

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

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.

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 “Phair Relief Act of
5 2019”.

1 **SEC. 2. PUBLIC DISCLOSURE OF DRUG DISCOUNTS.**

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

4 (1) in subsection (c), in the matter preceding
5 paragraph (1), by striking “this section” and insert-
6 ing “subsection (b)(1)”; and

7 (2) by adding at the end the following new sub-
8 section:

9 “(e) PUBLIC AVAILABILITY OF CERTAIN INFORMA-
10 TION.—In order to allow patients and employers to com-
11 pare PBMs’ ability to negotiate rebates, discounts, and
12 price concessions and the amount of such rebates, dis-
13 counts, and price concessions that are passed through to
14 plan sponsors, beginning January 1, 2020, the Secretary
15 shall make available on the Internet website of the Depart-
16 ment of Health and Human Services the information pro-
17 vided to the Secretary under paragraphs (2) and (3) of
18 subsection (b) with respect to each PBM. The Secretary
19 shall ensure that such information is displayed in a man-
20 ner that prevents the disclosure of information on rebates,
21 discounts, and price concessions with respect to an indi-
22 vidual drug or an individual plan.”.

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

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

3 (a) IN GENERAL.—Section 1150A of the Social Secu-
 4 rity Act (42 U.S.C. 1320b–23), as amended by section
 5 2(a)(2), is amended—

6 (1) in the heading, by inserting “**; MINIMUM**
 7 **DRUG DISCOUNTS REQUIRED TO BE PASSED**
 8 **THROUGH TO THE PLAN SPONSOR**” before the
 9 period at the end; and

10 (2) by adding at the end the following new sub-
 11 section:

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

14 “(1) REQUIREMENT.—Beginning January 1,
 15 2022, a PBM that manages prescription drug cov-
 16 erage under a contract with a PDP sponsor or MA
 17 organization described in subsection (b)(1) or a
 18 qualified health benefits plan described in subsection
 19 (b)(2), shall, with respect to the plan sponsor of a
 20 health benefits plan, pass through to the plan spon-
 21 sor a minimum percent (as established by the Sec-
 22 retary) of the aggregate amount of the rebates, dis-
 23 counts, or price concessions that the PBM nego-
 24 tiates that are attributable to patient utilization
 25 under the plan.

8 “(3) ENFORCEMENT.—A PDP sponsor of a
9 prescription drug plan or an MA organization offer-
10 ing an MA-PD plan under part D of title XVIII
11 may not contract with a PBM that is not in compli-
12 ance with the requirement under paragraph (1).”.

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

15 SEC. 4. REQUIREMENTS RELATING TO PHARMACY-NEGO-
16 TIATED PRICE CONCESSIONS AND PHAR-
17 MACY INCENTIVE PAYMENTS.

18 Section 1860D-2(d)(1)(B) of the Social Security Act
19 (42 U.S.C. 1395w-102(d)(1)(B)) is amended—

20 (1) by striking “PRICES.—For purposes” and
21 inserting “PRICES.—

22 “(i) IN GENERAL.—For purposes”;

23 and

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

1 “(ii) PRICES NEGOTIATED WITH
2 PHARMACY AT POINT-OF-SALE.—

3 “(I) TEMPORARY FREEZE ON DIR
4 PAYMENTS.—Subject to subclause
5 (IV), for plan years beginning on or
6 after January 1, 2021, and before
7 January 1, 2026, negotiated prices for
8 covered part D drugs described in
9 clause (i) provided under all phases of
10 coverage under a prescription drug
11 plan, including all contingent and
12 noncontingent concessions, payments,
13 and fees negotiated with the phar-
14 macy dispensing such drug, shall be
15 provided at the point-of-sale of such
16 drug. For purposes of the preceding
17 sentence, such negotiated price shall
18 not include any incentive payments
19 paid to pharmacies.

20 “(II) APPLICATION OF PRICE
21 CONCESSIONS.—For plan years begin-
22 ning on or after January 1, 2026, the
23 Secretary shall promulgate regulations
24 prohibiting the application of any
25 pharmacy price concessions that are

1 not based on quality measures estab-
2 lished or approved by the Secretary
3 under subclause (III).

