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(Original Signature of Member)

118TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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.

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**IN THE HOUSE OF REPRESENTATIVES**

Mr. GUTHRIE introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**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) of  
25 this section) for a single dosage form and strength of a

1 covered outpatient drug if a manufacturer offers such  
2 pricing structure to all States, shall have the force and  
3 effect of law.

4 (b) QUARTERLY REPORTING OBLIGATION.—

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

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

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

12 (C) by inserting after clause (v) the fol-  
13 lowing new clause:

14 “(vi) in conjunction with reporting re-  
15 quired under clause (i), in the case of a  
16 covered outpatient drug that is sold under  
17 a value-based purchasing arrangement (as  
18 defined in subsection (k)(12)) made avail-  
19 able by the manufacturer to a State plan—

20 “(I) the pricing structure for  
21 such drug based on pre-defined out-  
22 comes or measures specified in such  
23 value-based purchasing arrangement;  
24 and

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

13 (D) by adding at the end of the flush left  
14 matter at the end the following new sentence:  
15 “Information reported with respect to a rebate  
16 period under clause (i)(I) relating to average  
17 manufacturer price and clause (i)(II) relating to  
18 best price shall be updated for such rebate pe-  
19 riod if, subsequent to the date such information  
20 was reported, cumulative discounts, rebates, or  
21 other arrangements adjust such average price  
22 actually realized or best price available to the  
23 extent that such cumulative discounts, rebates,  
24 or other arrangements are not excluded under

1           this section from the determination of average  
2           manufacturer price or best price.”

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

6                   (A) requiring—

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

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

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

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

22           (c) DEFINITION OF AVERAGE MANUFACTURER  
23           PRICE.—Section 1927(k)(1) of the Social Security Act (42  
24           U.S.C. 1396r-8(k)(1)) is amended—

25                   (1) in subparagraph (B)(i)—

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

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

5 (C) by adding at the end the following new  
6 subclause:

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

13 “(aa) a refund, rebate, reim-  
14 bursement, or free goods from  
15 the manufacturer or third party  
16 on behalf of the manufacturer; or

17 “(bb) the withholding or re-  
18 duction of a payment to the man-  
19 ufacturer or third party on behalf  
20 of the manufacturer;

21 that is triggered by a patient who  
22 fails to achieve outcomes or measures  
23 defined under the terms of such value-  
24 based purchasing arrangement during

1 the period for which such agreement  
2 is effective.”; and

3 (2) by adding at the end the following new sub-  
4 paragraph:

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

17 (d) DEFINITION OF VALUE-BASED PURCHASING AR-  
18 RANGEMENT.—Section 1927(k) of the Social Security Act  
19 (42 U.S.C. 1396r-8(k)) shall be amended by adding at the  
20 end the following paragraph:

21 “(12) VALUE-BASED PURCHASING ARRANGE-  
22 MENT.—The term ‘value-based purchasing arrange-  
23 ment’ means an arrangement or agreement intended  
24 to align pricing or payments to an observed or ex-



1       pected therapeutic or clinical value in a select popu-  
2       lation and includes—

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

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

13 **SEC. 4. CALCULATION OF AVERAGE SALES PRICE UNDER**  
14 **MEDICARE.**

15       Section 1847A(c)(2) of the Social Security Act (42  
16 U.S.C. 1395w–3a(c)(2)) is amended by adding at the end  
17 the following new subparagraph:

18               “(C) SALES SUBJECT TO A VALUE-BASED  
19               PURCHASING ARRANGEMENT.—Sales of a drug  
20               made under a value-based purchasing arrange-  
21               ment (as defined in section 1927(k)(12)), but  
22               only if the manufacturer of such drug has elect-  
23               ed to report multiple best prices under section  
24               1927(c) with respect to such drug in accordance

1 with the revision described in section 3(a) of  
2 the MVP Act.”.

3 **SEC. 5. VALUE-BASED PURCHASING ARRANGEMENTS FOR**  
4 **INPATIENT DRUGS UNDER MEDICAID.**

5 Title XIX of the Social Security Act (42 U.S.C. 1396  
6 et seq.) is amended by adding at the end the following  
7 new section:

8 **“SEC. 1948. VALUE-BASED PURCHASING ARRANGEMENTS**  
9 **FOR INPATIENT DRUGS.**

10 “(a) IN GENERAL.—Notwithstanding section  
11 1902(a)(1) (relating to statewideness), section  
12 1902(a)(10)(b) (relating to comparability), and any other  
13 provision of this title for which the secretary determines  
14 it is necessary to waive in order to implement this section,  
15 beginning on January 1, 2024, the Secretary shall estab-  
16 lish a program under which States may provide under  
17 their State plans under this title (including such a plan  
18 operating under a statewide waiver under section 1115)  
19 medical assistance for drugs furnished to individuals in  
20 an inpatient setting pursuant to a value-based purchasing  
21 arrangement (as defined in section 1927(k)(12)) with  
22 manufacturers of such drugs.

