

116TH CONGRESS
1ST SESSION

H. R. 5304

To amend title XXVII of the Public Health Service Act to require health plan oversight of pharmacy benefit manager services, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 4, 2019

Mr. SCHRADER (for himself and Mr. GLANFORTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XXVII of the Public Health Service Act to require health plan oversight of pharmacy benefit manager services, and for other purposes.

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 “PBM Transparency
5 in Prescription Drug Costs Act”.

6 **SEC. 2. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT**
7 **MANAGER SERVICES.**

8 Subpart II of part A of title XXVII of the Public
9 Health Service Act (42 U.S.C. 300gg–11 et seq.) is
10 amended by adding at the end the following:

1 **“SEC. 2729A. HEALTH PLAN OVERSIGHT OF PHARMACY**
2 **BENEFIT MANAGER SERVICES.**

3 “(a) IN GENERAL.—A group health plan or health
4 insurance issuer offering group or individual health insur-
5 ance coverage or an entity or subsidiary providing phar-
6 macy benefits management services shall not enter into
7 a contract with a drug manufacturer, distributor, whole-
8 saler, subcontractor, rebate aggregator, or any associated
9 third party that limits the disclosure of information to
10 plan sponsors in such a manner that prevents the plan
11 or coverage, or an entity or subsidiary providing pharmacy
12 benefits management services on behalf of a plan or cov-
13 erage from making the reports described in subsection (b).

14 “(b) REPORTS TO GROUP PLAN SPONSORS.—

15 “(1) IN GENERAL.—Beginning with the first
16 plan year that begins after the date of enactment of
17 this section, not less frequently than once every six
18 months, a health insurance issuer offering group
19 health insurance coverage or an entity providing
20 pharmacy benefits management services on behalf of
21 a group health plan shall submit to the self-funded
22 group health plan and at the request of any other
23 group health plan a report in accordance with this
24 subsection and make such report available to the
25 plan sponsor in a machine-readable format. Each

1 such report shall include, with respect to the applica-
2 ble group health plan or health insurance coverage—

3 “(A) information collected from drug man-
4 ufacturers by such issuer or entity on the total
5 amount of copayment assistance dollars paid, or
6 copayment cards applied, that were funded by
7 the drug manufacturer with respect to the en-
8 rollees in such plan or coverage;

9 “(B) a list of each covered drug dispensed
10 during the reporting period, including, with re-
11 spect to each such drug during the reporting
12 period—

13 “(i) the brand name, chemical entity,
14 and National Drug Code;

15 “(ii) the number of enrollees for
16 whom the drug was filled during the plan
17 year, the total number of prescription fills
18 for the drug (including original prescrip-
19 tions and refills), and the total number of
20 dosage units of the drug dispensed across
21 the plan year, including whether the dis-
22 pensing channel was by retail, mail order,
23 or specialty pharmacy;

24 “(iii) the wholesale acquisition cost,
25 listed as cost per days supply and cost per

1 pill, or in the case of a drug in another
2 form, per dose;

3 “(iv) the total out-of-pocket spending
4 by enrollees on such drug, including en-
5 rollee spending through copayments, coin-
6 surance, and deductibles; and

7 “(v) for any drug for which gross
8 spending of the group health plan or
9 health insurance coverage exceeded
10 \$10,000 during the reporting period—

11 “(I) a list of all other available
12 drugs in the same therapeutic cat-
13 egory or class, including brand name
14 drugs and biological products and ge-
15 neric drugs or biosimilar biological
16 products that are in the same thera-
17 peutic category or class; and

18 “(II) the rationale for preferred
19 formulary placement of a particular
20 drug or drugs in that therapeutic cat-
21 egory or class;

22 “(C) a list of each therapeutic category or
23 class of drugs that were dispensed under the
24 health plan or health insurance coverage during
25 the reporting period, and, with respect to each

1 such therapeutic category or class of drugs,
2 during the reporting period—

3 “(i) total gross spending by the plan,
4 before manufacturer rebates, fees, or other
5 manufacturer remuneration;

6 “(ii) the number of enrollees who
7 filled a prescription for a drug in that cat-
8 egory or class;

