan or coverage is offered  
7                   by a specified large employer or whether it is a  
8                   specified large plan—

9                   “(i) a summary document for the  
10                  group health plan that includes such infor-  
11                  mation described in clauses (i) through (iv)  
12                  of subparagraph (A), as specified by the  
13                  Secretary through guidance, program in-  
14                  struction, or otherwise (with no require-  
15                  ment of notice and comment rulemaking),  
16                  that the Secretary determines useful to  
17                  group health plans for purposes of select-  
18                  ing pharmacy benefit management serv-  
19                  ices, such as an estimated net price to  
20                  group health plan and participant or bene-  
21                  ficiary, a cost per claim, the fee structure  
22                  or reimbursement model, and estimated  
23                  cost per participant or beneficiary;

24                  “(ii) a summary document for plans  
25                  and issuers to provide to participants and

1 beneficiaries, which shall be made available  
2 to participants or beneficiaries upon re-  
3 quest to their group health plan (including  
4 in the case of group health insurance cov-  
5 erage offered in connection with such a  
6 plan), that—

7 “(I) contains such information  
8 described in clauses (iii), (iv), (v), and  
9 (vi), as applicable, as specified by the  
10 Secretary through guidance, program  
11 instruction, or otherwise (with no re-  
12 quirement of notice and comment  
13 rulemaking) that the Secretary deter-  
14 mines useful to participants or bene-  
15 ficiaries in better understanding the  
16 plan or coverage or benefits under  
17 such plan or coverage;

18 “(II) contains only aggregate in-  
19 formation; and

20 “(III) states that participants  
21 and beneficiaries may request specific,  
22 claims-level information required to be  
23 furnished under subsection (c) from  
24 the group health plan or health insur-  
25 ance issuer;

1           “(iii) with respect to drugs covered by  
2 such plan or coverage during such report-  
3 ing period—

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

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

11                   “(III) to the extent feasible, in-  
12 formation on the total amount of re-  
13 munerated for such drugs, including  
14 copayment assistance dollars paid, co-  
15 payment cards applied, or other dis-  
16 counts provided by each drug manu-  
17 facturer (or entity administering co-  
18 payment assistance on behalf of such  
19 drug manufacturer) to participants  
20 and beneficiaries;

21                   “(iv) amounts paid directly or indi-  
22 rectly in rebates, fees, or any other type of  
23 compensation (as defined in section  
24 408(b)(2)(B)(ii)(dd)(AA)) to brokerage

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

3 “(I) the referral of the group  
4 health plan’s or health insurance  
5 issuer’s business to an entity pro-  
6 viding pharmacy benefit management  
7 services, including the identity of the  
8 recipient of such amounts;

9 “(II) consideration of the entity  
10 providing pharmacy benefit manage-  
11 ment services by the group health  
12 plan or health insurance issuer; or

13 “(III) the retention of the entity  
14 by the group health plan or health in-  
15 surance issuer;

16 “(v) an explanation of any benefit de-  
17 sign parameters that encourage or require  
18 participants and beneficiaries in such plan  
19 or coverage to fill prescriptions at mail  
20 order, specialty, or retail pharmacies that  
21 are affiliated with or under common own-  
22 ership with the entity providing pharmacy  
23 benefit management services under such  
24 plan or coverage, including mandatory mail  
25 and specialty home delivery programs, re-

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

4 “(vi) total gross spending on all drugs  
5 under the plan or coverage during the re-  
6 porting period.

7 “(3) OPT-IN FOR GROUP HEALTH INSURANCE  
8 COVERAGE OFFERED BY A SPECIFIED LARGE EM-  
9 PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In  
10 the case of group health insurance coverage offered  
11 in connection with a group health plan that is of-  
12 fered by a specified large employer or is a specified  
13 large plan, such group health plan may, on an an-  
14 nual basis, for plan years beginning on or after the  
15 date that is 30 months after the date of enactment  
16 of this section, elect to require an entity providing  
17 pharmacy benefit management services on behalf of  
18 the health insurance issuer to submit to such group  
19 health plan a report that includes all of the informa-  
20 tion described in paragraph (2)(A), in addition to  
21 the information described in paragraph (2)(B).

22 “(4) PRIVACY REQUIREMENTS.—

23 “(A) IN GENERAL.—An entity providing  
24 pharmacy benefit management services on be-  
25 half of a group health plan or a health insur-

1           ance issuer offering group health insurance cov-  
2           erage shall report information under paragraph  
3           (1) in a manner consistent with the privacy regu-  
4           lations promulgated under section 13402(a) of  
5           the Health Information Technology for Eco-  
6           nomic and Clinical Health Act (42 U.S.C.  
7           17932(a)) and consistent with the privacy regu-  
8           lations promulgated under the Health Insur-  
9           ance Portability and Accountability Act of 1996  
10          in part 160 and subparts A and E of part 164  
11          of title 45, Code of Federal Regulations (or suc-  
12          cessor regulations) (referred to in this para-  
13          graph as the ‘HIPAA privacy regulations’) and  
14          shall restrict the use and disclosure of such in-  
15          formation according to such privacy regulations  
16          and such HIPAA privacy regulations.

