Amendment in the Nature of a Substitute to H.R. 2666 Offered by M_.

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the "Medicaid VBPs for3 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.** (a) Codifying Multiple Best Price Points.— 8 9 (1) IN GENERAL.—Section 1927(c)(1)(C)(ii) of 10 Security Act (42 U.S.C. the Social 1396r-11 8(c)(1)(C)(ii)) is amended— (A) in subclause (IV), by striking "and" at 12 13 the end; 14 (B) in subclause (V), by striking the period and inserting "; and"; and 15 16 (C) by adding at the end the following new 17 subclause:

1	"(VI) may include varying best
2	price points for a single dosage form
3	and strength of a drug of a manufac-
4	turer subject to a value-based pur-
5	chasing arrangement (as defined in
6	subsection $(k)(12)$, but only if such
7	manufacturer offers such arrangement
8	to all States.".
9	(2) RULE OF CONSTRUCTION.—Nothing in the
10	amendments made by this subsection may be con-
11	strued to prohibit a manufacturer from treating a
12	value-based purchasing arrangement as a bundled
13	sale.
14	(b) Definition of Average Manufacturer
15	PRICE.—
16	(1) IN GENERAL.—Section $1927(k)(1)$ of the
17	Social Security Act (42 U.S.C. $1396r-8(k)(1)$) is
18	amended—
19	(A) in subparagraph (B)(i)—
20	(i) in subclause (VII), by striking at
21	the end "and";
22	(ii) in subclause (VIII), by striking
23	the period at the end and inserting ";
24	and"; and
21	the end "and";

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

3 "(IX) with respect to such cov-4 ered outpatient drug that is sold under a value-based purchasing ar-5 6 rangement (as defined in paragraph 7 (12)) during the rebate period, includ-8 ing such drug that is an inhalation, 9 infusion, instilled, implanted or 10 injectable drug that is not generally 11 dispensed through a retail community 12 pharmacy-

13 "(aa) a refund, rebate, reim-14 bursement, or free goods from 15 the manufacturer or third party 16 on behalf of the manufacturer; or 17 "(bb) the withholding or re-18 duction of a payment to the man-19 ufacturer or third party on behalf 20 of the manufacturer; 21 that is triggered by a patient who 22 fails to achieve outcomes or measures 23 defined under the terms of such value-24 based purchasing arrangement during

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the period for which such agreement
is effective."; and
(B) by adding at the end the following new
subparagraph:
"(D) Special rule for certain value-
BASED PURCHASING ARRANGEMENTS.—For
purposes of subparagraph (A), in determining
the average price paid to the manufacturer for
a covered outpatient drug that is sold under a
value-based purchasing arrangement (as defined
in paragraph (12)) that provides that payment
for such drug is made in installments over the
course of such agreement, such price shall be
determined as if the aggregate price per the
terms of the agreement was paid in full in the
first installment during the rebate period.".
(2) GUIDANCE.—Not later than 90 days after
the date of the enactment of this Act, the Secretary
of Health and Human Services shall issue guidance
to State Medicaid agencies on the implementation of
the amendments made by this subsection.
(c) Definition of Value-based Purchasing Ar-
RANGEMENT.—Section 1927(k) of the Social Security Act
(42 U.S.C. 1396r-8(k)) shall be amended by adding at the
end the following paragraph:

1	"(12) VALUE-BASED PURCHASING ARRANGE-
2	MENT.—The term 'value-based purchasing arrange-
3	ment' has the meaning given such term in section
4	447.502 of title 42, Code of Federal Regulations (or
5	an successor regulation).".
6	SEC. 3. CALCULATION OF AVERAGE SALES PRICE UNDER
7	MEDICARE.
8	Section $1847A(c)(2)$ of the Social Security Act (42
9	U.S.C. $1395w-3a(c)(2)$) is amended by adding at the end
10	the following new subparagraph:
11	"(C) SALES SUBJECT TO A VALUE-BASED
12	PURCHASING ARRANGEMENT.—Sales of a drug
13	made under a value-based purchasing arrange-
14	ment (as defined in section $1927(k)(12)$), but
15	only if the manufacturer of such drug has elect-
16	ed to include multiple best price points (as de-
17	scribed in section $1927(c)(1)(C)(ii)(VI))$ in re-
18	porting the best price of such drug under sec-
19	tion 1927(b).".
20	SEC. 4. GUIDANCE ON VALUE-BASED PURCHASING AR-
21	RANGEMENTS FOR INPATIENT DRUGS UNDER
22	MEDICAID.
23	Not later than 90 days after the date of the enact-
24	ment of this Act, the Secretary of Health and Human
25	Services shall issue guidance to State Medicaid agencies

