

117TH CONGRESS
2D SESSION

H. R. 7389

To amend title XIX of the Social Security Act to codify value-based purchasing arrangements under the Medicaid program and reforms related to price reporting under such arrangements, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 4, 2022

Mr. SCHRADER (for himself, Mr. GUTHRIE, and Mr. MULLIN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend title XIX of the Social Security Act to codify value-based purchasing arrangements under the Medicaid program and reforms related to price reporting under such arrangements, 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 “Medicaid VBPs for
5 Patients Act” or the “MVP Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

1 (1) Value-based payment (VBP) arrangements
2 are a critical component of a modernized reimburse-
3 ment system. By codifying elements of the recently
4 finalized “multiple best price” policies of the Centers
5 for Medicare & Medicaid Services, Congress is en-
6 shrining a sustainable and flexible payment ap-
7 proach for innovative treatments and cures.

8 (2) Many of these treatments, including gene
9 therapies, are different from traditional pharma-
10 ceutical and biologic products in that they can offer
11 long-lasting—sometimes lifelong—benefits for pa-
12 tients and long-term value for the health care system
13 alike.

14 (3) There are hundreds of innovative, curative,
15 and life-changing treatments currently in develop-
16 ment in the United States. However, the current re-
17 imbursement structure was not designed with these
18 therapies in mind, and allowing for innovative pay-
19 ment arrangements will spur greater development
20 and access to future cures and treatments.

21 (4) Medicaid is currently losing out on innova-
22 tive ways to ensure patients have access to these
23 treatments, while private payors continue to see the
24 value provided through flexible payment arrange-
25 ments.

1 (5) VBP arrangements include the ability to
 2 pay based on evidence-based outcomes and, over
 3 time, spreading the risk across all entities involved
 4 in the contract and ensuring that these often costly
 5 treatments are accessible.

6 (6) Evidence-based outcomes can demonstrate
 7 decreased cost to the health system and to patients,
 8 including reduced hospitalizations and lower utiliza-
 9 tion of other health care expenditures, including lab
 10 work, other medications, and office visits.

11 (7) By allowing VBPs in Medicaid, the health
 12 care system will continue to move towards quality
 13 over quantity, holding manufacturers and providers
 14 accountable for the best treatment for every patient.

15 **SEC. 3. CODIFYING VALUE-BASED PURCHASING ARRANGE-**
 16 **MENTS UNDER MEDICAID AND REFORMS RE-**
 17 **LATED TO PRICE REPORTING UNDER SUCH**
 18 **ARRANGEMENTS.**

19 (a) CODIFYING THE VBP RULE.—The revision to
 20 section 447.505(a) of title 42, Code of Federal Regula-
 21 tions related to the inclusion of varying best price points
 22 available under a value-based purchasing arrangement (as
 23 defined in section 1927(k)(12) of the Social Security Act
 24 (42 U.S.C. 1396r–8(k)(12), as added by subsection (d)
 25 of this section) for a single dosage form and strength of

1 a covered outpatient drug if a manufacturer offers such
 2 pricing structure to all States, as published by the Sec-
 3 retary of Health and Human Services on December 31,
 4 2020 (85 Federal Register 87000), shall have the force
 5 and effect of law.

6 (b) QUARTERLY REPORTING OBLIGATION.—

7 (1) IN GENERAL.—Section 1927(b)(3)(A) of the
 8 Social Security Act (42 U.S.C. 1396r–8(b)(3)(A)) is
 9 amended—

10 (A) in clause (iv), by striking at the end
 11 “and”;

12 (B) in clause (v), by striking at the end
 13 the period and inserting “; and”;

14 (C) by inserting after clause (v) the fol-
 15 lowing new clause:

16 “(vi) for calendar quarters beginning
 17 on or after July 1, 2022, in conjunction
 18 with reporting required under clause (i), in
 19 the case of a covered outpatient drug that
 20 is sold under a value-based purchasing ar-
 21 rangement (as defined in subsection
 22 (k)(12)) made available by the manufac-
 23 turer to a State plan—