17                   “(B) ADDITIONAL REQUIREMENTS.—

18                           “(i) IN GENERAL.—An entity pro-  
19                           viding pharmacy benefit management serv-  
20                           ices on behalf of a group health plan or  
21                           health insurance issuer offering group  
22                           health insurance coverage that submits a  
23                           report under paragraph (1) shall ensure  
24                           that such report contains only summary  
25                           health information, as defined in section

1 164.504(a) of title 45, Code of Federal  
2 Regulations (or successor regulations).

3 “(ii) RESTRICTIONS.—In carrying out  
4 this subsection, a group health plan shall  
5 comply with section 164.504(f) of title 45,  
6 Code of Federal Regulations (or a suc-  
7 cessor regulation), and a plan sponsor shall  
8 act in accordance with the terms of the  
9 agreement described in such section.

10 “(C) RULE OF CONSTRUCTION.—

11 “(i) Nothing in this section shall be  
12 construed to modify the requirements for  
13 the creation, receipt, maintenance, or  
14 transmission of protected health informa-  
15 tion under the HIPAA privacy regulations.

16 “(ii) Nothing in this section shall be  
17 construed to affect the application of any  
18 Federal or State privacy or civil rights law,  
19 including the HIPAA privacy regulations,  
20 the Genetic Information Nondiscrimination  
21 Act of 2008 (Public Law 110–233) (in-  
22 cluding the amendments made by such  
23 Act), the Americans with Disabilities Act  
24 of 1990 (42 U.S.C. 12101 et seq.), section  
25 504 of the Rehabilitation Act of 1973 (29

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

7 “(D) WRITTEN NOTICE.—Each plan year,  
8 group health plans, including with respect to  
9 group health insurance coverage offered in con-  
10 nection with a group health plan, shall provide  
11 to each participant or beneficiary written notice  
12 informing the participant or beneficiary of the  
13 requirement for entities providing pharmacy  
14 benefit management services on behalf of the  
15 group health plan or health insurance issuer of-  
16 fering group health insurance coverage to sub-  
17 mit reports to group health plans under para-  
18 graph (1), as applicable, which may include in-  
19 corporating such notification in plan documents  
20 provided to the participant or beneficiary, or  
21 providing individual notification.

22 “(E) LIMITATION TO BUSINESS ASSOCI-  
23 ATES.—A group health plan receiving a report  
24 under paragraph (1) may disclose such informa-  
25 tion only to the entity from which the report

1 was received or to that entity's business associ-  
2 ates as defined in section 160.103 of title 45,  
3 Code of Federal Regulations (or successor regu-  
4 lations) or as permitted by the HIPAA privacy  
5 regulations.

6 “(F) CLARIFICATION REGARDING PUBLIC  
7 DISCLOSURE OF INFORMATION.—Nothing in  
8 this section shall prevent an entity providing  
9 pharmacy benefit management services on be-  
10 half of a group health plan or health insurance  
11 issuer offering group health insurance coverage,  
12 from placing reasonable restrictions on the pub-  
13 lic disclosure of the information contained in a  
14 report described in paragraph (1), except that  
15 such plan, issuer, or entity may not—

16 “(i) restrict disclosure of such report  
17 to the Department of Health and Human  
18 Services, the Department of Labor, or the  
19 Department of the Treasury; or

20 “(ii) prevent disclosure for the pur-  
21 poses of subsection (c), or any other public  
22 disclosure requirement under this section.

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

1 required with respect to any group health plan  
2 established by a plan sponsor that is, or is af-  
3 filiated with, a drug manufacturer, drug whole-  
4 saler, or other direct participant in the drug  
5 supply chain, in order to prevent anti-competi-  
6 tive behavior.

7 “(5) STANDARD FORMAT AND REGULATIONS.—

8 “(A) IN GENERAL.—Not later than 18  
9 months after the date of enactment of this sec-  
10 tion, the Secretary shall specify through rule-  
11 making a standard format for entities providing  
12 pharmacy benefit management services on be-  
13 half of group health plans and health insurance  
14 issuers offering group health insurance cov-  
15 erage, to submit reports required under para-  
16 graph (1).

17 “(B) ADDITIONAL REGULATIONS.—Not  
18 later than 18 months after the date of enact-  
19 ment of this section, the Secretary shall,  
20 through rulemaking, promulgate any other final  
21 regulations necessary to implement the require-  
22 ments of this section. In promulgating such  
23 regulations, the Secretary shall, to the extent  
24 practicable, align the reporting requirements

1           under this section with the reporting require-  
2           ments under section 725.

3           “(c) REQUIREMENT TO PROVIDE INFORMATION TO  
4 PARTICIPANTS OR BENEFICIARIES.—A group health plan,  
5 including with respect to group health insurance coverage  
6 offered in connection with a group health plan, upon re-  
7 quest of a participant or beneficiary, shall provide to such  
8 participant or beneficiary—

9           “(1) the summary document described in sub-  
10          section (b)(2)(B)(ii); and

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

14          “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
15          tion shall be construed to permit a health insurance issuer,  
16          group health plan, entity providing pharmacy benefit man-  
17          agement services on behalf of a group health plan or  
18          health insurance issuer, or other entity to restrict dislo-  
19          sure to, or otherwise limit the access of, the Secretary to  
20          a report described in subsection (b)(1) or information re-  
21          lated to compliance with subsections (a), (b), or (c) of this  
22          section or section 502(c)(13) by such issuer, plan, or enti-  
23          ty.