9 “(iii) if applicable to that category or
10 class, a description of the formulary tiers
11 and utilization mechanisms (such as prior
12 authorization or step therapy) employed
13 for drugs in that category or class;

14 “(iv) the total out-of-pocket spending
15 by enrollees, including enrollee spending
16 through copayments, coinsurance, and
17 deductibles; and

18 “(v) for each therapeutic category or
19 class under which three or more drugs are
20 marketed and available—

21 “(I) the amount received, or ex-
22 pected to be received, from drug man-
23 ufacturers in rebates, fees, alternative
24 discounts, or other remuneration—

1 “(aa) to be paid by drug
2 manufacturers for claims in-
3 curred during the reporting pe-
4 riod; or

5 “(bb) that is related to utili-
6 zation of drugs, in such thera-
7 peutic category or class;

8 “(II) the total net spending by
9 the health plan or health insurance
10 coverage on that category or class of
11 drugs; and

12 “(III) the net price per dosage
13 unit or course of treatment incurred
14 by the health plan or health insurance
15 coverage and its enrollees, after man-
16 ufacturer rebates, fees, and other re-
17 muneration for drugs dispensed within
18 such therapeutic category or class
19 during the reporting period;

20 “(D) total gross spending on prescription
21 drugs by the plan or coverage during the re-
22 porting period, before rebates and other manu-
23 facturer fees or remuneration;

24 “(E) total amount received, or expected to
25 be received, by the health plan or health insur-

1 ance coverage in drug manufacturer rebates,
2 fees, alternative discounts, and all other remun-
3 eration received from the manufacturer or any
4 third party related to utilization of drug or
5 drug spending under that health plan or health
6 insurance coverage during the reporting period;

7 “(F) the total net spending on prescription
8 drugs by the health plan or health insurance
9 coverage during the reporting period; and

10 “(G) amounts paid directly or indirectly in
11 rebates, fees, or any other type of remuneration
12 to brokers, consultants, advisors, or any other
13 individual or firm who referred the group health
14 plan’s or health insurance issuer’s business to
15 the pharmacy benefit manager.

16 “(2) PRIVACY REQUIREMENTS.—Health insur-
17 ance issuers offering group health insurance cov-
18 erage and entities providing pharmacy benefits man-
19 agement services on behalf of a group health plan
20 shall provide information under paragraph (1) in a
21 manner consistent with the privacy, security, and
22 breach notification regulations promulgated under
23 section 264(c) of the Health Insurance Portability
24 and Accountability Act of 1996 (or successor regula-
25 tions), and shall restrict the use and disclosure of

1 such information according to such privacy regula-
2 tions.

3 “(3) DISCLOSURE AND REDISCLOSURE.—

4 “(A) LIMITATION TO BUSINESS ASSOCI-
5 ATES.—A group health plan receiving a report
6 under paragraph (1) may disclose such informa-
7 tion only to business associates of such plan as
8 defined in section 160.103 of title 45, Code of
9 Federal Regulations (or successor regulations).

10 “(B) CLARIFICATION REGARDING PUBLIC
11 DISCLOSURE OF INFORMATION.—Nothing in
12 this section prevents a health insurance issuer
13 offering group health insurance coverage or an
14 entity providing pharmacy benefits management
15 services on behalf of a group health plan from
16 placing reasonable restrictions on the public dis-
17 closure of the information contained in a report
18 described in paragraph (1).

19 “(c) LIMITATIONS ON SPREAD PRICING.—

20 “(1) PASS-THROUGH OFFERING TO PLAN.—A
21 designated plan administrator of an applicable self-
22 insured health plan, or an entity providing pharmacy
23 benefit management services to such health plan
24 shall offer at least one contractual arrangement that
25 does not charge the plan or enrollee, a price for a

1 prescription drug that exceeds the price paid to the
2 pharmacy, excluding penalties or fees paid by phar-
3 macies to such plan, issuer, or entity.

