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(Original Signature of Member)

119TH CONGRESS
2^D 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”.

1 **SEC. 2. CODIFYING VALUE-BASED PURCHASING ARRANGE-**
2 **MENTS UNDER MEDICAID AND REFORMS RE-**
3 **LATED TO PRICE REPORTING UNDER SUCH**
4 **ARRANGEMENTS.**

5 (a) CODIFYING MULTIPLE BEST PRICE POINTS.—

6 (1) IN GENERAL.—Section 1927(e)(1)(C)(ii) of
7 the Social Security Act (42 U.S.C. 1396r–
8 8(e)(1)(C)(ii)) is amended—

9 (A) in subclause (III), by adding a semi-
10 colon at the end;

11 (B) in subclause (IV), by striking “and” at
12 the end;

13 (C) in subclause (V), by striking the period
14 and inserting “; and”; and

15 (D) by adding at the end the following new
16 subclause:

17 “(VI) may include multiple best
18 price points for a single dosage form
19 and strength of a drug of a manufac-
20 turer subject to a value-based pur-
21 chasing arrangement (as defined in
22 subsection (k)(12)), but only if such
23 manufacturer offers such arrangement
24 to all States.”.

25 (2) RULE OF CONSTRUCTION.—Nothing in the
26 amendments made by this subsection may be con-

1 strued to prohibit a manufacturer from treating a
2 value-based purchasing arrangement as a bundled
3 sale.

4 (b) DEFINITION OF AVERAGE MANUFACTURER
5 PRICE.—

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

9 (A) in subparagraph (B)(i)—

10 (i) in subclause (IV), by adding a
11 semicolon at the end;

12 (ii) in subclause (VII), by striking at
13 the end “and”;

14 (iii) in subclause (VIII), by striking
15 the period at the end and inserting “;
16 and”;

17 (iv) by adding at the end the following
18 new subclause:

19 “(IX) with respect to a covered
20 outpatient drug that is sold under a
21 value-based purchasing arrangement
22 (as defined in paragraph (12)) during
23 the rebate period, including such a
24 drug that is an inhalation, infusion,
25 instilled, implanted, or injectable drug

1 that is not generally dispensed
2 through a retail community phar-
3 macy—

4 “(aa) a refund, rebate, reim-
5 bursement, or free goods from
6 the manufacturer or third party
7 on behalf of the manufacturer; or

8 “(bb) the withholding or re-
9 duction of a payment to the man-
10 ufacturer or third party on behalf
11 of the manufacturer;

12 that is triggered by a patient who
13 fails to achieve outcomes or measures
14 defined under the terms of such value-
15 based purchasing arrangement during
16 the period for which such arrange-
17 ment is effective.”; and

18 (B) by adding at the end the following new
19 subparagraph:

20 “(D) SPECIAL RULE FOR CERTAIN VALUE-
21 BASED PURCHASING ARRANGEMENTS.—For
22 purposes of subparagraph (A), in determining
23 the average price paid to a manufacturer for a
24 covered outpatient drug that is sold under a
25 value-based purchasing arrangement (as defined

1 in paragraph (12)) that provides that payment
2 for such drug is made in installments over the
3 course of such arrangement, such price shall be
4 determined as if the aggregate price per the
5 terms of the arrangement were paid in full in
6 the first installment during the rebate period.”.

7 (2) RULEMAKING.—Not later than 180 days
8 after the date of the enactment of this Act, the Sec-
9 retary of Health and Human Services shall imple-
10 ment the amendments made by this subsection
11 through rulemaking.

12 (c) DEFINITION OF VALUE-BASED PURCHASING AR-
13 RANGEMENT.—Section 1927(k) of the Social Security Act
14 (42 U.S.C. 1396r–8(k)) is amended by adding at the end
15 the following paragraph:

16 “(12) VALUE-BASED PURCHASING ARRANGE-
17 MENT.—The term ‘value-based purchasing arrange-
18 ment’ has the meaning given such term in section
19 447.502 of title 42, Code of Federal Regulations (or
20 any successor regulation).”.

21 **SEC. 3. CALCULATION OF AVERAGE SALES PRICE UNDER**
22 **MEDICARE.**

23 Section 1847A(c)(3) of the Social Security Act (42
24 U.S.C. 1395w–3a(c)(3)) is amended—

1 (1) by striking “In calculating” and inserting
2 the following:

3 “(A) IN GENERAL.—Subject to subpara-
4 graph (B), in calculating”; and

5 (2) by adding at the end the following new sub-
6 paragraph:

7 “(B) CERTAIN REMUNERATION UNDER
8 VALUE-BASED PURCHASING ARRANGEMENTS
9 EXCLUDED.—In calculating the manufacturer’s
10 average sales price under this subsection for a
11 drug or biological that is sold under a value-
12 based purchasing arrangement (as defined in
13 section 1927(k)(12)) and with respect to which
14 the manufacturer of such drug or biological has
15 elected to include multiple best price points (as
16 described in section 1927(c)(1)(C)(ii)(VI)) in
17 reporting the best price of such drug under sec-
18 tion 1927(b), such manufacturer’s average sales
19 price shall not include any amount that is ex-
20 cluded from the calculation of the average man-
21 ufacturer price of such drug or biological under
22 section 1927(k)(1)(B)(i)(IX).”.