24          “(e) DEFINITIONS.—In this section:

1           “(1) APPLICABLE ENTITY.—The term ‘applica-  
2           ble entity’ means—

3                   “(A) an applicable group purchasing orga-  
4                   nization, drug manufacturer, distributor, whole-  
5                   saler, rebate aggregator (or other purchasing  
6                   entity designed to aggregate rebates), or associ-  
7                   ated third party;

8                   “(B) any subsidiary, parent, affiliate, or  
9                   subcontractor of a group health plan, health in-  
10                  surance issuer, entity that provides pharmacy  
11                  benefit management services on behalf of such  
12                  a plan or issuer, or any entity described in sub-  
13                  paragraph (A); or

14                  “(C) such other entity as the Secretary  
15                  may specify through rulemaking.

16           “(2) APPLICABLE GROUP PURCHASING ORGANI-  
17           ZATION.—The term ‘applicable group purchasing or-  
18           ganization’ means a group purchasing organization  
19           that is affiliated with or under common ownership  
20           with an entity providing pharmacy benefit manage-  
21           ment services.

22           “(3) CONTRACTED COMPENSATION.—The term  
23           ‘contracted compensation’ means the sum of any in-  
24           gredient cost and dispensing fee for a drug (inclusive  
25           of the out-of-pocket costs to the participant or bene-

1        ficiary), or another analogous compensation struc-  
2        ture that the Secretary may specify through regula-  
3        tions.

4            “(4) GROSS SPENDING.—The term ‘gross  
5        spending’, with respect to prescription drug benefits  
6        under a group health plan or health insurance cov-  
7        erage, means the amount spent by a group health  
8        plan or health insurance issuer on prescription drug  
9        benefits, calculated before the application of rebates,  
10       fees, alternative discounts, or other remuneration.

11           “(5) NET SPENDING.—The term ‘net spending’,  
12        with respect to prescription drug benefits under a  
13        group health plan or health insurance coverage,  
14        means the amount spent by a group health plan or  
15        health insurance issuer on prescription drug bene-  
16        fits, calculated after the application of rebates, fees,  
17        alternative discounts, or other remuneration.

18           “(6) PLAN SPONSOR.—The term ‘plan sponsor’  
19        has the meaning given such term in section  
20        3(16)(B).

21           “(7) REMUNERATION.—The term ‘remunera-  
22        tion’ has the meaning given such term by the Sec-  
23        retary through rulemaking, which shall be reeval-  
24        ated by the Secretary every 5 years.



1 (i) in subsection (a)(6), by striking  
2 “or (9)” and inserting “(9), or (13)”;

3 (ii) in subsection (b)(3), by striking  
4 “under subsection (c)(9)” and inserting  
5 “under paragraphs (9) and (13) of sub-  
6 section (c)”;

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

9 “(13) SECRETARIAL ENFORCEMENT AUTHORITY  
10 RELATING TO OVERSIGHT OF PHARMACY BENEFIT  
11 MANAGEMENT SERVICES.—

12 “(A) FAILURE TO PROVIDE INFORMA-  
13 TION.—The Secretary may impose a penalty  
14 against a plan administrator of a group health  
15 plan, a health insurance issuer offering group  
16 health insurance coverage, or an entity pro-  
17 viding pharmacy benefit management services  
18 on behalf of such a plan or issuer, or an appli-  
19 cable entity (as defined in section 726(f)) that  
20 violates section 726(a); an entity providing  
21 pharmacy benefit management services on be-  
22 half of such a plan or issuer that fails to pro-  
23 vide the information required under section  
24 726(b); or any person who causes a group  
25 health plan to fail to provide the information

1 required under section 726(e), in the amount of  
2 \$10,000 for each day during which such viola-  
3 tion continues or such information is not dis-  
4 closed or reported.

5 “(B) FALSE INFORMATION.—The Sec-  
6 retary may impose a penalty against a plan ad-  
7 ministrator of a group health plan, a health in-  
8 surance issuer offering group health insurance  
9 coverage, an entity providing pharmacy benefit  
10 management services, or an applicable entity  
11 (as defined in section 726(f)) that knowingly  
12 provides false information under section 726, in  
13 an amount not to exceed \$100,000 for each  
14 item of false information. Such penalty shall be  
15 in addition to other penalties as may be pre-  
16 scribed by law.

17 “(C) WAIVERS.—The Secretary may waive  
18 penalties under subparagraph (A), or extend  
19 the period of time for compliance with a re-  
20 quirement of this section, for an entity in viola-  
21 tion of section 726 that has made a good-faith  
22 effort to comply with the requirements of sec-  
23 tion 726.”; and

1 (C) in section 732(a) (29 U.S.C.  
2 1191a(a)), by striking “section 711” and in-  
3 serting “sections 711 and 726”.