4 “(III) STANDARD PHARMACY
5 QUALITY MEASURES.—Subject to sub-
6 clause (I), not later than January 1,
7 2021, the Secretary shall establish or
8 approve standard quality measures for
9 use in the application of pharmacy
10 price concessions and incentive pay-
11 ments with respect to payment for
12 covered part D drugs dispensed by a
13 pharmacy. Such measures shall be—

14 “(aa) focused on improving
15 patient health outcomes;

16 “(bb) standardized across
17 PDP sponsors;

18 “(cc) pharmacy-specific in
19 application;

20 “(dd) relevant to the type of
21 pharmacy concerned (such as
22 specialty pharmacies), taking into
23 account the items and services
24 furnished by the pharmacy and

1 the patient population served by
2 the pharmacy;

3 “(ee) applied only when rel-
4 evant to the specific drug (or
5 drug class of such drug) being
6 furnished by the pharmacy or
7 when relevant to management of
8 the condition for which such drug
9 has been prescribed; and

10 “(ff) based on achievable
11 and proven criteria measuring
12 pharmacy performance over
13 which the pharmacy has mean-
14 ingful control and ability to influ-
15 ence.

16 In establishing such standards, the
17 Secretary shall consult with stake-
18 holders, including PDP sponsors and
19 MA organizations, pharmacies across
20 pharmacy practice types, pharmacy
21 benefit managers, patient advocacy or-
22 ganizations, drug manufacturers, ap-
23 propriate standard-setting organiza-
24 tions, professional pharmacy organiza-
25 tions, and other entities determined

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

7 “(IV) NO INCREASE IN COST
8 SHARING DURING TEMPORARY
9 FREEZE.—Subclause (I) shall not
10 apply in the case where application of
11 such subclause would increase the
12 amount owed by an individual in cost
13 sharing above the amount such indi-
14 vidual would have owed in cost shar-
15 ing without application of such sub-
16 clause.

17 “(V) DISCREPANCIES BETWEEN
18 NEGOTIATED PRICES AND ACTUAL RE-
19 IMBURSEMENT.—In the case that the
20 Secretary determines that the nego-
21 tiated price of a PDP sponsor applied
22 at the point-of-sale with respect to a
23 covered part D drug for a year dis-
24 pensed by a pharmacy was greater
25 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-

1 plicability of incentive payments
2 and pharmacy price concessions.

3 “(bb) PDP SPONSOR.—The
4 term ‘PDP sponsor’ includes an
5 MA organization offering an
6 MA–PD plan under part C and
7 an entity that contracts with
8 such sponsor or organization,
9 such as a pharmacy benefit man-
10 ager.

11 “(iii) AUDITS OF PDP SPONSORS AND
12 NEGOTIATED PRICE.—

13 “(I) IN GENERAL.—Beginning
14 January 1, 2021, the Secretary shall
15 conduct annual audits of PDP spon-
16 sors by reviewing a representative
17 sample of claims between PDP spon-
18 sors or other intermediary contracting
19 organizations and all pharmacy types
20 and those pharmacies’ lowest actual
21 acquisition and dispensing costs to as-
22 sess whether reimbursement for indi-
23 vidual network pharmacies is below
24 the pharmacy’s lowest actual cost of
25 acquiring and dispensing covered part

1 D drugs and providing pharmacy
2 services necessary for dispensing such
3 drugs. In conducting such audits, the
4 Secretary shall focus on determining
5 whether or not the requirements
6 under clause (ii) are negatively im-
7 pacting network pharmacy participa-
8 tion in the program under this part
9 and beneficiary access to pharmacy
10 providers. Such audits shall occur not
11 less than annually and when re-
12 quested by the Medicare Pharma-
13 ceutical and Technology Ombudsman.

14 “(II) APPEAL.—If a network
15 pharmacy believes that a PDP spon-
16 sor has reimbursed for a covered part
17 D drug below the pharmacy’s lowest
18 actual acquisition and dispensing
19 costs, the pharmacy may appeal the
20 reimbursement, in writing, to the
21 Medicare Pharmaceutical and Tech-
22 nology Ombudsman within 60 days
23 following notification of the reim-
24 bursement and provide necessary doc-
25 umentation to support its claim.

1 “(III) ANNUAL REPORT TO CON-
2 GRESS.—Not later than January 1,
3 2022, and annually thereafter, the
4 Secretary shall submit to Congress a
5 report that contains a summary of the
6 audits conducted under subclause (I)
7 and activity under subclause (II), to-
8 gether with recommendations for such
9 legislation and administrative action
10 as the Secretary determines appro-
11 priate.

12 “(iv) CLAIM REIMBURSEMENT DIS-
13 CLOSURE REQUIREMENTS.—With respect
14 to payment made by a PDP sponsor to a
15 pharmacy for a covered part D drug fur-
16 nished by such pharmacy during a plan
17 year beginning on or after January 1,
18 2020, such sponsor shall promptly furnish
19 all pricing components including the Net-
20 work Reimbursement ID used to price the
21 claim, any fees, pharmacy price conces-
22 sions, discounts, incentives or any other
23 forms of remuneration to or from the
24 pharmacy that affect payment and pricing
25 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”.

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

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