4 “(2) DEFAULT TO PASS-THROUGH PRICING.—
5 For purposes of paragraph (1), a designated plan
6 administrator of an applicable self-insured health
7 plan, or an entity providing pharmacy benefit man-
8 agement services to such health plan shall not
9 charge the plan or enrollee an amount for a
10 prescription drug that exceeds the price paid to the
11 pharmacy, excluding penalties paid by pharmacies to
12 such plan or entity, without the express permission
13 of the health plan sponsor.

14 “(3) SUPPLEMENTARY REPORTING FOR INTRA-
15 COMPANY PRESCRIPTION DRUG TRANSACTIONS.—A
16 health insurance issuer of group health insurance
17 coverage or an entity providing pharmacy benefits
18 management services under a group health plan or
19 group health insurance coverage that conducts
20 transactions with a wholly or partially owned phar-
21 macy, as described in paragraph (2), shall submit,
22 together with the report under subsection (b), a sup-
23 plementary quarterly report to the plan sponsor that
24 includes—

1 “(A) an explanation of any benefit design
2 parameters that encourage enrollees in the plan
3 or coverage to fill prescriptions at mail order,
4 specialty, or retail pharmacies that are wholly
5 or partially owned by that issuer or entity;

6 “(B) the percentage of total prescriptions
7 charged to the plan, coverage, or enrollees in
8 the plan or coverage, that were dispensed by
9 mail order, specialty, or retail pharmacies that
10 are wholly or partially owned by the issuer or
11 entity providing pharmacy benefits management
12 services; and

13 “(C) a list of all drugs dispensed by such
14 wholly or partially owned pharmacy and
15 charged to the plan or coverage, or enrollees of
16 the plan or coverage, during the applicable
17 quarter, and, with respect to each drug—

18 “(i) the amount charged per dosage
19 unit or course of treatment with respect to
20 enrollees in the plan or coverage, including
21 amounts charged to the plan or coverage
22 and amounts charged to the enrollee;

23 “(ii) the median amount charged to
24 the plan or coverage, per dosage unit or
25 course of treatment, and including

1 amounts paid by the enrollee, when the
2 same drug is dispensed by other phar-
3 macies that are not wholly or partially
4 owned by the issuer or entity and that are
5 included in the pharmacy network of that
6 plan or coverage;

7 “(iii) the interquartile range of the
8 costs, per dosage unit or course of treat-
9 ment, and including amounts paid by the
10 enrollee, when the same drug is dispensed
11 by other pharmacies that are not wholly or
12 partially owned by the issuer or entity and
13 that are included in the pharmacy network
14 of that plan or coverage; and

15 “(iv) the lowest cost per dosage unit
16 or course of treatment, for such drug, in-
17 cluding amounts charged to the plan or
18 issuer and enrollee, that is available from
19 any pharmacy included in the network of
20 the plan or coverage.

21 “(d) FULL REBATE PASS-THROUGH TO PLAN.—

22 “(1) IN GENERAL.—A pharmacy benefits man-
23 ager, a third-party administrator of a group health
24 plan, a health insurance issuer offering group health
25 insurance coverage, or an entity providing pharmacy

1 benefits management services under such health
2 plan or health insurance coverage shall remit 100
3 percent of rebates, fees, alternative discounts, and
4 all other remuneration received from a pharma-
5 ceutical manufacturer, distributor or any other third
6 party, that are related to utilization of drugs under
7 such health plan or health insurance coverage, to the
8 health plan issuer.

9 “(2) FORM AND MANNER OF REMITTANCE.—

10 Such rebates, fees, alternative discounts, and other
11 remuneration shall be—

12 “(A) remitted to the group health plan in
13 a timely fashion after the period for which such
14 rebates, fees, or other remuneration is cal-
15 culated, and in no case later than 120 days
16 after the end of such period;

17 “(B) fully disclosed and enumerated to the
18 group health plan sponsor, as described in
19 (b)(1);

20 “(C) available for audit by the plan spon-
21 sor, or a third party designated by a plan spon-
22 sor no less than once per plan year; and

23 “(D) returned to the issuer or entity pro-
24 viding pharmaceutical benefit management
25 services by the group health plan if audits by

1 such issuer or entity indicate that the amounts
2 received are incorrect after such amounts have
3 been paid to the group health plan.

