Committee Print

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118TH CONGRESS 1ST SESSION H. R. 2666

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

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,

1	SECTION 1. SHORT TITLE.
2	This Act may be cited as the "Medicaid VBPs for
3	Patients Act" or the "MVP Act".
4	SEC. 2. CODIFYING VALUE-BASED PURCHASING ARRANGE-
5	MENTS UNDER MEDICAID AND REFORMS RE-
6	LATED TO PRICE REPORTING UNDER SUCH
7	ARRANGEMENTS.
8	(a) Codifying Multiple Best Price Points.—
9	(1) In general.—Section 1927(c)(1)(C)(ii) of
10	the Social Security Act (42 U.S.C. 1396r–
11	8(c)(1)(C)(ii)) is amended—
12	(A) in subclause (IV), by striking "and" at
13	the end;
14	(B) in subclause (V), by striking the period
15	and inserting "; and; and
16	(C) by adding at the end the following new
17	subclause:
18	"(VI) may include varying best
19	price points for a single dosage form
20	and strength of a drug of a manufac-
21	turer subject to a value-based pur-
22	chasing arrangement (as defined in
23	subsection (k)(12)), but only if such
24	manufacturer offers such arrangement
25	to all States.".

1	(2) Rule of Construction.—Nothing in the
2	amendments made by this subsection may be con-
3	strued to prohibit a manufacturer from treating a
4	value-based purchasing arrangement as a bundled
5	sale.
6	(b) Definition of Average Manufacturer
7	Price.—
8	(1) In General.—Section 1927(k)(1) of the
9	Social Security Act (42 U.S.C. 1396r-8(k)(1)) is
10	amended—
11	(A) in subparagraph (B)(i)—
12	(i) in subclause (VII), by striking at
13	the end "and";
14	(ii) in subclause (VIII), by striking
15	the period at the end and inserting ";
16	and"; and
17	(iii) by adding at the end the fol-
18	lowing new subclause:
19	"(IX) with respect to such cov-
20	ered outpatient drug that is sold
21	under a value-based purchasing ar-
22	rangement (as defined in paragraph
23	(12)) during the rebate period, includ-
24	ing such drug that is an inhalation,
25	infusion, instilled, implanted or

1	injectable drug that is not generally
2	dispensed through a retail community
3	pharmacy—
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 agreement
17	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 the manufacturer for
24	a 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 agreement, such price shall be
4	determined as if the aggregate price per the
5	terms of the agreement was paid in full in the
6	first installment during the rebate period.".
7	(2) Guidance.—Not later than 90 days after
8	the date of the enactment of this Act, the Secretary
9	of Health and Human Services shall issue guidance
10	to State Medicaid agencies on the implementation of
11	the amendments made by this subsection.
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)) shall be amended by adding at the
15	end 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	an successor regulation).".
21	SEC. 3. CALCULATION OF AVERAGE SALES PRICE UNDER
22	MEDICARE.
23	Section 1847A(c)(2) of the Social Security Act (42
23 24	Section $1847A(c)(2)$ of the Social Security Act $(42$ U.S.C. $1395w-3a(c)(2))$ is amended by adding at the end

1	"(C) Sales subject to a value-based
2	PURCHASING ARRANGEMENT.—Sales of a drug
3	made under a value-based purchasing arrange-
4	ment (as defined in section $1927(k)(12)$), but
5	only if the manufacturer of such drug has elect-
6	ed to include multiple best price points (as de-
7	scribed in section $1927(c)(1)(C)(ii)(VI)$ in re-
8	porting the best price of such drug under sec-
9	tion 1927(b).".
10	SEC. 4. GUIDANCE ON VALUE-BASED PURCHASING AR-
11	RANGEMENTS FOR INPATIENT DRUGS UNDER
12	MEDICAID.
13	Not later than 90 days after the date of the enact-
14	ment of this Act, the Secretary of Health and Human
15	Carriers shall issue gridenes to State Medicaid agencies
	Services shall issue guidance to State Medicaid agencies
16	on the option of entering into a value-based purchasing
16 17	on the option of entering into a value-based purchasing
16 17	on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the So-
16 17 18 19	on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for drugs or biological products provided as part
16 17 18 19	on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for drugs or biological products provided as part
116 117 118 119 220 221	on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for drugs or biological products provided as part of, or as incident to and in the same setting as, inpatient
116 117 118 119 220 221	on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for drugs or biological products provided as part of, or as incident to and in the same setting as, inpatient hospital services furnished under a State plan under title
116 117 118 119 220 221 222	on the option of entering into a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manufacturers for drugs or biological products provided as part of, or as incident to and in the same setting as, inpatient hospital services furnished under a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.),

