116TH CONGRESS
1ST SESSION

S. 2247

To amend titles XI and XVIII of the Social Security Act to provide greater transparency of discounts provided by drug manufacturers, to establish requirements relating to pharmacy-negotiated price concessions, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 24, 2019

Mr. KENNEDY (for himself, Mr. TESTER, Mrs. CAPITO, Mr. BROWN, Mr. CASSIDY, Mr. LANKFORD, Mr. DAINES, Mr. CRAMER, Mrs. HYDE-SMITH, Mr. MANCHIN, and Mr. WICKER) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend titles XI and XVIII of the Social Security Act to provide greater transparency of discounts provided by drug manufacturers, to establish requirements relating to pharmacy-negotiated price concessions, 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 ''Phair Relief Act of 2019''.

SEC. 2. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.

(a) IN GENERAL.—Section 1150A of the Social Security Act (42 U.S.C. 1320b–23) is amended—

(1) in subsection (c), in the matter preceding paragraph (1), by striking ''this section'' and inserting ''subsection (b)(1)''; and

(2) by adding at the end the following new subsection:

''(e) PUBLIC AVAILABILITY OF CERTAIN INFORMATION.—In order to allow patients and employers to compare PBMs' ability to negotiate rebates, discounts, and price concessions and the amount of such rebates, discounts, and price concessions that are passed through to plan sponsors, beginning January 1, 2020, the Secretary shall make available on the Internet website of the Department of Health and Human Services the information provided to the Secretary under paragraphs (2) and (3) of subsection (b) with respect to each PBM. The Secretary shall ensure that such information is displayed in a manner that prevents the disclosure of information on rebates, discounts, and price concessions with respect to an individual drug or an individual plan.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on January 1, 2020.

SEC. 3. MINIMUM DRUG DISCOUNTS REQUIRED TO BE PASSED THROUGH TO THE PLAN SPONSOR.

(a) IN GENERAL.—Section 1150A of the Social Security Act (42 U.S.C. 1320b–23), as amended by section 2(a)(2), is amended—

(1) in the heading, by inserting "**; MINIMUM DRUG DISCOUNTS REQUIRED TO BE PASSED THROUGH TO THE PLAN SPONSOR**" before the period at the end; and

(2) by adding at the end the following new subsection:

"(f) MINIMUM DRUG DISCOUNTS REQUIRED TO BE PASSED THROUGH TO THE PLAN SPONSOR.—

"(1) REQUIREMENT.—Beginning January 1, 2022, a PBM that manages prescription drug coverage under a contract with a PDP sponsor or MA organization described in subsection (b)(1) or a qualified health benefits plan described in subsection (b)(2), shall, with respect to the plan sponsor of a health benefits plan, pass through to the plan sponsor a minimum percent (as established by the Secretary) of the aggregate amount of the rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan.

''(2) ESTABLISHMENT.—The Secretary shall establish the minimum percent described in paragraph (1) in such a manner as will ensure that patients receive the maximum benefit of rebates, discounts, or price concessions while taking into account the costs of negotiating such rebates, discounts, and price concessions.

''(3) ENFORCEMENT.—A PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII may not contract with a PBM that is not in compliance with the requirement under paragraph (1).''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on January 1, 2022.

SEC. 4. REQUIREMENTS RELATING TO PHARMACY-NEGOTIATED PRICE CONCESSIONS AND PHARMACY INCENTIVE PAYMENTS.

Section 1860D–2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)(B)) is amended—

(1) by striking ''PRICES.—For purposes'' and inserting ''PRICES.—

''(i) IN GENERAL.—For purposes''; and

(2) by adding at the end the following new clauses:

"(ii) PRICES NEGOTIATED WITH PHARMACY AT POINT-OF-SALE.—

"(I) TEMPORARY FREEZE ON DIR PAYMENTS.—Subject to subclause (IV), for plan years beginning on or after January 1, 2021, and before January 1, 2026, negotiated prices for covered part D drugs described in clause (i) provided under all phases of coverage under a prescription drug plan, including all contingent and noncontingent concessions, payments, and fees negotiated with the pharmacy dispensing such drug, shall be provided at the point-of-sale of such drug. For purposes of the preceding sentence, such negotiated price shall not include any incentive payments paid to pharmacies.

"(II) APPLICATION OF PRICE CONCESSIONS.—For plan years beginning on or after January 1, 2026, the Secretary shall promulgate regulations prohibiting the application of any pharmacy price concessions that are

not based on quality measures established or approved by the Secretary under subclause (III).

''(III) STANDARD PHARMACY QUALITY MEASURES.—Subject to subclause (I), not later than January 1, 2021, the Secretary shall establish or approve standard quality measures for use in the application of pharmacy price concessions and incentive payments with respect to payment for covered part D drugs dispensed by a pharmacy. Such measures shall be—

''(aa) focused on improving patient health outcomes;

''(bb) standardized across PDP sponsors;

''(cc) pharmacy-specific in application;

''(dd) relevant to the type of pharmacy concerned (such as specialty pharmacies), taking into account the items and services furnished by the pharmacy and

the patient population served by the pharmacy;

"(ee) applied only when relevant to the specific drug (or drug class of such drug) being furnished by the pharmacy or when relevant to management of the condition for which such drug has been prescribed; and

"(ff) based on achievable and proven criteria measuring pharmacy performance over which the pharmacy has meaningful control and ability to influence.