24 “(I) the pricing structure for
 25 such drug based on pre-defined out-

1 comes or measures specified in such
2 value-based purchasing arrangement;
3 and

4 “(II) the best price for such cov-
5 ered outpatient drug outside of a
6 value-based purchasing arrangement,
7 which in the event such drug is sold
8 exclusively through such an arrange-
9 ment, means the lowest price available
10 net of any discounts or offsets that
11 are unrelated to a refund, rebate, re-
12 imbursement, free item, withholding,
13 or repayment made under a value-
14 based purchasing arrangement for
15 such drug.”; and

16 (D) by adding at the end of the flush left
17 matter at the end the following new sentence:
18 “Information reported with respect to a rebate
19 period under clause (i)(I) relating to average
20 manufacturer price and clause (i)(II) relating to
21 best price shall be updated for such rebate pe-
22 riod if, subsequent to the date such information
23 was reported, cumulative discounts, rebates, or
24 other arrangements adjust such average price
25 actually realized or best price available to the

1 extent that such cumulative discounts, rebates,
2 or other arrangements are not excluded under
3 this section from the determination of average
4 manufacturer price or best price.”

5 (2) RULES OF CONSTRUCTION.—Nothing in the
6 amendments made by paragraph (1) shall be con-
7 strued as—

8 (A) requiring—

9 (i) a State to enter into a value-based
10 purchasing arrangement with a manufac-
11 turer for a covered outpatient drug; or

12 (ii) a manufacturer to enter into a
13 value-based purchasing arrangement with
14 a State for a covered outpatient drug;

15 (B) prohibiting a manufacturer from treat-
16 ing a value-based purchasing arrangement as a
17 bundled sale; or

18 (C) precluding the execution of a supple-
19 mental rebate agreement, as provided in section
20 1927(a)(1) of the Social Security Act (42
21 U.S.C. 1396r–8(a)(1)), for a covered outpatient
22 drug sold under a value-based purchasing ar-
23 rangement.

1 (c) DEFINITION OF AVERAGE MANUFACTURER

2 PRICE.—Section 1927(k)(1) of the Social Security Act (42

3 U.S.C. 1396r–8(k)(1)) is amended—

4 (1) in subparagraph (B)(i)—

5 (A) in subclause (IV), by striking at the
6 end “and”;

7 (B) in subclause (V), by striking the period
8 at the end and inserting “; and”; and

9 (C) by adding at the end the following new
10 subclause:

11 “(VI) in accordance with sub-
12 section (b)(3)(A)(vi), with respect to
13 such covered outpatient drug that is
14 sold under a value-based purchasing
15 arrangement (as defined in paragraph
16 (12)) during the rebate period—

17 “(aa) a refund, rebate, reim-
18 bursement, or free goods from
19 the manufacturer or third party
20 on behalf of the manufacturer; or

21 “(bb) the withholding or re-
22 duction of a payment to the man-
23 ufacturer or third party on behalf
24 of the manufacturer;

1 that is triggered by a patient who
2 fails to achieve outcomes or measures
3 defined under the terms of such value-
4 based purchasing arrangement during
5 the period for which such agreement
6 is effective.”; and

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

9 “(D) SPECIAL RULE FOR CERTAIN VALUE-
10 BASED PURCHASING ARRANGEMENTS.—For
11 purposes of subparagraph (A), in determining
12 the average price paid to the manufacturer for
13 a covered outpatient drug that is sold under a
14 value-based purchasing arrangement (as defined
15 in paragraph (12)) that provides that payment
16 for such drug is made in installments over the
17 course of such agreement, such price shall be
18 determined as if the aggregate price per the
19 terms of the agreement was paid in full in the
20 first installment during the rebate period.”.

