

118TH CONGRESS
2D SESSION

S. 4204

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 SENATE OF THE UNITED STATES

APRIL 30, 2024

Mr. MULLIN (for himself, Ms. SINEMA, Mr. SCOTT of South Carolina, and Ms. HASSAN) introduced the following bill; which was read twice and referred to the Committee on Finance

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 (IV), by striking “and” at
10 the end;

11 (B) in subclause (V), by striking the period
12 and inserting “; and”; and

13 (C) by adding at the end the following new
14 subclause:

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

23 (2) RULE OF CONSTRUCTION.—Nothing in the
24 amendments made by this subsection may be con-
25 strued to prohibit a manufacturer from treating a

1 value-based purchasing arrangement as a bundled
2 sale.

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

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

8 (A) in subparagraph (B)(i)—

9 (i) in subclause (VII), by striking at
10 the end “and”;

11 (ii) in subclause (VIII), by striking
12 the period at the end and inserting “;
13 and”; and

14 (iii) by adding at the end the fol-
15 lowing new subclause:

16 “(IX) with respect to a covered
17 outpatient drug that is sold under a
18 value-based purchasing arrangement
19 (as defined in paragraph (12)) during
20 the rebate period, including such a
21 drug that is an inhalation, infusion,
22 instilled, implanted, or injectable drug
23 that is not generally dispensed
24 through a retail community phar-
25 macy—

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

5 “(bb) the withholding or re-
6 duction of a payment to the man-
7 ufacturer or third party on behalf
8 of the manufacturer;

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

15 (B) by adding at the end the following new
16 subparagraph:

17 “(D) SPECIAL RULE FOR CERTAIN VALUE-
18 BASED PURCHASING ARRANGEMENTS.—For
19 purposes of subparagraph (A), in determining
20 the average price paid to a manufacturer for a
21 covered outpatient drug that is sold under a
22 value-based purchasing arrangement (as defined
23 in paragraph (12)) that provides that payment
24 for such drug is made in installments over the
25 course of such arrangement, such price shall be

1 determined as if the aggregate price per the
2 terms of the arrangement were paid in full in
3 the first installment during the rebate period.”.

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

9 (c) DEFINITION OF VALUE-BASED PURCHASING AR-
10 RANGEMENT.—Section 1927(k) of the Social Security Act
11 (42 U.S.C. 1396r–8(k)) is amended by adding at the end
12 the following paragraph:

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

18 **SEC. 3. CALCULATION OF AVERAGE SALES PRICE UNDER**
19 **MEDICARE.**

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

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

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

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

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

19 **SEC. 4. GUIDANCE ON VALUE-BASED PURCHASING AR-**
 20 **RANGEMENTS FOR INPATIENT DRUGS UNDER**
 21 **MEDICAID.**

22 Not later than 180 days after the date of the enact-
 23 ment of this Act, the Secretary of Health and Human
 24 Services shall issue guidance to State Medicaid agencies
 25 on the option of entering into a value-based purchasing

1 arrangement (as defined in section 1927(k)(12) of the So-
2 cial Security Act (42 U.S.C. 1396r–8(k)(12))) with manu-
3 facturers for drugs or biological products provided as part
4 of, or as incident to and in the same setting as, inpatient
5 hospital services furnished under a State plan under title
6 XIX of the Social Security Act (42 U.S.C. 1396 et seq.),
7 or under a waiver of such plan, where such drugs or bio-
8 logical products are reimbursed directly and not paid for
9 as part of payment for such inpatient hospital services,
10 including guidance on how multiple States may enter into
11 agreements with one another and with manufacturers
12 which permit the transfer of funds between the partici-
13 pating States so that individuals who reside in a State
14 different from the State in which they receive a drug sub-
15 ject to a value-based purchasing arrangement as an inpa-
16 tient may be treated as if they received such drug in the
17 State in which they reside.

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

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

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

23 (2) in subparagraph (K)—

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

1 (B) by striking “and” at the end;

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

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

6 “(M) any remuneration provided by a
7 manufacturer or third party on behalf of a
8 manufacturer to a State under a value-based
9 purchasing arrangement (as defined in section
10 1927(k)(12)) under a State plan under title
11 XIX (or waiver of such plan) in the case a pa-
12 tient fails to achieve outcomes or measures de-
13 fined in such arrangement following the admin-
14 istration of a covered outpatient drug (as de-
15 fined in section 1927(k)(2)).”.

16 (b) RULEMAKING.—Not later than 180 days after the
17 date of the enactment of this Act, the Inspector General
18 of the Department of Health and Human Services shall
19 through rulemaking implement the amendments made by
20 this section.

21 **SEC. 6. 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.
2 1396r–8(k)(12)) facilitate patient access to covered out-
3 patient drugs, improve patient outcomes, lower overall
4 health system costs, and lower costs for patients in Fed-
5 eral health care programs. In conducting such study, the
6 Comptroller 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;

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;

1 (D) expenditures under State Medicaid
2 programs; and

3 (E) prices for such drugs under the Med-
4 icaid program in States that do not enter into
5 such arrangements;

6 (2) analyze all the types of value-based pur-
7 chasing arrangement pricing structures, which struc-
8 tures are working well (as measured by price and
9 ease of implementing), and which need improvement;
10 and

11 (3) study the potential long-term savings for
12 States that enter into such arrangements under
13 State Medicaid programs.

14 (b) REPORT.—Not later than June 30, 2028, the
15 Comptroller General of the United States shall submit to
16 Congress a report containing the results of the study con-
17 ducted under subsection (a).

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