on the option of entering into a value-based purchasing 1 2 arrangement (as defined in section 1927(k)(12) of the Social Security Act (42 U.S.C. 1396r–8(k)(12))) with manu-3 4 facturers for drugs or biological products provided as part 5 of, or as incident to and in the same setting as, inpatient hospital services furnished under a State plan under title 6 7 XIX of the Social Security Act (42 U.S.C. 1396 et seq.), 8 or under a waiver of such plan, where such drugs or bio-9 logical products are reimbursed directly and not paid for 10 as part of payment for such inpatient hospital services, including guidance on how multiple States may enter into 11 12 agreements with one another and with manufacturers 13 which permit the transfer of funds between the participating States so that individuals who reside in a State 14 15 different from the State in which they receive a drug subject to an value-based purchasing arrangement as an inpa-16 tient may be treated as if they received such drug in the 17 18 State in which they reside.

19 SEC. 5. REMUNERATION IN FEDERAL HEALTH CARE PRO-

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GRAMS.

21 Section 1128B(b)(3) of the Social Security Act (42
22 U.S.C. 1320a-7b(b)(3)) is amended—

- 23 (1) in subclause (J)—
- 24 (A) by moving the left margin of such sub-25 paragraph 2 ems to the left; and

1	(B) by striking "and" after the semicolon
2	at the end;
3	(2) in subclause (K)—
4	(A) by moving the left margin of such sub-
5	paragraph 2 ems to the left; and
6	(B) by striking the period at the end and
7	inserting "; and"; and
8	(3) by adding at the end the following new sub-
9	paragraph:
10	"(L) any remuneration provided by a man-
11	ufacturer or third party on behalf of a manu-
12	facturer to a plan under a value-based pur-
13	chasing arrangement (as defined in section
14	1927(k)(12)) in the case a patient fails to
15	achieve outcomes or measures defined in such
16	arrangement following the administration of a
17	covered outpatient drug (as defined in section
18	1927(k)(2)).".
19	SEC. 6. GAO STUDY AND REPORT ON USE OF VALUE-BASED
20	PURCHASING ARRANGEMENTS.
21	(a) Study.—The Comptroller General of the United
22	States shall conduct a study on the extent to which value-
23	based purchasing arrangements (as defined in section
24	$1927({\bf k})(12)$ of the Social Security Act (42 U.S.C. 1396r-
25	8(k)(12)) facilitate patient access to covered outpatient

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drugs, improve patient outcomes, lower overall health sys tem costs, and lower costs for patients in Federal health
 care programs. In conducting such study, the Comptroller
 General shall—

- 5 (1) study the impact of this Act on—
 6 (A) access to transformative therapies
 - (A) access to transformative therapies, including rare disease gene therapies, generally;
- 8 (B) mitigating socioeconomic disparities in 9 accessing covered outpatient drugs sold under 10 value-based purchasing arrangements through 11 its requirement that State Medicaid programs 12 have access to the same value-based purchasing 13 arrangement pricing structure that are available 14 in the commercial market for such drugs;
- 15 (C) the Medicaid drug rebate program 16 under section 1927 of the Social Security Act 17 (42 U.S.C. 1396r–8), the 340B drug pricing 18 program under section 340B of the Public 19 Health Service Act (42 U.S.C. 256b), and part 20 B of title XVIII of the Social Security Act (42) 21 U.S.C. 1395j et seq.), including compliance 22 with such programs; and

23 (D) prices for such drugs under the Med24 icaid program in States that do not enter into
25 such arrangements;

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

6 (3) study the potential long-term savings for
7 States that enter into such arrangements under
8 State Medicaid programs.

9 (b) REPORT.—Not later than June 30, 2027, the
10 Comptroller General of the United States shall submit to
11 Congress a report containing the results of the study con12 ducted under subsection (a).

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