4 (2) CLERICAL AMENDMENT.—The table of con-  
5 tents in section 1 of the Employee Retirement In-  
6 come Security Act of 1974 (29 U.S.C. 1001 et seq.)  
7 is amended by inserting after the item relating to  
8 section 725 the following new item:

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

9 (c) INTERNAL REVENUE CODE OF 1986.—

10 (1) IN GENERAL.—Chapter 100 of the Internal  
11 Revenue Code of 1986 is amended by adding at the  
12 end of subchapter B the following:

13 **“SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-**  
14 **MACY BENEFIT MANAGEMENT SERVICES.**

15 “(a) IN GENERAL.—For plan years beginning on or  
16 after the date that is 30 months after the date of enact-  
17 ment of this section (referred to in this subsection and  
18 subsection (b) as the ‘effective date’), a group health plan,  
19 or an entity providing pharmacy benefit management serv-  
20 ices on behalf of such a plan, shall not enter into a con-  
21 tract, including an extension or renewal of a contract, en-  
22 tered into on or after the effective date, with an applicable  
23 entity unless such applicable entity agrees to—

1           “(1) not limit or delay the disclosure of infor-  
2           mation to the group health plan in such a manner  
3           that prevents an entity providing pharmacy benefit  
4           management services on behalf of a group health  
5           plan from making the reports described in sub-  
6           section (b); and

7           “(2) provide the entity providing pharmacy ben-  
8           efit management services on behalf of a group health  
9           plan relevant information necessary to make the re-  
10          ports described in subsection (b).

11         “(b) REPORTS.—

12           “(1) IN GENERAL.—For plan years beginning  
13           on or after the effective date, in the case of any con-  
14           tract between a group health plan and an entity pro-  
15           viding pharmacy benefit management services on be-  
16           half of such plan, including an extension or renewal  
17           of such a contract, entered into on or after the effec-  
18           tive date, the entity providing pharmacy benefit  
19           management services on behalf of such a group  
20           health plan, not less frequently than every 6 months  
21           (or, at the request of a group health plan, not less  
22           frequently than quarterly, and under the same con-  
23           ditions, terms, and cost of the semiannual report  
24           under this subsection), shall submit to the group  
25           health plan a report in accordance with this section.

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

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

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

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

20 “(I) the contracted compensation  
21 paid by the group health plan for each  
22 covered drug (identified by the Na-  
23 tional Drug Code) to the entity pro-  
24 viding pharmacy benefit management

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

3 “(II) the contracted compensa-  
4 tion paid to the pharmacy, by any en-  
5 tity providing pharmacy benefit man-  
6 agement services or other applicable  
7 entity on behalf of the group health  
8 plan, for each covered drug (identified  
9 by the National Drug Code);

10 “(III) for each such claim, the  
11 difference between the amount paid  
12 under subclause (I) and the amount  
13 paid under subclause (II);

14 “(IV) the proprietary name, es-  
15 tablished name or proper name, and  
16 National Drug Code;

17 “(V) for each claim for the drug  
18 (including original prescriptions and  
19 refills) and for each dosage unit of the  
20 drug for which a claim was filed, the  
21 type of dispensing channel used to  
22 furnish the drug, including retail, mail  
23 order, or specialty pharmacy;

24 “(VI) with respect to each drug  
25 dispensed, for each type of dispensing

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

3 “(aa) whether such drug is a  
4 brand name drug or a generic  
5 drug, and—

6 “(AA) in the case of a  
7 brand name drug, the whole-  
8 sale acquisition cost, listed  
9 as cost per days supply and  
10 cost per dosage unit, on the  
11 date such drug was dis-  
12 pensed; and

13 “(BB) in the case of a  
14 generic drug, the average  
15 wholesale price, listed as  
16 cost per days supply and  
17 cost per dosage unit, on the  
18 date such drug was dis-  
19 pensed; and

20 “(bb) the total number of—

21 “(AA) prescription  
22 claims (including original  
23 prescriptions and refills);

24 “(BB) participants and  
25 beneficiaries for whom a

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

4 “(CC) dosage units and  
5 dosage units per fill of such  
6 drug; and

7 “(DD) days supply of  
8 such drug per fill;

9 “(VII) the net price per course of  
10 treatment or single fill, such as a 30-  
11 day supply or 90-day supply to the  
12 plan after rebates, fees, alternative  
13 discounts, or other remuneration re-  
14 ceived from applicable entities;

15 “(VIII) the total amount of out-  
16 of-pocket spending by participants  
17 and beneficiaries on such drug, in-  
18 cluding spending through copayments,  
19 coinsurance, and deductibles, but not  
20 including any amounts spent by par-  
21 ticipants and beneficiaries on drugs  
22 not covered under the plan, or for  
23 which no claim is submitted under the  
24 plan;

1           “(IX) the total net spending on  
2 the drug;

3           “(X) the total amount received,  
4 or expected to be received, by the plan  
5 from any applicable entity in rebates,  
6 fees, alternative discounts, or other  
7 remuneration;

8           “(XI) the total amount received,  
9 or expected to be received, by the enti-  
10 ty providing pharmacy benefit man-  
11 agement services, from applicable en-  
12 tities, in rebates, fees, alternative dis-  
13 counts, or other remuneration from  
14 such entities—