1	including guidance on how multiple States may enter into
2	agreements with one another and with manufacturers
3	which permit the transfer of funds between the partici-
4	pating States so that individuals who reside in a State
5	different from the State in which they receive a drug sub-
6	ject to an value-based purchasing arrangement as an inpa-
7	tient may be treated as if they received such drug in the
8	State in which they reside.
9	SEC. 5. REMUNERATION IN FEDERAL HEALTH CARE PRO-
10	GRAMS.
11	Section 1128B(b)(3) of the Social Security Act (42
12	U.S.C. 1320a-7b(b)(3)) is amended—
13	(1) in subclause (J)—
14	(A) by moving the left margin of such sub-
15	paragraph 2 ems to the left; and
16	(B) by striking "and" after the semicolon
17	at the end;
18	(2) in subclause (K)—
19	(A) by moving the left margin of such sub-
20	paragraph 2 ems to the left; and
21	(B) by striking the period at the end and
22	inserting "; and; and
23	(3) by adding at the end the following new sub-
24	paragraph:

1	"(L) any remuneration provided by a man-
2	ufacturer or third party on behalf of a manu-
3	facturer to a plan under a value-based pur-
4	chasing arrangement (as defined in section
5	1927(k)(12)) in the case a patient fails to
6	achieve outcomes or measures defined in such
7	arrangement following the administration of a
8	covered outpatient drug (as defined in section
9	1927(k)(2)).".
10	SEC. 6. GAO STUDY AND REPORT ON USE OF VALUE-BASED
11	PURCHASING ARRANGEMENTS.
12	(a) Study.—The Comptroller General of the United
13	States shall conduct a study on the extent to which value-
14	based purchasing arrangements (as defined in section
15	1927(k)(12) of the Social Security Act (42 U.S.C. 1396r-
16	8(k)(12)) facilitate patient access to covered outpatient
17	drugs, improve patient outcomes, lower overall health sys-
18	tem costs, and lower costs for patients in Federal health
19	care programs. In conducting such study, the Comptroller
20	General shall—
21	(1) study the impact of this Act on—
22	(A) access to transformative therapies, in-
23	cluding rare disease gene therapies, generally;
24	(B) mitigating socioeconomic disparities in
25	accessing covered outpatient drugs sold under

1	value-based purchasing arrangements through
2	its requirement that State Medicaid programs
3	have access to the same value-based purchasing
4	arrangement pricing structure that are available
5	in the commercial market for such drugs;
6	(C) the Medicaid drug rebate program
7	under section 1927 of the Social Security Act
8	(42 U.S.C. 1396r-8), the 340B drug pricing
9	program under section 340B of the Public
10	Health Service Act (42 U.S.C. 256b), and part
11	B of title XVIII of the Social Security Act (42
12	U.S.C. 1395j et seq.), including compliance
13	with such programs; and
14	(D) prices for such drugs under the Med-
15	icaid program in States that do not enter into
16	such arrangements;
17	(2) analyze all the types of value-based pur-
18	chasing arrangement pricing structures, which struc-
19	tures are working well (as measured by price and
20	ease of implementing), and which need improvement;
21	and
22	(3) study the potential long-term savings for
23	States that enter into such arrangements under
24	State Medicaid programs.

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