

116TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To amend titles XI, XVIII, and XIX of the Social Security Act to promote value-based arrangements.

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IN THE SENATE OF THE UNITED STATES

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Mr. CASSIDY (for himself and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on

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**A BILL**

To amend titles XI, XVIII, and XIX of the Social Security Act to promote value-based arrangements.

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 “Patient Affordability  
5 Value and Efficiency Act”.

1 **SEC. 2. EXCLUSION OF CERTAIN VALUE-BASED ARRANGE-**  
2 **MENTS FROM ANTI-KICKBACK AND PHYSI-**  
3 **CIAN SELF-REFERRAL PROHIBITIONS.**

4 (a) ANTI-KICKBACK.—Section 1128B(b)(3) of the  
5 Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amend-  
6 ed—

7 (1) in subparagraph (J)—

8 (A) by moving such subparagraph 2 ems to  
9 the left; and

10 (B) by striking “and” at the end;

11 (2) in subparagraph (K)—

12 (A) by moving such subparagraph 2 ems to  
13 the left; and

14 (B) by striking the period at the end and  
15 inserting a semicolon; and

16 (3) by adding at the end the following new sub-  
17 paragraphs:

18 “(L) a value-based arrangement pursuant  
19 to a written agreement in which each partici-  
20 pant agrees to assume varying levels of finan-  
21 cial risk relative to a participant’s contribution  
22 to the achievement of the targeted outcomes  
23 (including but not limited to rebates, discounts,  
24 price reductions, contributions, reimbursements,  
25 guarantees, patient care, shared savings pay-

1           ments, withholds, or bonuses or anything of  
2           value) based on—

3                   “(i) the future performance of the  
4                   goods or services described in the arrange-  
5                   ment;

6                   “(ii) the achievement of preidentified  
7                   clinical or economic target metrics that are  
8                   specifically tailored to improve patient out-  
9                   comes or reduce the costs of health care  
10                  delivery without negatively affecting pa-  
11                  tient outcomes;

12                  “(iii) implementation of processes or  
13                  procedures that otherwise optimize the de-  
14                  livery, efficiency, or quality of patient-cen-  
15                  tered care; and

16                  “(iv) any other evidence-based out-  
17                  come or circumstance as defined by the  
18                  Secretary through notice-and-comment  
19                  rulemaking; and

20                  “(M) a medication adherence support pro-  
21                  gram pursuant to a written agreement (includ-  
22                  ing a program that is part of a value-based ar-  
23                  rangement and any agreement with respect to  
24                  the collection and use of derived adherence data  
25                  and information) that establishes the protocol

1 for a patient’s substantial compliance with a  
2 covered medication regimen prescribed by the  
3 patient’s health care provider under title XVIII,  
4 a Federal health care program, or a State  
5 health care program.”.

6 (b) PHYSICIAN SELF-REFERRAL.—Section  
7 1877(h)(1)(C) of the Social Security Act (42 U.S.C.  
8 1395nn(h)(1)(C)) is amended by adding the following sub-  
9 clause:

10 “(iv) Any amounts determined under  
11 a value-based arrangement described in  
12 section 1128(b)(3)(L).”.

13 (c) EFFECTIVE DATE.—The amendments made by  
14 this section shall take effect [\_\_\_\_\_].

15 **SEC. 3. EXCLUSION OF DRUGS PURCHASED THROUGH**  
16 **VALUE-BASED ARRANGEMENTS FROM MED-**  
17 **ICAID BEST PRICE AND AVERAGE MANUFAC-**  
18 **TURER PRICE DETERMINATIONS.**

19 (a) IN GENERAL.—Section 1927 of the Social Secu-  
20 rity Act (42 U.S.C. 1396r–8) is amended—

21 (1) in subsection (c)(1)(C)(i)—

22 (A) in subclause (V), by striking “and”  
23 after the semicolon;

24 (B) in subclause (VI), by striking the pe-  
25 riod at the end and inserting “; and”; and

1 (C) by adding at the end the following:

2 “(VII) any prices charged under  
3 a value-based purchasing arrange-  
4 ment.”; and

5 (2) in subsection (k)—

6 (A) in paragraph (1)(B)(i)—

7 (i) in subclause (IV), by striking  
8 “and” after the semicolon;

9 (ii) in subclause (V), by striking the  
10 period at the end and inserting “; and”;  
11 and

12 (iii) by adding at the end the fol-  
13 lowing:

14 “(VI) any prices charged under a  
15 value-based purchasing arrange-  
16 ment.”; and

17 (B) by adding at the end the following:

18 “(12) VALUE-BASED PURCHASING ARRANGE-  
19 MENT.—The term ‘value-based purchasing arrange-  
20 ment’ means any arrangement documented in writ-  
21 ing under which the price of a covered outpatient  
22 drug (net of any discounts under the arrangement)  
23 is based in whole or in part on—

24 “(A) the achievement of measurable and  
25 defined evidence-based patient outcomes;

1                   “(B) clinical circumstances or measures;

2                   “(C) the relative values of multiple indica-

3                   tions; or

4                   “(D) any other measure of value as speci-

5                   fied by the Secretary through notice-and-com-

6                   ment rulemaking.”.

7           (b) **EFFECTIVE DATE.**—The amendments made by  
8 subsection (a) shall apply with respect to rebate periods  
9 beginning on or after the first day of the first calendar  
10 year beginning after the date of the enactment of this sec-  
11 tion.