15           “(aa) for claims incurred  
16 during the reporting period; and

17           “(bb) that is related to utili-  
18 zation of such drug or spending  
19 on such drug; and

20           “(XII) to the extent feasible, in-  
21 formation on the total amount of re-  
22 munerated for such drug, including  
23 copayment assistance dollars paid, co-  
24 payment cards applied, or other dis-  
25 counts provided by each drug manu-

1            factorer (or entity administering co-  
2            payment assistance on behalf of such  
3            drug manufacturer), to the partici-  
4            pants and beneficiaries enrolled in  
5            such plan;

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

11                   “(I) the total gross spending on  
12                   drugs in such class before rebates,  
13                   price concessions, alternative dis-  
14                   counts, or other remuneration from  
15                   applicable entities;

16                   “(II) the net spending in such  
17                   class after such rebates, price conces-  
18                   sions, alternative discounts, or other  
19                   remuneration from applicable entities;

20                   “(III) the total amount received,  
21                   or expected to be received, by the enti-  
22                   ty providing pharmacy benefit man-  
23                   agement services, from applicable en-  
24                   tities, in rebates, fees, alternative dis-

1 counts, or other remuneration from  
2 such entities—

3 “(aa) for claims incurred  
4 during the reporting period; and

5 “(bb) that is related to utili-  
6 zation of drugs or drug spending;

7 “(IV) the average net spending  
8 per 30-day supply and per 90-day  
9 supply by the plan and its partici-  
10 pants and beneficiaries, among all  
11 drugs within the therapeutic class for  
12 which a claim was filed during the re-  
13 porting period;

14 “(V) the number of participants  
15 and beneficiaries who filled a prescrip-  
16 tion for a drug in such class, includ-  
17 ing the National Drug Code for each  
18 such drug;

19 “(VI) if applicable, a description  
20 of the formulary tiers and utilization  
21 mechanisms (such as prior authoriza-  
22 tion or step therapy) employed for  
23 drugs in that class; and

24 “(VII) the total out-of-pocket  
25 spending under the plan by partici-

1 pants and beneficiaries, including  
2 spending through copayments, coin-  
3 surance, and deductibles, but not in-  
4 cluding any amounts spent by partici-  
5 pants and beneficiaries on drugs not  
6 covered under the plan or for which  
7 no claim is submitted under the plan;  
8 “(iii) with respect to any drug for  
9 which gross spending under the group  
10 health plan exceeded \$10,000 during the  
11 reporting period or, in the case that gross  
12 spending under the group health plan ex-  
13 ceeded \$10,000 during the reporting pe-  
14 riod with respect to fewer than 50 drugs,  
15 with respect to the 50 prescription drugs  
16 with the highest spending during the re-  
17 porting period—

18 “(I) a list of all other drugs in  
19 the same therapeutic class as such  
20 drug;

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

1           retary, in consultation with stake-  
2           holders; and

3                   “(III) any change in formulary  
4           placement compared to the prior plan  
5           year; and

6                   “(iv) in the case that such plan (or an  
7           entity providing pharmacy benefit manage-  
8           ment services on behalf of such plan) has  
9           an affiliated pharmacy or pharmacy under  
10          common ownership, including mandatory  
11          mail and specialty home delivery programs,  
12          retail and mail auto-refill programs, and  
13          cost sharing assistance incentives funded  
14          by an entity providing pharmacy benefit  
15          services—

16                   “(I) an explanation of any ben-  
17          efit design parameters that encourage  
18          or require participants and bene-  
19          ficiaries in the plan to fill prescrip-  
20          tions at mail order, specialty, or retail  
21          pharmacies;

22                   “(II) the percentage of total pre-  
23          scriptions dispensed by such phar-  
24          macies to participants or beneficiaries  
25          in such plan; and

1           “(III) a list of all drugs dis-  
2           pensed by such pharmacies to partici-  
3           pants or beneficiaries enrolled in such  
4           plan, and, with respect to each drug  
5           dispensed—

6                   “(aa) the amount charged,  
7                   per dosage unit, per 30-day sup-  
8                   ply, or per 90-day supply (as ap-  
9                   plicable) to the plan, and to par-  
10                  ticipants and beneficiaries;

11                  “(bb) the median amount  
12                  charged to such plan, and the  
13                  interquartile range of the costs,  
14                  per dosage unit, per 30-day sup-  
15                  ply, and per 90-day supply, in-  
16                  cluding amounts paid by the par-  
17                  ticipants and beneficiaries, when  
18                  the same drug is dispensed by  
19                  other pharmacies that are not af-  
20                  filiated with or under common  
21                  ownership with the entity and  
22                  that are included in the phar-  
23                  macy network of such plan;

24                  “(cc) the lowest cost per  
25                  dosage unit, per 30-day supply

1 and per 90-day supply, for each  
2 such drug, including amounts  
3 charged to the plan and to par-  
4 ticipants and beneficiaries, that  
5 is available from any pharmacy  
6 included in the network of such  
7 plan; and

8 “(dd) the net acquisition  
9 cost per dosage unit, per 30-day  
10 supply, and per 90-day supply, if  
11 such drug is subject to a max-  
12 imum price discount; and