1 **SEC. 4. GUIDANCE ON VALUE-BASED PURCHASING AR-**
2 **RANGEMENTS FOR INPATIENT DRUGS UNDER**
3 **MEDICAID.**

4 Not later than 180 days after the date of the enact-
5 ment of this Act, the Secretary of Health and Human
6 Services shall issue guidance to State Medicaid agencies
7 on the option of entering into a value-based purchasing
8 arrangement (as defined in section 1927(k)(12) of the So-
9 cial Security Act (42 U.S.C. 1396r-8(k)(12))) with manu-
10 facturers for drugs or biological products provided as part
11 of, or as incident to and in the same setting as, inpatient
12 hospital services furnished under a State plan under title
13 XIX of the Social Security Act (42 U.S.C. 1396 et seq.),
14 or under a waiver of such plan, where such drugs or bio-
15 logical products are reimbursed directly and not paid for
16 as part of payment for such inpatient hospital services,
17 including guidance on how multiple States may enter into
18 agreements with one another and with manufacturers
19 which permit the transfer of funds between the partici-
20 pating States so that individuals who reside in a State
21 different from the State in which they receive a drug sub-
22 ject to a value-based purchasing arrangement as an inpa-
23 tient may be treated as if they received such drug in the
24 State in which they reside.

1 **SEC. 5. EXCEPTION UNDER THE ANTIKICKBACK STATUTE.**

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

4 (1) in subparagraph (J), by moving the left
5 margin of such subparagraph 2 ems to the left;

6 (2) in subparagraph (K)—

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

9 (B) by striking “and” at the end;

10 (3) in subparagraph (L)(iii), by striking the pe-
11 riod and inserting “; and”; and

12 (4) by adding at the end the following new sub-
13 paragraph:

14 “(M) any remuneration provided by a
15 manufacturer or third party on behalf of a
16 manufacturer to a State under a value-based
17 purchasing arrangement (as defined in section
18 1927(k)(12)) under a State plan under title
19 XIX (or waiver of such plan) in the case a pa-
20 tient fails to achieve outcomes or measures de-
21 fined in such arrangement following the admin-
22 istration of a covered outpatient drug (as de-
23 fined in section 1927(k)(2)).”.

24 (b) RULEMAKING.—Not later than 180 days after the
25 date of the enactment of this Act, the Inspector General
26 of the Department of Health and Human Services shall

1 through rulemaking implement the amendments made by
2 this section.

3 **SEC. 6. GAO STUDY AND REPORT ON USE OF VALUE-BASED**
4 **PURCHASING ARRANGEMENTS.**

5 (a) STUDY.—The Comptroller General of the United
6 States shall conduct a study on the extent to which value-
7 based purchasing arrangements (as defined in section
8 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r-
9 8(k)(12))) facilitate patient access to covered outpatient
10 drugs, improve patient outcomes, lower overall health sys-
11 tem costs, and lower costs for patients in Federal health
12 care programs. In conducting such study, the Comptroller
13 General shall—

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

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

17 (B) mitigating socioeconomic disparities in
18 accessing covered outpatient drugs sold under
19 value-based purchasing arrangements through
20 its requirement that State Medicaid programs
21 have access to the same value-based purchasing
22 arrangement pricing structure that are available
23 in the commercial market for such drugs;

24 (C) the Medicaid drug rebate program
25 under section 1927 of the Social Security Act

1 (42 U.S.C. 1396r-8), the 340B drug pricing
2 program under section 340B of the Public
3 Health Service Act (42 U.S.C. 256b), and part
4 B of title XVIII of the Social Security Act (42
5 U.S.C. 1395j et seq.), including compliance
6 with such programs;

7 (D) expenditures under State Medicaid
8 programs; and

9 (E) prices for such drugs under the Med-
10 icaid program in States that do not enter into
11 such arrangements;

12 (2) analyze all the types of value-based pur-
13 chasing arrangement pricing structures, which struc-
14 tures are working well (as measured by price and
15 ease of implementing), and which need improvement;
16 and

17 (3) study the potential long-term savings for
18 States that enter into such arrangements under
19 State Medicaid programs.

20 (b) REPORT.—Not later than June 30, 2029, the
21 Comptroller General of the United States shall submit to
22 Congress a report containing the results of the study con-
23 ducted under subsection (a).