4 “(3) AUDIT OF REBATE CONTRACTS.—A phar-
5 macy benefits manager, a third-party administrator
6 of a group health plan, a health insurance issuer of-
7 fering a group health insurance coverage, or an enti-
8 ty providing pharmacy benefits management services
9 under such health plan or health insurance coverage
10 shall make rebate contracts with drug manufactur-
11 ers available for audit by such plan sponsor or des-
12 ignated third party, subject to confidentiality agree-
13 ments to prevent re-disclosure of such contracts.

14 “(e) ENFORCEMENT.—

15 “(1) IN GENERAL.—The Secretary, in consulta-
16 tion with the Secretary of Labor and the Secretary
17 of the Treasury, shall enforce this section.

18 “(2) FAILURE TO PROVIDE TIMELY INFORMA-
19 TION.—A health insurance issuer or an entity pro-
20 viding pharmacy benefit management services that
21 violates subsection (a), fails to provide information
22 required under subsection (b), engages in spread
23 pricing as defined in subsection (c), or fails to com-
24 ply with the requirements of subsection (d), or a
25 drug manufacturer that fails to provide information

1 under subsection (b)(1)(A), in a timely manner shall
2 be subject to a civil monetary penalty in the amount
3 of \$10,000 for each day during which such violation
4 continues or such information is not disclosed or re-
5 ported.

6 “(3) FALSE INFORMATION.—A health insurance
7 issuer, entity providing pharmacy benefit manage-
8 ment services, or drug manufacturer that knowingly
9 provides false information under this section shall be
10 subject to a civil money penalty in an amount not
11 to exceed \$100,000 for each item of false informa-
12 tion. Such civil money penalty shall be in addition to
13 other penalties as may be prescribed by law.

14 “(4) PROCEDURE.—The provisions of section
15 1128A of the Social Security Act, other than sub-
16 sections (a) and (b) and the first sentence of sub-
17 section (c)(1) of such section shall apply to civil
18 monetary penalties under this subsection in the
19 same manner as such provisions apply to a penalty
20 or proceeding under section 1128A of the Social Se-
21 curity Act.

22 “(5) SAFE HARBOR.—The Secretary may waive
23 penalties under paragraph (2), or extend the period
24 of time for compliance with a requirement of this
25 section, for an entity in violation of this section that

1 has made a good-faith effort to comply with this sec-
2 tion.

3 “(f) RULE OF CONSTRUCTION.—Nothing in this sec-
4 tion shall be construed to prohibit entities providing phar-
5 macy benefits management services from retaining bona
6 fide service fees, provided that such fees are transparent
7 to group health plans and health insurance issuers and
8 are not linked directly to the price or formulary placement
9 or position of a drug.

10 “(g) DEFINITIONS.—In this section—

11 “(1) the term ‘similarly situated pharmacy’
12 means, with respect to a particular pharmacy, an-
13 other pharmacy that is approximately the same size
14 (as measured by the number of prescription drugs
15 dispensed), and that serves patients in the same geo-
16 graphical area, whether through physical locations or
17 mail order;

18 “(2) the term ‘wholesale acquisition cost’ has
19 the meaning given such term in section
20 1847A(c)(6)(B) of the Social Security Act; and

21 “(3) the term ‘bona fide service fees’ means
22 fees paid by a manufacturer, customer, or client
23 (other than a group health plan or health insurance
24 issuer) of an entity providing pharmacy benefit man-
25 agement services, to an entity providing pharmacy

1 benefit management services, that represent fair
2 market value for bona fide, itemized services actually
3 performed on behalf of the manufacturer, customer,
4 or client would otherwise perform or contract for in
5 the absence of the service arrangement, without
6 prior consent for any specific arrangements.”.

7 **SEC. 3. THIRD-PARTY ADMINISTRATORS.**

8 Any obligation on a third-party administrator under
9 this Act (including the amendment made by this Act) shall
10 not affect any other direct or indirect requirement under
11 any other provision of Federal law that applies to third-
12 party administrators offering services to group health
13 plans.

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