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

17 “(i) a summary document for the  
18 group health plan that includes such infor-  
19 mation described in clauses (i) through (iv)  
20 of subparagraph (A), as specified by the  
21 Secretary through guidance, program in-  
22 struction, or otherwise (with no require-  
23 ment of notice and comment rulemaking),  
24 that the Secretary determines useful to  
25 group health plans for purposes of select-

1 ing pharmacy benefit management serv-  
2 ices, such as an estimated net price to  
3 group health plan and participant or bene-  
4 ficiary, a cost per claim, the fee structure  
5 or reimbursement model, and estimated  
6 cost per participant or beneficiary;

7 “(ii) a summary document for plans  
8 to provide to participants and beneficiaries,  
9 which shall be made available to partici-  
10 pants or beneficiaries upon request to their  
11 group health plan, that—

12 “(I) contains such information  
13 described in clauses (iii), (iv), (v), and  
14 (vi), as applicable, as specified by the  
15 Secretary through guidance, program  
16 instruction, or otherwise (with no re-  
17 quirement of notice and comment  
18 rulemaking) that the Secretary deter-  
19 mines useful to participants or bene-  
20 ficiaries in better understanding the  
21 plan or benefits under such plan;

22 “(II) contains only aggregate in-  
23 formation; and

24 “(III) states that participants  
25 and beneficiaries may request specific,

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

4 “(iii) with respect to drugs covered by  
5 such plan during such reporting period—

6 “(I) the total net spending by the  
7 plan for all such drugs;

8 “(II) the total amount received,  
9 or expected to be received, by the plan  
10 from any applicable entity in rebates,  
11 fees, alternative discounts, or other  
12 remuneration; and

13 “(III) to the extent feasible, in-  
14 formation on the total amount of re-  
15 munerated for such drugs, including  
16 copayment assistance dollars paid, co-  
17 payment cards applied, or other dis-  
18 counts provided by each drug manu-  
19 facturer (or entity administering co-  
20 payment assistance on behalf of such  
21 drug manufacturer) to participants  
22 and beneficiaries;

23 “(iv) amounts paid directly or indi-  
24 rectly in rebates, fees, or any other type of  
25 compensation (as defined in section

1 408(b)(2)(B)(ii)(dd)(AA) of the Employee  
2 Retirement Income Security Act (29  
3 U.S.C. 1108(b)(2)(B)(ii)(dd)(AA))) to bro-  
4 kerage firms, brokers, consultants, advi-  
5 sors, or any other individual or firm, for—

6 “(I) the referral of the group  
7 health plan’s business to an entity  
8 providing pharmacy benefit manage-  
9 ment services, including the identity  
10 of the recipient of such amounts;

11 “(II) consideration of the entity  
12 providing pharmacy benefit manage-  
13 ment services by the group health  
14 plan; or

15 “(III) the retention of the entity  
16 by the group health plan;

17 “(v) an explanation of any benefit de-  
18 sign parameters that encourage or require  
19 participants and beneficiaries in such plan  
20 to fill prescriptions at mail order, specialty,  
21 or retail pharmacies that are affiliated with  
22 or under common ownership with the enti-  
23 ty providing pharmacy benefit management  
24 services under such plan, including manda-  
25 tory mail and specialty home delivery pro-

1           grams, retail and mail auto-refill pro-  
2           grams, and cost-sharing assistance incen-  
3           tives directly or indirectly funded by such  
4           entity; and

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

7           “(3) OPT-IN FOR GROUP HEALTH INSURANCE  
8           COVERAGE OFFERED BY A SPECIFIED LARGE EM-  
9           PLOYER OR THAT IS A SPECIFIED LARGE PLAN.—In  
10          the case of group health insurance coverage offered  
11          in connection with a group health plan that is of-  
12          fered by a specified large employer or is a specified  
13          large plan, such group health plan may, on an an-  
14          nual basis, for plan years beginning on or after the  
15          date that is 30 months after the date of enactment  
16          of this section, elect to require an entity providing  
17          pharmacy benefit management services on behalf of  
18          the health insurance issuer to submit to such group  
19          health plan a report that includes all of the informa-  
20          tion described in paragraph (2)(A), in addition to  
21          the information described in paragraph (2)(B).

22                   “(4) PRIVACY REQUIREMENTS.—

23                           “(A) IN GENERAL.—An entity providing  
24                           pharmacy benefit management services on be-  
25                           half of a group health plan shall report infor-

1           mation under paragraph (1) in a manner con-  
2           sistent with the privacy regulations promul-  
3           gated under section 13402(a) of the Health In-  
4           formation Technology for Economic and Clin-  
5           ical Health Act (42 U.S.C. 17932(a)) and con-  
6           sistent with the privacy regulations promul-  
7           gated under the Health Insurance Portability  
8           and Accountability Act of 1996 in part 160 and  
9           subparts A and E of part 164 of title 45, Code  
10          of Federal Regulations (or successor regula-  
11          tions) (referred to in this paragraph as the  
12          ‘HIPAA privacy regulations’) and shall restrict  
13          the use and disclosure of such information ac-  
14          cording to such privacy regulations and such  
15          HIPAA privacy regulations.

