

118TH CONGRESS
2D SESSION

H. R. 7716

To amend title XVIII of the Social Security Act to provide for enforcement of standards for reasonable and relevant contract terms and conditions and essential retail pharmacy protections under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 19, 2024

Mr. GALLEG0 introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to provide for enforcement of standards for reasonable and relevant contract terms and conditions and essential retail pharmacy protections under the Medicare program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. PROVIDING FOR ENFORCEMENT OF STAND-**
2 **ARDS FOR REASONABLE AND RELEVANT**
3 **CONTRACT TERMS AND CONDITIONS AND ES-**
4 **SENTIAL RETAIL PHARMACY PROTECTIONS**
5 **UNDER THE MEDICARE PROGRAM.**

6 (a) IN GENERAL.—Section 1860D–4(b)(1) of the So-
7 cial Security Act (42 U.S.C. 1395w–104(b)(1)) is amend-
8 ed by adding at the end the following new subparagraph:

9 “(F) ENFORCEMENT OF STANDARDS FOR
10 REASONABLE AND RELEVANT CONTRACT TERMS
11 AND CONDITIONS AND ESSENTIAL RETAIL
12 PHARMACY PROTECTIONS.—

13 “(i) ALLEGATION SUBMISSION PROC-
14 ESS.—

15 “(I) IN GENERAL.—Not later
16 than January 1, 2028, the Secretary
17 shall establish a process through
18 which a pharmacy may submit an al-
19 legation of a violation by a PDP spon-
20 sor offering a prescription drug plan
21 of—

22 “(aa) the standards for rea-
23 sonable and relevant contract
24 terms and conditions under sub-
25 paragraph (A)(ii); or

“(bb) the requirements for total reimbursement for essential retail pharmacies that are independent community pharmacies under subparagraph (C)(v)(II).

“(II) FREQUENCY OF SUBMISSION.—

“(aa) VIOLATIONS OF REASONABLE AND RELEVANT CONTRACT TERMS AND CONDITIONS.—

“(AA) IN GENERAL.—

Except as provided in subitem (BB), the allegation submission process under this clause shall allow pharmacies to submit any allegations of violations described in item (aa) of subclause (I) not more frequently than once per plan year per contract between a pharmacy and a PDP sponsor.

“(BB) ALLEGATIONS RELATING TO CONTRACT

1 CHANGES.—In the case
2 where a contract is amended
3 or otherwise updated fol-
4 lowing the submission of al-
5 legations by a pharmacy
6 with respect to such contract
7 and plan year, the allegation
8 submission process under
9 this clause shall allow such
10 pharmacy to submit an addi-
11 tional allegation related to
12 those changes with respect
13 to such contract and plan
14 year.

15 “(CC) SUBMISSIONS.—
16 Submissions of any allega-
17 tions under this item shall
18 be separate from any sub-
19 missions under item (bb)
20 and may include multiple al-
21 legations of such violations.

22 “(bb) VIOLATIONS OF ES-
23 SENTIAL RETAIL PHARMACY PRO-
24 TECTIONS.—

1 “(AA) IN GENERAL.—

2 The allegation submission
3 process under this clause
4 shall allow essential retail
5 pharmacies that are inde-
6 pendent community phar-
7 macies to submit any allega-
8 tions of violations described
9 in item (bb) of subclause (I)
10 once per calendar quarter.

11 “(BB) SUBMISSIONS.—

12 Submissions of any allega-
13 tions under this item shall
14 be separate from any sub-
15 missions under item (aa)
16 and may include multiple al-
17 legations of such violations.

18 “(III) ACCESS TO RELEVANT

19 DOCUMENTS AND MATERIALS.—A
20 PDP sponsor subject to an allegation
21 under this clause—

22 “(aa) shall provide docu-
23 ments or materials, as specified
24 by the Secretary, including con-
25 tract offers made by such spon-

1 sor to such pharmacy or cor-
2 respondence related to such of-
3 fers, to the Secretary at a time
4 and in a form and manner speci-
5 fied by the Secretary; and

6 “(bb) shall not prohibit or
7 otherwise limit the ability of a
8 pharmacy to submit such docu-
9 ments or materials to the Sec-
10 retary for the purpose of submit-
11 ting an allegation or providing
12 evidence for such an allegation
13 under this clause.