In establishing such standards, the Secretary shall consult with stakeholders, including PDP sponsors and MA organizations, pharmacies across pharmacy practice types, pharmacy benefit managers, patient advocacy organizations, drug manufacturers, appropriate standard-setting organizations, professional pharmacy organizations, and other entities determined

appropriate by the Secretary. The Secretary shall review and update the standard pharmacy quality measures on an ongoing basis with appropriate notice and period for comments from stakeholders.

''(IV) NO INCREASE IN COST SHARING DURING TEMPORARY FREEZE.—Subclause (I) shall not apply in the case where application of such subclause would increase the amount owed by an individual in cost sharing above the amount such individual would have owed in cost sharing without application of such subclause.

''(V) DISCREPANCIES BETWEEN NEGOTIATED PRICES AND ACTUAL REIMBURSEMENT.—In the case that the Secretary determines that the negotiated price of a PDP sponsor applied at the point-of-sale with respect to a covered part D drug for a year dispensed by a pharmacy was greater than the total reimbursement made to

such pharmacy for such drug for such year, such sponsor shall, not later than 90 days after receiving notice of such determination, furnish to the pharmacy that dispensed such drug and to the Secretary a written explanation of why such negotiated price was greater than such reimbursement.

''(VI) SPECIALTY PHARMACY.—For purposes of carrying out this clause (including subclause (III)(dd)), the Secretary shall, not later than December 31, 2020, define the term 'specialty pharmacy' in consultation with relevant stakeholders.

''(VII) DEFINITIONS.—In this clause:

''(aa) QUALITY MEASURE.—The term 'quality measure' means criteria used by a PDP sponsor (including an entity that contracts with such sponsor, such as a pharmacy benefit manager) to determine the amount or ap-

plicability of incentive payments and pharmacy price concessions.

''(bb) PDP SPONSOR.—The term 'PDP sponsor' includes an MA organization offering an MA–PD plan under part C and an entity that contracts with such sponsor or organization, such as a pharmacy benefit manager.

''(iii) AUDITS OF PDP SPONSORS AND NEGOTIATED PRICE.—

''(I) IN GENERAL.—Beginning January 1, 2021, the Secretary shall conduct annual audits of PDP sponsors by reviewing a representative sample of claims between PDP sponsors or other intermediary contracting organizations and all pharmacy types and those pharmacies' lowest actual acquisition and dispensing costs to assess whether reimbursement for individual network pharmacies is below the pharmacy's lowest actual cost of acquiring and dispensing covered part

D drugs and providing pharmacy services necessary for dispensing such drugs. In conducting such audits, the Secretary shall focus on determining whether or not the requirements under clause (ii) are negatively impacting network pharmacy participation in the program under this part and beneficiary access to pharmacy providers. Such audits shall occur not less than annually and when requested by the Medicare Pharmaceutical and Technology Ombudsman.

''(II) APPEAL.—If a network pharmacy believes that a PDP sponsor has reimbursed for a covered part D drug below the pharmacy's lowest actual acquisition and dispensing costs, the pharmacy may appeal the reimbursement, in writing, to the Medicare Pharmaceutical and Technology Ombudsman within 60 days following notification of the reimbursement and provide necessary documentation to support its claim.

"(III) ANNUAL REPORT TO CONGRESS.—Not later than January 1, 2022, and annually thereafter, the Secretary shall submit to Congress a report that contains a summary of the audits conducted under subclause (I) and activity under subclause (II), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

"(iv) CLAIM REIMBURSEMENT DISCLOSURE REQUIREMENTS.—With respect to payment made by a PDP sponsor to a pharmacy for a covered part D drug furnished by such pharmacy during a plan year beginning on or after January 1, 2020, such sponsor shall promptly furnish all pricing components including the Network Reimbursement ID used to price the claim, any fees, pharmacy price concessions, discounts, incentives or any other forms of remuneration to or from the pharmacy that affect payment and pricing of the claim as part of the claim adjudica-

tion response at the point-of-sale. Each of the aforementioned data elements shall each be identified in a predetermined line item in the remittance advice that is standard across the industry, which shall include suitable claim-level detail needed to properly identify the claim, including the Claim Authorization Number, date of service, date of payment remittance, ingredient cost reimbursed, dispensing fee reimbursed, payment amounts including the specific dollar amounts and the appropriate qualifier codes for each payment adjustment including fees, pharmacy price concessions, or incentives.

''(v) VIOLATION PROCESS.—A PDP sponsor shall participate in any process established by the Secretary for purposes of determining whether such sponsor has violated a provision of clause (ii) or (iii).''.

SEC. 5. PHARMACY BENEFIT MANAGER PROVISION OF INFORMATION.

(a) IN GENERAL.—Section 1150A(b)(2) of the Social Security Act (42 U.S.C. 1320b–23(b)(2)) is amended by striking ''excluding'' and inserting ''including''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to contract years beginning on or after January 1, 2020.

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