..... (Original Signature of Member)

118TH CONGRESS 1ST SESSION



To amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare part D, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GRIFFITH introduced the following bill; which was referred to the Committee on

A BILL

- To amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare part D, 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. ENSURING FAIR ASSESSMENT OF PHARMACY

4 **PERFORMANCE AND QUALITY UNDER MEDI-**5 **CARE PART D.**

6 (a) STANDARDIZED PHARMACY PERFORMANCE
7 MEASURES.—Section 1860D–2 of the Social Security Act

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1 (42 U.S.C. 1395w-102) is amended by adding at the end2 the following new subsection:

3 "(f) Application of Standardized Pharmacy4 Performance Measures.—

5 "(1) MEASURES.—For plan years beginning on 6 or after January 1, 2025, a PDP sponsor offering 7 a prescription drug plan and an MA organization of-8 fering an MA–PD plan shall, for purposes of incen-9 tive payments, price concessions, or any fees or 10 other remuneration paid or charged to a pharmacy 11 based on performance measures, only use measures 12 that are—

"(A) established or adopted by the Secretary under paragraph (2) and included on the
list described in subparagraph (B) of such
paragraph; and

"(B) relevant to the performance of such
pharmacy based on the type of pharmacy (including retail, mail order, specialty, long term
care, and home infusion or other types of pharmacies), drugs dispensed, and pharmacy services used to dispense and manage drugs.

23 "(2) STANDARDIZED PHARMACY PERFORMANCE
24 MEASURES.—

25 "(A) MEASURES.—

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1	"(i) IN GENERAL Notwithstanding
2	any other provision of law, the Secretary
3	shall establish (or adopt pursuant to clause
4	(iii)) standardized pharmacy performance
5	measures to be used by a PDP sponsor of-
6	fering a prescription drug plan and an MA
7	organization offering an MA–PD plan for
8	the purpose of determining incentive pay-
9	ments, price concessions, or fees described
10	in paragraph (1).
11	"(ii) Requirements.—The measures
12	under clause (i) shall focus on pharmacy
13	performance and quality of care based on
14	the type of pharmacy, as determined by
15	the Secretary. Such measures shall be evi-
16	dence-based, feasible, appropriate and rea-
17	sonable. The Secretary may rely on data
18	and information collected from relevant
19	stakeholders to make determinations about
20	whether a measure satisfies the require-
21	ments of this clause.
22	"(iii) Adoption of measure.—In
23	lieu of establishing some or all of the
24	measures under this paragraph, the Sec-
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retary may adopt measures and measure

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1	performance criteria that are endorsed by
2	1 or more multi-stakeholder consensus or-
3	ganizations (such as the Pharmacy Quality
4	Alliance), that has participation from phar-
5	macies (including retail and specialty phar-
6	macies not owned or affiliated with a plan,
7	pharmacy benefit manager, or other phar-
8	macy), health plans, pharmacy benefit
9	managers, and the Centers for Medicare $\&$
10	Medicaid Services. Any measure adopted
11	under this clause shall be deemed to meet
12	the requirements under clause (ii).
13	"(B) MAINTENANCE OF LIST.—
14	"(i) IN GENERAL.—The Secretary
15	shall maintain, and publish on a publicly
16	available internet website, a list of meas-
17	ures established or adopted under this
18	paragraph. Such list shall initially be pub-
19	lished no later than June 1, 2024.
20	"(ii) UPDATE.—The Secretary shall
21	periodically evaluate measures, measure
22	criteria, and how measures are applied by
23	type of pharmacy and update the measures
24	on the list under clause (i) to ensure such

1	measures	meet	the	requirements	under
2	subparagr	aph (A)(ii).		

3 "(3) OIG REPORTS ON PHARMACY PERFORM4 ANCE MEASURES.—

"(A) OIG STUDY.—The Office of the In-5 6 spector General of the Department of Health and Human Services (in this paragraph re-7 8 ferred to as the 'Inspector General') shall con-9 duct a study of the use of performance meas-10 ures and other quality-related mechanisms in 11 network pharmacy agreements and other rel-12 evant contracting arrangements among PDP 13 sponsors offering a prescription drug plan, MA 14 organizations offering a MA-PD plan, phar-15 macy benefit managers acting on behalf of such 16 sponsors and organizations, and network phar-17 macies. Such study may include audits, reviews 18 of relevant enforcement actions, consultation 19 with relevant stakeholders, and other activities 20 determined appropriate by the Inspector Gen-21 eral, consistent with other provisions of law. 22 Such study shall, to the extent feasible, include 23 analysis of-

24 "(i) oversight and enforcement activi25 ties undertaken with respect to current

statutory and regulatory requirements re-
lated to network pharmacy agreements, in-
cluding under sections $423.505(b)(18)$ and
423.505(i) of title 42 of the Code of Fed-
eral Regulations (or any successor regula-
tion) and under section 1860D–4(b)(1)(A);
"(ii) penalties or other corrective ac-
tions imposed with respect to the require-
ments described in clause (i);
"(iii) the prevalence of the application
of performance measures in network phar-
macy agreements, and the manner in
which such measures are applied, including
variation based on the type of pharmacy,
the type of drug dispensed, and the serv-
ices required to manage and dispense such
drug;
"(iv) the extent to which the perform-
ance measures and related criteria applied
under network agreements vary among
similar types of pharmacies within a single
network, and the extent to which the appli-
cation of such measures or criteria differ
between pharmacies—