14 “(IV) STANDARDIZED TEM-
15 PLATE.—The Secretary shall establish
16 separate standardized templates for
17 pharmacies to use for the submission
18 of allegations described in items (aa)
19 and (bb) of subclause (I). Each such
20 template shall require that the sub-
21 mission include a certification by the
22 pharmacy that the information in-
23 cluded is accurate, complete, and true
24 to the best of the knowledge, informa-
25 tion, and belief of such pharmacy.

1 “(V) PREVENTING FRIVOLOUS
2 ALLEGATIONS.—In the case where the
3 Secretary determines that a pharmacy
4 has submitted frivolous allegations
5 under this clause on a routine basis,
6 the Secretary may temporarily pro-
7 hibit such pharmacy from using the
8 allegation submission process under
9 this clause, as determined appropriate
10 by the Secretary.

11 “(VI) EXEMPTION FROM FREE-
12 DOM OF INFORMATION ACT.—Allega-
13 tions submitted under this clause shall
14 be exempt from disclosure under sec-
15 tion 552 of title 5, United States
16 Code.

17 “(ii) INVESTIGATION.—The Secretary
18 shall investigate, as determined appro-
19 priate by the Secretary, allegations sub-
20 mitted pursuant to clause (i).

21 “(iii) ENFORCEMENT.—

22 “(I) REASONABLE AND REL-
23 EVANT CONTRACT TERMS AND CONDI-
24 TIONS.—In the case where the Sec-
25 retary determines that a PDP sponsor

1 offering a prescription drug plan has
2 violated the standards for reasonable
3 and relevant contract terms and con-
4 ditions under subparagraph (A)(ii),
5 the Secretary shall use existing au-
6 thorities under sections 1857(g) and
7 1860D–12(b)(3)(E) to impose civil
8 monetary penalties or take other en-
9 forcement actions.

10 “(II) ESSENTIAL RETAIL PHAR-
11 MACY PROTECTIONS.—In the case
12 where the Secretary determines that a
13 PDP sponsor offering a prescription
14 drug plan has violated the require-
15 ments for total reimbursement for es-
16 sential retail pharmacies that are
17 independent community pharmacies
18 under subparagraph (C)(v)(II), the
19 Secretary shall—

20 “(aa) if the amount of total
21 reimbursement paid by the spon-
22 sor to an essential retail phar-
23 macy that is an independent
24 community pharmacy for a cov-
25 ered part D drug was less than

1 the amount of total reimburse-
2 ment required to be paid to the
3 pharmacy under subparagraph
4 (C)(v)(II) for such drug, require
5 the PDP sponsor to pay to the
6 pharmacy an amount equal to
7 the difference between such
8 amounts; and

9 “(bb) use existing authori-
10 ties under section 1857(g) and
11 1860D–12(b)(3)(E) to impose
12 civil monetary penalties or take
13 other enforcement actions.

14 “(III) APPLICATION OF CIVIL
15 MONETARY PENALTIES.—The provi-
16 sions of section 1128A (other than
17 subsections (a) and (b)) shall apply to
18 a civil monetary penalty under this
19 clause in the same manner as such
20 provisions apply to a penalty or pro-
21 ceeding under section 1128A(a).

22 “(iv) DEFINITIONS.—In this subpara-
23 graph, the terms ‘essential retail phar-
24 macy’, ‘independent community pharmacy’,
25 and ‘total reimbursement’ have the mean-

1 ing given those terms in subparagraph
2 (C)(v).”.

3 (b) CONFORMING AMENDMENT.—Section 1857(g)(1)
4 of the Social Security Act (42 U.S.C. 1395w–27(g)(1)) is
5 amended—

6 (1) in subparagraph (J), by striking “or” after
7 the semicolon;

8 (2) by redesignating subparagraph (K) as sub-
9 paragraph (L);

10 (3) by inserting after subparagraph (J), the fol-
11 lowing new subparagraph:

12 “(K) fails to comply with—

13 “(i) the standards for reasonable and
14 relevant contract terms and conditions
15 under subparagraph (A)(ii) of section
16 1860D–4(b)(1); or

17 “(ii) the requirements for total reim-
18 bursement for essential retail pharmacies
19 that are independent community phar-
20 macies under subparagraph (C)(v)(II) of
21 such section; or”;

22 (4) in subparagraph (L), as redesignated by
23 subparagraph (B), by striking “through (J)” and in-
24 serting “through (K)”; and

1 (5) in the flush matter following subparagraph
2 (L), as so redesignated, by striking “subparagraphs
3 (A) through (K)” and inserting “subparagraphs (A)
4 through (L)”.

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