

H.R.2666 - MVP Act

118th Congress (2023-2024) |

Sponsor:

Rep. Guthrie, Brett [R-KY-2] (Introduced 04/18/2023)

Committees:

House - Energy and Commerce; Ways and Means

Committee Meetings:

05/24/23 10:00AM 05/17/23 10:00AM 04/26/23 10:00AM (All Meetings)

Committee Reports:

H. Rept. 118-743

Latest Action:

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Tracker:

Introduced

Passed House

Passed Senate

To President

Summary(1) Text(1) Actions(12) Titles(3) Amendments(0) Cosponsors(42) Committees(2) Related Bills(0)

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Introduced in House (04/18/2023)

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Medicaid VBPs for Patients Act” or the “MVP Act”.

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Value-based payment (VBP) arrangements are a critical component of a modernized reimbursement system. By codifying elements of the recently finalized “multiple best price” policies of the Centers for Medicare & Medicaid Services, Congress is enshrining a sustainable and flexible payment approach for innovative treatments and cures.

(2) Many of these treatments, including gene therapies, are different from traditional pharmaceutical and biologic products in that they can offer long-lasting—sometimes lifelong—benefits for patients and long-term value for the health care system alike.

(3) There are hundreds of innovative, curative, and life-changing treatments currently in development in the United States. However, the current reimbursement structure was not designed with these therapies in mind, and allowing for innovative payment arrangements will spur greater development and access to future cures and treatments.

(4) Medicaid is currently losing out on innovative ways to ensure patients have access to these treatments, while private payors continue to see the value provided through flexible payment arrangements.

(5) VBP arrangements include the ability to pay based on evidence-based outcomes and, over time, spreading the risk across all entities involved in the contract and ensuring that these often costly treatments are accessible.

(6) Evidence-based outcomes can demonstrate decreased cost to the health system and to patients, including reduced hospitalizations and lower utilization of other health care expenditures, including lab work, other medications, and office visits.

(7) By allowing VBPs in Medicaid, the health care system will continue to move towards quality over quantity, holding manufacturers and providers accountable for the best treatment for every patient.

SEC. 3. CODIFYING VALUE-BASED PURCHASING ARRANGEMENTS UNDER MEDICAID AND REFORMS RELATED TO PRICE REPORTING UNDER SUCH ARRANGEMENTS.

(a) **CODIFYING THE VBP RULE.**—The revision to section 447.505(a) of title 42, Code of Federal Regulations, related to the inclusion of varying best price points available under a value-based purchasing arrangement (as defined in section 1927(k)(12) of the Social Security Act ([42 U.S.C. 1396r-8\(k\)\(12\)](#)), as added by subsection (d) of this section) for a single dosage form and strength of a covered outpatient drug if a manufacturer offers such pricing structure to all States, shall have the force and effect of law.

(b) **QUARTERLY REPORTING OBLIGATION.**—

(1) **IN GENERAL.**—Section 1927(b)(3)(A) of the Social Security Act ([42 U.S.C. 1396r-8\(b\)\(3\)\(A\)](#)) is amended—

(A) in clause (iv), by striking at the end “and”;

(B) in clause (v), by striking at the end the period and inserting “; and”;

(C) by inserting after clause (v) the following new clause:

“(vi) in conjunction with reporting required under clause (i), in the case of a covered outpatient drug that is sold under a value-based purchasing arrangement (as

defined in subsection (k)(12)) made available by the manufacturer to a State plan—

“(I) the pricing structure for such drug based on pre-defined outcomes or measures specified in such value-based purchasing arrangement; and

“(II) the best price for such covered outpatient drug outside of a value-based purchasing arrangement, which in the event such drug is sold exclusively through such an arrangement, means the lowest price available net of any discounts or offsets that are unrelated to a refund, rebate, reimbursement, free item, withholding, or repayment made under a value-based purchasing arrangement for such drug.”; and

(D) by adding at the end of the flush left matter at the end the following new sentence: “Information reported with respect to a rebate period under clause (i)(I) relating to average manufacturer price and clause (i)(II) relating to best price shall be updated for such rebate period if, subsequent to the date such information was reported, cumulative discounts, rebates, or other arrangements adjust such average price actually realized or best price available to the extent that such cumulative discounts, rebates, or other arrangements are not excluded under this section from the determination of average manufacturer price or best price.”

(2) RULES OF CONSTRUCTION.—Nothing in the amendments made by paragraph (1) shall be construed as—

(A) requiring—

(i) a State to enter into a value-based purchasing arrangement with a manufacturer for a covered outpatient drug; or

(ii) a manufacturer to enter into a value-based purchasing arrangement with a State for a covered outpatient drug;

(B) prohibiting a manufacturer from treating a value-based purchasing arrangement as a bundled sale; or

(C) precluding the execution of a supplemental rebate agreement, as provided in section 1927(a)(1) of the Social Security Act ([42 U.S.C. 1396r-8\(a\)\(1\)](#)), for a covered outpatient drug sold under a value-based purchasing arrangement.

(c) DEFINITION OF AVERAGE MANUFACTURER PRICE.—Section 1927(k)(1) of the Social Security Act ([42 U.S.C. 1396r-8\(k\)\(1\)](#)) is amended—

(1) in subparagraph (B)(i)—

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

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

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

“(VI) in accordance with subsection (b)(3)(A)(vi), with respect to such covered outpatient drug that is sold under a value-based purchasing arrangement (as defined in paragraph (12)) during the rebate period—

“(aa) a refund, rebate, reimbursement, or free goods from the manufacturer or third party on behalf of the manufacturer; or

“(bb) the withholding or reduction of a payment to the manufacturer or third party on behalf of the manufacturer;

that is triggered by a patient who fails to achieve outcomes or measures defined under the terms of such value-based purchasing arrangement during the period for which such agreement is effective.”; and

(2) 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.”.