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1	"(I) affiliated with a pharmacy
2	benefit manager, a PDP sponsor of-
3	fering a prescription drug plan, or an
4	MA organization offering a MA-PD
5	plan; and
6	"(II) those not affiliated with an
7	entity described in subclause (I);
8	"(v) patterns and trends in the per-
9	formance measures applied under phar-
10	macy network agreements, including if the
11	measure is being used in accordance with
12	published measure specifications which
13	have been validated and tested, if the
14	measure is being used according to licens-
15	ing agreements with measure stewards,
16	and the level of attribution and attribution
17	criteria;
18	"(vi) the extent to which performance
19	measures result in incentive payments,
20	fees, price concessions, or other forms of
21	remuneration between pharmacies and
22	PDP sponsors or MA organizations (or
23	pharmacy benefit managers acting on their
24	behalf), including an analysis of which
25	measures most often result in incentive

1	payments to pharmacies (and the general
2	amount of such payments) and which
3	measures most often result in remunera-
4	tion paid by pharmacies to other entities
5	(and the general amount of such pay-
6	ments);
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7 "(vii) variation in the type of remu-8 neration (as described in clause (vi) result-9 ing from the application of performance 10 including measures. between different 11 types of pharmacies, different types of drugs dispensed, and affiliation status of 12 13 pharmacies (as described in clause (iv));

14 "(viii) when, in what manner, dif15 ferent types of pharmacies receive notice of
16 the application of performance measures,
17 the measures that will be utilized, the per18 formance criteria that will be applied, and
19 the data and methodologies that will be
20 used to evaluate performance; and

"(ix) the extent to which the Centers for Medicare & Medicaid Services has implemented the pharmacy performance reporting requirements of section 423.514(a)(5) of title 42, Code of Federal

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1	Regulations, the extent to which PDP
2	sponsors or MA organizations (or phar-
3	macy benefit managers acting on their be-
4	half) comply with such provision, and the
5	extent to which the Centers for Medicare $\&$
6	Medicaid Services has sought enforcement.
7	"(B) OIG REPORTS.—
8	"(i) Report on initial findings.—
9	Not later than December 31, 2024, the In-
10	spector General shall submit a report to
11	Congress outlining, to the extent prac-
12	ticable, a status update on the study under
13	subparagraph (A), together with initial
14	findings with respect to the issues included
15	under such study. Such report may include
16	an analysis of barriers to accessing any of
17	the information required under such study,
18	along with recommendations for addressing
19	such barriers. Such report may also in-
20	clude recommendations for the effective
21	implementation of the requirements en-
22	acted under this subsection as well as ex-
23	isting regulations, including section
24	423.514(a)(5) of title 42, Code of Federal
25	Regulations, along with other recommenda-

tions, as determined appropriate by the In spector General.

"(ii) 3 INTERIM REPORT.—Not later 4 than July 31, 2025, the Inspector General shall submit to Congress an interim report 5 6 on the study under subparagraph (A), in-7 cluding additional recommendations for the 8 implementation of the requirements en-9 acted under this subsection as well as under existing regulations, including sec-10 11 tion 423.514(a)(5) of title 42, Code of 12 Federal Regulations.

13 "(iii) FINAL REPORT.—Not later than
14 December 31, 2025, the Inspector General
15 shall submit to Congress a final report on
16 the study under subparagraph (A), to17 gether with additional recommendations,
18 as determined appropriate by the Inspector
19 General.

"(4) NONAPPLICATION OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States
Code, shall not apply to any data collection undertaken by the Secretary under this paragraph.".

(b) FUNDING.—In addition to amounts otherwiseavailable, there is appropriated to the Centers for Medi-

care & Medicaid Services Program Management Account,
 out of any money in the Treasury not otherwise appro priated, \$4,000,000 for fiscal year 2025, to remain avail able until expended, to carry out the amendment made
 by subsection (a).

6 SEC. 2. PROMOTING TRANSPARENCY FOR PHARMACIES 7 UNDER MEDICARE PART D.

8 (a) TRANSPARENCY FOR PHARMACIES.—Section
9 1860D-2(f) of the Social Security Act (42 U.S.C. 1395w10 102(f)), as added by section 3, is amended by adding at
11 the end the following new paragraph:

12 "(3) TRANSPARENCY FOR PHARMACIES.—

13 "(A) IN GENERAL.—For plan years begin-14 ning on or after January 1, 2025, a PDP spon-15 sor offering a prescription drug plan and an 16 MA organization offering an MA–PD plan, with 17 respect to payment made by such PDP sponsor 18 or such MA organization to a pharmacy for a 19 covered part D drug dispensed by such phar-20 macy during a plan year, shall promptly fur-21 nish, upon receiving a claim for a covered Part 22 D drug from a pharmacy, to such pharmacy in-23 formation related to such claim, such as the 24 Network Reimbursement ID, fees, pharmacy 25 price concessions, discounts, incentives, or any

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other forms of remuneration that affect payment and pricing of the claim.

3 "(B) STANDARDIZED FORMAT.—The PDP
4 sponsor and the MA organization shall furnish
5 the information described in subparagraph (A)
6 in a standardized format (as specified by the
7 Secretary) that includes all fields needed to
8 price the claim for a covered part D drug dis9 pensed by such pharmacy.

10 "(C) IMPLEMENTATION.—The Secretary 11 shall implement this paragraph by program in-12 struction or other forms of program guidance.". 13 (b) FUNDING.—In addition to amounts otherwise 14 available, there is appropriated to the Centers for Medi-15 care & Medicaid Services Program Management Account, 16 out of any money in the Treasury not otherwise appro-17 priated, \$2,000,000 for fiscal year 2025, to remain available until expended, to carry out the amendment made 18 by subsection (a). 19