

Union Calendar No. 768

118TH CONGRESS
2D SESSION

H. R. 2666

[Report No. 118–743, Part I]

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 18, 2023

Mr. GUTHRIE (for himself, Ms. ESHOO, Mr. JOYCE of Pennsylvania, Mr. AUCHINCLOSS, Mrs. MILLER-MEEKS, and Mr. PETERS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

NOVEMBER 18, 2024

Reported from the Committee on Energy and Commerce with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

NOVEMBER 18, 2024

Referral to the Committee on Ways and Means extended for a period ending not later than December 19, 2024

DECEMBER 19, 2024

Additional sponsors: Mr. SWALWELL, Mr. CRENSHAW, Mr. BILIRAKIS, Mr. DUNN of Florida, Mr. BALDERSON, Mr. PHILLIPS, Mr. BERA, Mr. LIEU, Mr. THOMPSON of California, Ms. SHERRILL, Ms. HOULAHAN, Mr. CARTER of Georgia, Mr. GOTTHEIMER, Mr. CARTER of Louisiana, Mr. FERGUSON, Mr. HUFFMAN, Mr. MULLIN, Ms. PETTERSEN, Mr. BURGESS, Mr. IVEY, Mr. KELLY of Pennsylvania, Mr. AUSTIN SCOTT of Georgia, Mr. OWENS, Mr. MOOLENAAR, Mr. MEUSER, Mr. CISCOMANI, Ms. CARAVEO, Mr. VAN DREW, Mr. DUNCAN, Ms. MALLIOTAKIS, Mrs. STEEL, Mrs. CAMMACK, Ms. VAN DUYNE and Ms. STRICKLAND

DECEMBER 19, 2024

Committee on Ways and Means discharged; committed to the Committee of the Whole House on the State of the Union and ordered to be printed

[For text of introduced bill, see copy of bill as introduced on April 18, 2023]

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 Pa-*
 5 *tients Act” or the “MVP Act”.*

6 **SEC. 2. CODIFYING VALUE-BASED PURCHASING ARRANGE-**
 7 **MENTS UNDER MEDICAID AND REFORMS RE-**
 8 **LATED TO PRICE REPORTING UNDER SUCH**
 9 **ARRANGEMENTS.**

10 *(a) CODIFYING MULTIPLE BEST PRICE POINTS.—*

11 *(1) IN GENERAL.—Section 1927(c)(1)(C)(ii) of*
 12 *the Social Security Act (42 U.S.C. 1396r-*
 13 *8(c)(1)(C)(ii)) is amended—*

14 *(A) in subclause (IV), by striking “and” at*
 15 *the end;*

16 *(B) in subclause (V), by striking the period*
 17 *and inserting “; and”; and*

18 *(C) by adding at the end the following new*
 19 *subclause:*

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

1 *manufacturer offers such arrangement*
 2 *to all States.”.*

3 (2) *RULE OF CONSTRUCTION.*—*Nothing in the*
 4 *amendments made by this subsection may be con-*
 5 *strued to prohibit a manufacturer from treating a*
 6 *value-based purchasing arrangement as a bundled*
 7 *sale.*

8 (b) *DEFINITION OF AVERAGE MANUFACTURER*
 9 *PRICE.*—

10 (1) *IN GENERAL.*—*Section 1927(k)(1) of the So-*
 11 *cial Security Act (42 U.S.C. 1396r-8(k)(1)) is amend-*
 12 *ed—*

13 (A) *in subparagraph (B)(i)—*

14 (i) *in subclause (VII), by striking at*
 15 *the end “and”;*

16 (ii) *in subclause (VIII), by striking the*
 17 *period at the end and inserting “; and”;*
 18 *and*

19 (iii) *by adding at the end the following*
 20 *new subclause:*

21 “(IX) *with respect to such covered*
 22 *outpatient drug that is sold under a*
 23 *value-based purchasing arrangement*
 24 *(as defined in paragraph (12)) during*
 25 *the rebate period, including such drug*

1 *that is an inhalation, infusion, in-*
2 *stilled, implanted, or injectable drug*
3 *that is not generally dispensed through*
4 *a retail community pharmacy—*