23 “(b) APPLICATION OF CERTAIN OUTPATIENT PROVI-  
24 SIONS TO INPATIENT DRUGS.—

1           “(1) IN GENERAL.—Under the program estab-  
2           lished under subsection (a), the Secretary shall pro-  
3           vide for the application of the provisions described in  
4           paragraph (2) to value-based purchasing arrange-  
5           ments relating to drugs administered in the inpa-  
6           tient setting in a manner similar to the manner in  
7           which such provisions would apply if such drugs  
8           were administered in an outpatient setting.

9           “(2) PROVISIONS DESCRIBED.—The provisions  
10          described in this paragraph are as follows:

11               “(A) QUARTERLY PRICE REPORTING OBLI-  
12               GATION.—Section 1927(b)(3)(E).

13               “(B) DEFINITION OF BEST PRICE.—  
14               Clauses (i)(VII) and (ii)(V) of section  
15               1927(c)(1)(C).

16               “(C) DEFINITION OF AVERAGE MANUFAC-  
17               TURER PRICE.—Subparagraphs (B)(i)(VI) and  
18               (D) of section 1927(k)(1).

19               “(D) ANTI-KICKBACK AND PHYSICIAN  
20               SELF-REFERRAL SAFE HARBORS.—Section  
21               1128B(b)(3)(L) and section 1877(h)(1)(C)(iv).

22          “(c) CARVE-OUT OF DRUGS.—In the case of a drug  
23          that is sold under a value-based purchasing arrangement,  
24          the Secretary shall permit States to pay for such drug  
25          under the terms and conditions of the arrangement sepa-

1 rately from other inpatient items and services furnished  
2 to the individual.

3 “(d) MULTI-STATE AGREEMENTS.—Under the pro-  
4 gram established under subsection (a), the Secretary shall  
5 permit multiple States to enter into agreements with one  
6 another and with manufacturers which permit the transfer  
7 of funds between the participating states so that individ-  
8 uals who reside in a State different from the State in  
9 which they receive a drug subject to an value-based pur-  
10 chasing arrangement as an inpatient may be treated as  
11 if they received such drug in the State in which they re-  
12 side.

13 “(e) CONSTRUCTION.—Nothing in this subparagraph  
14 shall be construed as deeming a drug furnished to an inpa-  
15 tient as being subject to the drug discount program under  
16 section 340B of the Public Health Service Act.”.

17 **SEC. 6. REMUNERATION IN FEDERAL HEALTH CARE PRO-**  
18 **GRAMS.**

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

21 (1) in subclause (J)—

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

24 (B) by striking “and” after the semicolon  
25 at the end;

1 (2) in subclause (K)—

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

4 (B) by striking the period at the end and  
5 inserting “; and”; and

6 (3) by adding at the end the following new sub-  
7 paragraph:

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

17 **SEC. 7. GAO STUDY AND REPORT ON USE OF VALUE-BASED**  
18 **PURCHASING ARRANGEMENTS.**

19 (a) STUDY.—The Comptroller General of the United  
20 States shall conduct a study on the extent to which value-  
21 based purchasing arrangements (as defined in section  
22 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r-  
23 8(k)(12)) facilitate patient access to covered outpatient  
24 drugs, improve patient outcomes, lower overall health sys-  
25 tem costs, and lower costs for patients in Federal health

1 care programs. In conducting such study, the Comptroller  
2 General shall—

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

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

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

13 (C) the Medicaid drug rebate program  
14 under section 1927 of the Social Security Act  
15 (42 U.S.C. 1396r–8), the 340B drug pricing  
16 program under section 340B of the Public  
17 Health Service Act (42 U.S.C. 256b), and part  
18 B of title XVIII of the Social Security Act (42  
19 U.S.C. 1395j et seq.), including compliance  
20 with such programs; and

21 (2) using data submitted pursuant to clause  
22 (vi) of section 1927(b)(3)(A) of the Social Security  
23 Act (42 U.S.C. 1396r-8(b)(3)(A)), as added by sec-  
24 tion 3 of this Act, analyze all the types of value-  
25 based purchasing arrangement pricing structures,

1       which structures are working well (as measured by  
2       price and ease of implementing), and which need im-  
3       provement.

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

8   **SEC. 8. SUNSET.**

9       The provisions of, and the amendments made by, this  
10   Act shall have no effect beginning 5 years after the date  
11   of the enactment of this Act. The preceding sentence shall  
12   not apply to any value-based purchasing arrangement in  
13   effect as of the date that is 5 years after such date of  
14   enactment.