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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.

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

22 “(I) the pricing structure for
23 such drug based on pre-defined out-
24 comes or measures specified in such

1 value-based purchasing arrangement;
2 and

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

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

1 or other arrangements are not excluded under
2 this section from the determination of average
3 manufacturer price or best price.”

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

7 (A) requiring—

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

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

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

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

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

1 (1) in subparagraph (B)(i)—

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

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

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

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

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

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

22 that is triggered by a patient who
23 fails to achieve outcomes or measures
24 defined under the terms of such value-
25 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).