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

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

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

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

21 *“(D) SPECIAL RULE FOR CERTAIN VALUE-*
22 *BASED PURCHASING ARRANGEMENTS.—For pur-*
23 *poses of subparagraph (A), in determining the*
24 *average price paid to the manufacturer for a*
25 *covered outpatient drug that is sold under a*

1 *value-based purchasing arrangement (as defined*
 2 *in paragraph (12)) that provides that payment*
 3 *for such drug is made in installments over the*
 4 *course of such agreement, such price shall be de-*
 5 *termined as if the aggregate price per the terms*
 6 *of the agreement was paid in full in the first in-*
 7 *stallment during the rebate period.”.*

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

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

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

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

24 *Section 1847A(c)(3) of the Social Security Act (42*
 25 *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 EX-*
9 *CLUDED.—In calculating the manufacturer’s av-*
10 *erage sales price under this subsection for a drug*
11 *or biological that is sold under a value-based*
12 *purchasing arrangement (as defined in section*
13 *1927(k)(12)) and with respect to which the man-*
14 *ufacturer of such drug or biological has elected to*
15 *include multiple best price points (as described*
16 *in section 1927(c)(1)(C)(ii)(VI)) in reporting the*
17 *best price of such drug under section 1927(b),*
18 *such price shall not include any amount that is*
19 *excluded from the calculation of the average*
20 *manufacturer price of such drug or biological*
21 *under 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 enactment*
5 *of this Act, the Secretary of Health and Human Services*
6 *shall issue guidance to State Medicaid agencies on the op-*
7 *tion of entering into a value-based purchasing arrangement*
8 *(as defined in section 1927(k)(12) of the Social Security*
9 *Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for*
10 *drugs or biological products provided as part of, or as inci-*
11 *dent to and in the same setting as, inpatient hospital serv-*
12 *ices furnished under a State plan under title XIX of the*
13 *Social Security Act (42 U.S.C. 1396 et seq.), or under a*
14 *waiver of such plan, where such drugs or biological products*
15 *are reimbursed directly and not paid for as part of pay-*
16 *ment for such inpatient hospital services, including guid-*
17 *ance on how multiple States may enter into agreements*
18 *with one another and with manufacturers which permit the*
19 *transfer of funds between the participating States so that*
20 *individuals who reside in a State different from the State*
21 *in which they receive a drug subject to a value-based pur-*
22 *chasing arrangement as an inpatient may be treated as if*
23 *they received such drug in the State in which they reside.*

24 **SEC. 5. EXCEPTION UNDER THE ANTICKICKBACK STATUTE.**

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

1 (1) in subparagraph (J), by moving the left mar-
2 gin of such subparagraph 2 ems to the left;

3 (2) in subparagraph (K)—

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

6 (B) by striking “and” at the end;

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

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

11 “(M) any remuneration provided by a man-
12 ufacturer or third party on behalf of a manufac-
13 turer to a State under a value-based purchasing
14 arrangement (as defined in section 1927(k)(12))
15 under a State plan under title XIX (or waiver
16 of such plan) in the case a patient fails to
17 achieve outcomes or measures defined in such ar-
18 rangement following the administration of a cov-
19 ered outpatient drug (as defined in section
20 1927(k)(2)).”.

21 (b) RULEMAKING.—Not later than 180 days after the
22 date of the enactment of this Act, the Inspector General of
23 the Department of Health and Human Services shall
24 through rulemaking implement the amendments made by
25 this section.

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

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

12 (1) *study the impact of this Act on—*

13 (A) *access to transformative therapies, in-*
14 *cluding rare disease gene therapies, generally;*

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

22 (C) *the Medicaid drug rebate program*
23 *under section 1927 of the Social Security Act (42*
24 *U.S.C. 1396r–8), the 340B drug pricing pro-*
25 *gram under section 340B of the Public Health*
26 *Service Act (42 U.S.C. 256b), and part B of title*

1 *XVIII of the Social Security Act (42 U.S.C.*
2 *1395j et seq.), including compliance with such*
3 *programs;*

4 *(D) expenditures under State Medicaid pro-*
5 *grams; and*

6 *(E) prices for such drugs under the Med-*
7 *icaid program in States that do not enter into*
8 *such arrangements;*

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

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

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

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