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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. GIANFORTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''PBM Transparency in Prescription Drug Costs Act''.

SEC. 2. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

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

"SEC. 2729A. HEALTH PLAN OVERSIGHT OF PHARMACY BENEFIT MANAGER SERVICES.

''(a) IN GENERAL.—A group health plan or health insurance issuer offering group or individual health insurance coverage or an entity or subsidiary providing pharmacy benefits management services shall not enter into a contract with a drug manufacturer, distributor, wholesaler, subcontractor, rebate aggregator, or any associated third party that limits the disclosure of information to plan sponsors in such a manner that prevents the plan or coverage, or an entity or subsidiary providing pharmacy benefits management services on behalf of a plan or coverage from making the reports described in subsection (b).

''(b) REPORTS TO GROUP PLAN SPONSORS.—

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

such report shall include, with respect to the applicable group health plan or health insurance coverage—

''(A) information collected from drug manufacturers by such issuer or entity on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer with respect to the enrollees in such plan or coverage;

''(B) a list of each covered drug dispensed during the reporting period, including, with respect to each such drug during the reporting period—

''(i) the brand name, chemical entity, and National Drug Code;

''(ii) the number of enrollees for whom the drug was filled during the plan year, the total number of prescription fills for the drug (including original prescriptions and refills), and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy;

''(iii) the wholesale acquisition cost, listed as cost per days supply and cost per

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

''(iv) the total out-of-pocket spending by enrollees on such drug, including enrollee spending through copayments, coinsurance, and deductibles; and

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

''(I) a list of all other available drugs in the same therapeutic category or class, including brand name drugs and biological products and generic drugs or biosimilar biological products that are in the same therapeutic category or class; and

''(II) the rationale for preferred formulary placement of a particular drug or drugs in that therapeutic category or class;

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

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

"(i) total gross spending by the plan, before manufacturer rebates, fees, or other manufacturer remuneration;

"(ii) the number of enrollees who filled a prescription for a drug in that category or class;

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

"(iv) the total out-of-pocket spending by enrollees, including enrollee spending through copayments, coinsurance, and deductibles; and

"(v) for each therapeutic category or class under which three or more drugs are marketed and available—

"(I) the amount received, or expected to be received, from drug manufacturers in rebates, fees, alternative discounts, or other remuneration—

"(aa) to be paid by drug manufacturers for claims incurred during the reporting period; or

"(bb) that is related to utilization of drugs, in such therapeutic category or class;

"(II) the total net spending by the health plan or health insurance coverage on that category or class of drugs; and

"(III) the net price per dosage unit or course of treatment incurred by the health plan or health insurance coverage and its enrollees, after manufacturer rebates, fees, and other remuneration for drugs dispensed within such therapeutic category or class during the reporting period;

"(D) total gross spending on prescription drugs by the plan or coverage during the reporting period, before rebates and other manufacturer fees or remuneration;

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

ance coverage in drug manufacturer rebates, fees, alternative discounts, and all other remuneration received from the manufacturer or any third party related to utilization of drug or drug spending under that health plan or health insurance coverage during the reporting period;

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

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

''(2) PRIVACY REQUIREMENTS.—Health insurance issuers offering group health insurance coverage and entities providing pharmacy benefits management services on behalf of a group health plan shall provide information under paragraph (1) in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (or successor regulations), and shall restrict the use and disclosure of

such information according to such privacy regulations.

''(3) DISCLOSURE AND REDISCLOSURE.—

''(A) LIMITATION TO BUSINESS ASSOCIATES.—A group health plan receiving a report under paragraph (1) may disclose such information only to business associates of such plan as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations).

''(B) CLARIFICATION REGARDING PUBLIC DISCLOSURE OF INFORMATION.—Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefits management services on behalf of a group health plan from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1).

''(c) LIMITATIONS ON SPREAD PRICING.—

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

prescription drug that exceeds the price paid to the pharmacy, excluding penalties or fees paid by pharmacies to such plan, issuer, or entity.

''(2) DEFAULT TO PASS-THROUGH PRICING.—For purposes of paragraph (1), a designated plan administrator of an applicable self-insured health plan, or an entity providing pharmacy benefit management services to such health plan shall not charge the plan or enrollee an amount for a presciption drug that exceeds the price paid to the pharmacy, excluding penalties paid by pharmacies to such plan or entity, without the express permission of the health plan sponsor.

''(3) SUPPLEMENTARY REPORTING FOR INTRACOMPANY PRESCRIPTION DRUG TRANSACTIONS.—A health insurance issuer of group health insurance coverage or an entity providing pharmacy benefits management services under a group health plan or group health insurance coverage that conducts transactions with a wholly or partially owned pharmacy, as described in paragraph (2), shall submit, together with the report under subsection (b), a supplementary quarterly report to the plan sponsor that includes—

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

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

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

''(i) the amount charged per dosage unit or course of treatment with respect to enrollees in the plan or coverage, including amounts charged to the plan or coverage and amounts charged to the enrollee;

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

amounts paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly or partially owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage;

''(iii) the interquartile range of the costs, per dosage unit or course of treatment, and including amounts paid by the enrollee, when the same drug is dispensed by other pharmacies that are not wholly or partially owned by the issuer or entity and that are included in the pharmacy network of that plan or coverage; and

''(iv) the lowest cost per dosage unit or course of treatment, for such drug, including amounts charged to the plan or issuer and enrollee, that is available from any pharmacy included in the network of the plan or coverage.

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

''(1) IN GENERAL.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy

benefits management services under such health plan or health insurance coverage shall remit 100 percent of rebates, fees, alternative discounts, and all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of drugs under such health plan or health insurance coverage, to the health plan issuer.

''(2) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

''(A) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, or other remuneration is calculated, and in no case later than 120 days after the end of such period;

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

''(C) available for audit by the plan sponsor, or a third party designated by a plan sponsor no less than once per plan year; and

''(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by

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

''(3) AUDIT OF REBATE CONTRACTS.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering a group health insurance coverage, or an entity providing pharmacy benefits management services under such health plan or health insurance coverage shall make rebate contracts with drug manufacturers available for audit by such plan sponsor or designated third party, subject to confidentiality agreements to prevent re-disclosure of such contracts.

''(e) ENFORCEMENT.—

''(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.

''(2) FAILURE TO PROVIDE TIMELY INFORMATION.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a), fails to provide information required under subsection (b), engages in spread pricing as defined in subsection (c), or fails to comply with the requirements of subsection (d), or a drug manufacturer that fails to provide information

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

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

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

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

has made a good-faith effort to comply with this section.

''(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit entities providing pharmacy benefits management services from retaining bona fide service fees, provided that such fees are transparent to group health plans and health insurance issuers and are not linked directly to the price or formulary placement or position of a drug.

''(g) DEFINITIONS.—In this section—

''(1) the term 'similarly situated pharmacy' means, with respect to a particular pharmacy, another pharmacy that is approximately the same size (as measured by the number of prescription drugs dispensed), and that serves patients in the same geographical area, whether through physical locations or mail order;

''(2) the term 'wholesale acquisition cost' has the meaning given such term in section 1847A(c)(6)(B) of the Social Security Act; and

''(3) the term 'bona fide service fees' means fees paid by a manufacturer, customer, or client (other than a group health plan or health insurance issuer) of an entity providing pharmacy benefit management services, to an entity providing pharmacy

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

SEC. 3. THIRD-PARTY ADMINISTRATORS.

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

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