116TH CONGRESS 1ST SESSION S.

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

Mr. KENNEDY (for himself, Mr. TESTER, Mrs. CAPITO, Mr. BROWN, and Mr. CASSIDY) introduced the following bill; which was read twice and referred to the Committee on

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 Secu3 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 insert6 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 plan sponsors, beginning January 1, 2020, the Secretary 14 shall make available on the Internet website of the Depart-15 16 ment of Health and Human Services the information provided to the Secretary under paragraphs (2) and (3) of 17 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 by24 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 Security Act (42 U.S.C. 1320b–23), as amended by section 4 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.

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1	"(2) ESTABLISHMENT.—The Secretary shall es-
2	tablish the minimum percent described in paragraph
3	(1) in such a manner as will ensure that patients re-
4	ceive the maximum benefit of rebates, discounts, or
5	price concessions while taking into account the costs
6	of negotiating such rebates, discounts, and price
7	concessions.
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).".
13	(b) EFFECTIVE DATE.—The amendments made by
14	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
24	(2) by adding at the end the following new
25	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

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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

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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

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1	such pharmacy for such drug for such
2	year, such sponsor shall, not later
3	than 90 days after receiving notice of
4	such determination, furnish to the
5	pharmacy that dispensed such drug
6	and to the Secretary a written expla-
7	nation of why such negotiated price
8	was greater than such reimbursement.
9	"(VI) Specialty pharmacy.—
10	For purposes of carrying out this
11	clause (including subclause (III)(dd)),
12	the Secretary shall, not later than De-
13	cember 31, 2020, define the term
14	'specialty pharmacy' in consultation
15	with relevant stakeholders.
16	"(VII) DEFINITIONS.—In this
17	clause:
18	"(aa) Quality measure.—
19	The term 'quality measure'
20	means criteria used by a PDP
21	sponsor (including an entity that
22	contracts with such sponsor, such
23	as a pharmacy benefit manager)
24	to determine the amount or ap-

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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-

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1 tion response at the point-of-sale. Each of 2 the aforementioned data elements shall 3 each be identified in a predetermined line 4 item in the remittance advice that is stand-5 ard across the industry, which shall include 6 suitable claim-level detail needed to prop-7 erly identify the claim, including the Claim 8 Authorization Number, date of service, 9 date of payment remittance, ingredient 10 cost reimbursed, dispensing fee reim-11 bursed, payment amounts including the 12 specific dollar amounts and the appro-13 priate qualifier codes for each payment ad-14 justment including fees, pharmacy price 15 concessions, or incentives. "(v) VIOLATION PROCESS.—A PDP 16 17 sponsor shall participate in any process es-18 tablished by the Secretary for purposes of 19 determining whether such sponsor has vio-20 lated a provision of clause (ii) or (iii).". 21 SEC. 5. PHARMACY BENEFIT MANAGER PROVISION OF IN-22 FORMATION. 23 (a) IN GENERAL.—Section 1150A(b)(2) of the Social 24 Security Act (42 U.S.C. 1320b-23(b)(2)) is amended by striking "excluding" and inserting "including". 25

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