16                 “(B) ADDITIONAL REQUIREMENTS.—

17                         “(i) IN GENERAL.—An entity pro-  
18                         viding pharmacy benefit management serv-  
19                         ices on behalf of a group health plan that  
20                         submits a report under paragraph (1) shall  
21                         ensure that such report contains only sum-  
22                         mary health information, as defined in sec-  
23                         tion 164.504(a) of title 45, Code of Fed-  
24                         eral Regulations (or successor regulations).

1           “(ii) RESTRICTIONS.—In carrying out  
2 this subsection, a group health plan shall  
3 comply with section 164.504(f) of title 45,  
4 Code of Federal Regulations (or a suc-  
5 cessor regulation), and a plan sponsor shall  
6 act in accordance with the terms of the  
7 agreement described in such section.

8           “(C) RULE OF CONSTRUCTION.—

9           “(i) Nothing in this section shall be  
10 construed to modify the requirements for  
11 the creation, receipt, maintenance, or  
12 transmission of protected health informa-  
13 tion under the HIPAA privacy regulations.

14           “(ii) Nothing in this section shall be  
15 construed to affect the application of any  
16 Federal or State privacy or civil rights law,  
17 including the HIPAA privacy regulations,  
18 the Genetic Information Nondiscrimination  
19 Act of 2008 (Public Law 110–233) (in-  
20 cluding the amendments made by such  
21 Act), the Americans with Disabilities Act  
22 of 1990 (42 U.S.C. 12101 et seq.), section  
23 504 of the Rehabilitation Act of 1973 (29  
24 U.S.C. 794), section 1557 of the Patient  
25 Protection and Affordable Care Act (42

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

5 “(D) WRITTEN NOTICE.—Each plan year,  
6 group health plans shall provide to each partici-  
7 pant or beneficiary written notice informing the  
8 participant or beneficiary of the requirement for  
9 entities providing pharmacy benefit manage-  
10 ment services on behalf of the group health  
11 plan to submit reports to group health plans  
12 under paragraph (1), as applicable, which may  
13 include incorporating such notification in plan  
14 documents provided to the participant or bene-  
15 ficiary, or providing individual notification.

16 “(E) LIMITATION TO BUSINESS ASSOCI-  
17 ATES.—A group health plan receiving a report  
18 under paragraph (1) may disclose such informa-  
19 tion only to the entity from which the report  
20 was received or to that entity’s business associ-  
21 ates as defined in section 160.103 of title 45,  
22 Code of Federal Regulations (or successor regu-  
23 lations) or as permitted by the HIPAA privacy  
24 regulations.

1           “(F) CLARIFICATION REGARDING PUBLIC  
2 DISCLOSURE OF INFORMATION.—Nothing in  
3 this section shall prevent an entity providing  
4 pharmacy benefit management services on be-  
5 half of a group health plan, from placing rea-  
6 sonable restrictions on the public disclosure of  
7 the information contained in a report described  
8 in paragraph (1), except that such plan or enti-  
9 ty may not—

10           “(i) restrict disclosure of such report  
11 to the Department of Health and Human  
12 Services, the Department of Labor, or the  
13 Department of the Treasury; or

14           “(ii) prevent disclosure for the pur-  
15 poses of subsection (c), or any other public  
16 disclosure requirement under this section.

17           “(G) LIMITED FORM OF REPORT.—The  
18 Secretary shall define through rulemaking a  
19 limited form of the report under paragraph (1)  
20 required with respect to any group health plan  
21 established by a plan sponsor that is, or is af-  
22 filiated with, a drug manufacturer, drug whole-  
23 saler, or other direct participant in the drug  
24 supply chain, in order to prevent anti-competi-  
25 tive behavior.

1 “(5) STANDARD FORMAT AND REGULATIONS.—

2 “(A) IN GENERAL.—Not later than 18  
3 months after the date of enactment of this sec-  
4 tion, the Secretary shall specify through rule-  
5 making a standard format for entities providing  
6 pharmacy benefit management services on be-  
7 half of group health plans, to submit reports re-  
8 quired under paragraph (1).

9 “(B) ADDITIONAL REGULATIONS.—Not  
10 later than 18 months after the date of enact-  
11 ment of this section, the Secretary shall,  
12 through rulemaking, promulgate any other final  
13 regulations necessary to implement the require-  
14 ments of this section. In promulgating such  
15 regulations, the Secretary shall, to the extent  
16 practicable, align the reporting requirements  
17 under this section with the reporting require-  
18 ments under section 9825.

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

23 “(1) the summary document described in sub-  
24 section (b)(2)(B)(ii); and

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

4           “(d) RULE OF CONSTRUCTION.—Nothing in this sec-  
5           tion shall be construed to permit a health insurance issuer,  
6           group health plan, entity providing pharmacy benefit man-  
7           agement services on behalf of a group health plan or  
8           health insurance issuer, or other entity to restrict dislo-  
9           sure to, or otherwise limit the access of, the Secretary to  
10          a report described in subsection (b)(1) or information re-  
11          lated to compliance with subsections (a), (b), or (c) of this  
12          section or section 4980D(g) by such issuer, plan, or entity.