21 (d) DEFINITION OF VALUE-BASED PURCHASING AR-
22 RANGEMENT.—Section 1927(k) of the Social Security Act
23 (42 U.S.C. 1396r–8(k)) shall be amended by adding at
24 the end the following paragraph:

1 “(12) VALUE-BASED PURCHASING ARRANGE-
 2 MENT.—The term ‘value-based purchasing arrange-
 3 ment’ means an arrangement or agreement intended
 4 to align pricing or payments to an observed or ex-
 5 pected therapeutic or clinical value in a select popu-
 6 lation and includes—

7 “(A) evidence-based measures, which sub-
 8 stantially link the cost of a covered outpatient
 9 drug to existing evidence of effectiveness and
 10 potential value for specific uses of that product;
 11 or

12 “(B) outcomes-based measures, which sub-
 13 stantially link payment for the covered out-
 14 patient drug to that of the drug’s actual per-
 15 formance in patient or a population, or a reduc-
 16 tion in other medical expenses.”.

17 (e) EFFECTIVE DATE.—The amendments made by
 18 this section shall apply beginning on July 1, 2022.

19 **SEC. 4. REMUNERATION IN FEDERAL HEALTH CARE PRO-**
 20 **GRAMS.**

21 (a) IN GENERAL.—Section 1128B(b)(3) of the Social
 22 Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

23 (1) in subclause (J)—

24 (A) by moving the left margin of such sub-
 25 paragraph 2 ems to the left; and

1 (B) by striking “and” after the semicolon
 2 at the end;

3 (2) in subclause (K)—

4 (A) by moving the left margin of such sub-
 5 paragraph 2 ems to the left; and

6 (B) by striking the period at the end and
 7 inserting “; and”; and

8 (3) by adding at the end the following new sub-
 9 paragraph:

10 “(L) any remuneration provided by a man-
 11 ufacturer or third party on behalf of a manu-
 12 facturer to a plan under a value-based pur-
 13 chasing arrangement (as defined in section
 14 1927(k)(12)) in the case a patient fails to
 15 achieve outcomes or measures defined in such
 16 arrangement following the administration of a
 17 covered outpatient drug (as defined in section
 18 1927(k)(2)).”.

19 (b) EFFECTIVE DATE.—The amendments made by
 20 this section shall apply beginning on July 1, 2022.

21 **SEC. 5. GAO STUDY AND REPORT ON USE OF VALUE-BASED**
 22 **PURCHASING ARRANGEMENTS.**

23 (a) STUDY.—The Comptroller General of the United
 24 States shall conduct a study on the extent to which value-
 25 based purchasing arrangements (as defined in section

1 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–
2 8(k)(12)) facilitate patient access to covered outpatient
3 drugs, improve patient outcomes, lower overall health sys-
4 tem costs, and lower costs for patients in Federal health
5 care programs. In conducting such study, the Comptroller
6 General shall—

7 (1) study the impact of this Act on—

8 (A) access to transformative therapies, in-
9 cluding rare disease gene therapies, generally;

10 (B) mitigating socioeconomic disparities in
11 accessing covered outpatient drugs sold under
12 value-based purchasing arrangements through
13 its requirement that State Medicaid programs
14 have access to the same value-based purchasing
15 arrangement pricing structure that are available
16 in the commercial market for such drugs; and

17 (C) the Medicaid drug rebate program
18 under section 1927 of the Social Security Act
19 (42 U.S.C. 1396r–8), the 340B drug pricing
20 program under section 340B of the Public
21 Health Service Act (42 U.S.C. 256b), and part
22 B of title XVIII of the Social Security Act (42
23 U.S.C. 1395j et seq.), including compliance
24 with such programs; and

1 (2) using data submitted pursuant to clause
2 (vi) of section 1927(b)(3)(A) of the Social Security
3 Act (42 U.S.C. 1396r–8(b)(3)(A)), as added by sec-
4 tion 3 of this Act, analyze all the types of value-
5 based purchasing arrangement pricing structures,
6 which structures are working well (as measured by
7 price and ease of implementing), and which need im-
8 provement.

9 (b) REPORT.—Not later than June 30, 2027, the
10 Comptroller General of the United States shall submit to
11 Congress a report containing the results of the study con-
12 ducted under subsection (a).

○