13          “(e) DEFINITIONS.—In this section:

14                 “(1) APPLICABLE ENTITY.—The term ‘applica-  
15                 ble entity’ means—

16                         “(A) an applicable group purchasing orga-  
17                         nization, drug manufacturer, distributor, whole-  
18                         saler, rebate aggregator (or other purchasing  
19                         entity designed to aggregate rebates), or associ-  
20                         ated third party;

21                         “(B) any subsidiary, parent, affiliate, or  
22                         subcontractor of a group health plan, health in-  
23                         surance issuer, entity that provides pharmacy  
24                         benefit management services on behalf of such

1 a plan or issuer, or any entity described in sub-  
2 paragraph (A); or

3 “(C) such other entity as the Secretary  
4 may specify through rulemaking.

5 “(2) APPLICABLE GROUP PURCHASING ORGANI-  
6 ZATION.—The term ‘applicable group purchasing or-  
7 ganization’ means a group purchasing organization  
8 that is affiliated with or under common ownership  
9 with an entity providing pharmacy benefit manage-  
10 ment services.

11 “(3) CONTRACTED COMPENSATION.—The term  
12 ‘contracted compensation’ means the sum of any in-  
13 gredient cost and dispensing fee for a drug (inclusive  
14 of the out-of-pocket costs to the participant or bene-  
15 ficiary), or another analogous compensation struc-  
16 ture that the Secretary may specify through regula-  
17 tions.

18 “(4) GROSS SPENDING.—The term ‘gross  
19 spending’, with respect to prescription drug benefits  
20 under a group health plan, means the amount spent  
21 by a group health plan on prescription drug benefits,  
22 calculated before the application of rebates, fees, al-  
23 ternative discounts, or other remuneration.

24 “(5) NET SPENDING.—The term ‘net spending’,  
25 with respect to prescription drug benefits under a

1 group health plan, means the amount spent by a  
2 group health plan on prescription drug benefits, cal-  
3 culated after the application of rebates, fees, alter-  
4 native discounts, or other remuneration.

5 “(6) PLAN SPONSOR.—The term ‘plan sponsor’  
6 has the meaning given such term in section 3(16)(B)  
7 of the Employee Retirement Income Security Act of  
8 1974 (29 U.S.C. 1002(16)(B)).

9 “(7) REMUNERATION.—The term ‘remunera-  
10 tion’ has the meaning given such term by the Sec-  
11 retary, through rulemaking, which shall be reevalu-  
12 ated by the Secretary every 5 years.

13 “(8) SPECIFIED LARGE EMPLOYER.—The term  
14 ‘specified large employer’ means, in connection with  
15 a group health plan established or maintained by a  
16 single employer, with respect to a calendar year or  
17 a plan year, as applicable, an employer who em-  
18 ployed an average of at least 100 employees on busi-  
19 ness days during the preceding calendar year or plan  
20 year and who employs at least 1 employee on the  
21 first day of the calendar year or plan year.

22 “(9) SPECIFIED LARGE PLAN.—The term ‘spec-  
23 ified large plan’ means a group health plan estab-  
24 lished or maintained by a plan sponsor described in  
25 clause (ii) or (iii) of section 3(16)(B) of the Em-

1        ployee Retirement Income Security Act of 1974 (29  
2        U.S.C. 1002(16)(B)) that had an average of at least  
3        100 participants on business days during the pre-  
4        ceding calendar year or plan year, as applicable.

5            “(10) WHOLESALE ACQUISITION COST.—The  
6        term ‘wholesale acquisition cost’ has the meaning  
7        given such term in section 1847A(c)(6)(B) of the  
8        Social Security Act (42 U.S.C. 1395w-  
9        3a(c)(6)(B)).”.

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

15           (3) ENFORCEMENT.—Section 4980D of the In-  
16        ternal Revenue Code of 1986 is amended by adding  
17        at the end the following new subsection:

18           “(g) APPLICATION TO REQUIREMENTS IMPOSED ON  
19        CERTAIN ENTITIES PROVIDING PHARMACY BENEFIT  
20        MANAGEMENT SERVICES.—In the case of any requirement  
21        under section 9826 that applies with respect to an entity  
22        providing pharmacy benefit management services on be-  
23        half of a group health plan, any reference in this section  
24        to such group health plan (and the reference in subsection

1 (e)(1) to the employer) shall be treated as including a ref-  
2 erence to such entity.”.

3 (4) CLERICAL AMENDMENT.—The table of sec-  
4 tions for subchapter B of chapter 100 of the Inter-  
5 nal Revenue Code of 1986 is amended by adding at  
6 the end the following new item:

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

7 **SEC. 202. FUNDING COST SHARING REDUCTION PAYMENTS.**

8 Section 1402 of the Patient Protection and Afford-  
9 able Care Act (42 U.S.C. 18071) is amended by adding  
10 at the end the following new subsection:

11 “(h) FUNDING.—

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

17 “(2) LIMITATION.—

18 “(A) IN GENERAL.—The amounts appro-  
19 priated under paragraph (1) may not be used  
20 for purposes of making payments under this  
21 section for a qualified health plan that provides  
22 health benefit coverage that includes coverage  
23 of abortion.

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

○