(d) DEFINITION OF VALUE-BASED PURCHASING ARRANGEMENT.—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:

“(12) VALUE-BASED PURCHASING ARRANGEMENT.—The term ‘value-based purchasing arrangement’ means an arrangement or agreement intended to align pricing or payments to an observed or expected therapeutic or clinical value in a select population and includes—

“(A) evidence-based measures, which substantially link the cost of a covered outpatient drug to existing evidence of effectiveness and potential value for specific uses of that product; or

“(B) outcomes-based measures, which substantially link payment for the covered outpatient drug to that of the drug’s actual performance in patient or a population, or a reduction in other medical expenses.”.

SEC. 4. CALCULATION OF AVERAGE SALES PRICE UNDER MEDICARE.

Section 1847A(c)(2) of the Social Security Act ([42 U.S.C. 1395w–3a\(c\)\(2\)](#)) is amended by adding at the end the following new subparagraph:

“(C) SALES SUBJECT TO A VALUE-BASED PURCHASING ARRANGEMENT.—Sales of a drug made under a value-based purchasing arrangement (as defined in section 1927(k)(12)), but only if the manufacturer of such drug has elected to report multiple best prices under section 1927(c) with respect to such drug in accordance with the revision described in section 3(a) of the MVP Act.”.

SEC. 5. VALUE-BASED PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS UNDER MEDICAID.

Title XIX of the Social Security Act ([42 U.S.C. 1396 et seq.](#)) is amended by adding at the end the following new section:

“SEC. 1948. VALUE-BASED PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS.

“(a) IN GENERAL.—Notwithstanding section 1902(a)(1) (relating to statewideness), section 1902(a)(10)(b) (relating to comparability), and any other provision of this title for which the secretary determines it is necessary to waive in order to implement this section, beginning on January 1, 2024,

the Secretary shall establish a program under which States may provide under their State plans under this title (including such a plan operating under a statewide waiver under section 1115) medical assistance for drugs furnished to individuals in an inpatient setting pursuant to a value-based purchasing arrangement (as defined in section 1927(k)(12)) with manufacturers of such drugs.

“(b) APPLICATION OF CERTAIN OUTPATIENT PROVISIONS TO INPATIENT DRUGS.—

“(1) IN GENERAL.—Under the program established under subsection (a), the Secretary shall provide for the application of the provisions described in paragraph (2) to value-based purchasing arrangements relating to drugs administered in the inpatient setting in a manner similar to the manner in which such provisions would apply if such drugs were administered in an outpatient setting.

“(2) PROVISIONS DESCRIBED.—The provisions described in this paragraph are as follows:

“(A) QUARTERLY PRICE REPORTING OBLIGATION.—Section 1927(b)(3)(E).

“(B) DEFINITION OF BEST PRICE.—Clauses (i)(VII) and (ii)(V) of section 1927(c)(1)(C).

“(C) DEFINITION OF AVERAGE MANUFACTURER PRICE.—Subparagraphs (B)(i)(VI) and (D) of section 1927(k)(1).

“(D) ANTI-KICKBACK AND PHYSICIAN SELF-REFERRAL SAFE HARBORS.—Section 1128B(b)(3)(L) and section 1877(h)(1)(C)(iv).

“(c) CARVE-OUT OF DRUGS.—In the case of a drug that is sold under a value-based purchasing arrangement, the Secretary shall permit States to pay for such drug under the terms and conditions of the arrangement separately from other inpatient items and services furnished to the individual.

“(d) MULTI-STATE AGREEMENTS.—Under the program established under subsection (a), the Secretary shall permit multiple States to enter into agreements with one another and with manufacturers which permit the transfer of funds between the participating states so that individuals who reside in a State different from the State in which they receive a drug subject to an value-based purchasing arrangement as an inpatient may be treated as if they received such drug in the State in which they reside.

“(e) CONSTRUCTION.—Nothing in this subparagraph shall be construed as deeming a drug furnished to an inpatient as being subject to the drug discount program under section 340B of the Public Health Service Act.”.

SEC. 6. REMUNERATION IN FEDERAL HEALTH CARE PROGRAMS.

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

(1) in subclause (J)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

(B) by striking “and” after the semicolon at the end;

(2) in subclause (K)—

(A) by moving the left margin of such subparagraph 2 ems to the left; and

(B) by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following new subparagraph:

“(L) any remuneration provided by a manufacturer or third party on behalf of a manufacturer to a plan under a value-based purchasing arrangement (as defined in section 1927(k)(12)) in the case a patient fails to achieve outcomes or measures defined in such arrangement following the administration of a covered outpatient drug (as defined in section 1927(k)(2)).”.

SEC. 7. GAO STUDY AND REPORT ON USE OF VALUE-BASED PURCHASING ARRANGEMENTS.

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

(1) study the impact of this Act on—

(A) access to transformative therapies, including rare disease gene therapies, generally;

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

(C) the Medicaid drug rebate program under section 1927 of the Social Security Act ([42 U.S.C. 1396r–8](#)), the 340B drug pricing program under section 340B of the Public Health Service Act ([42 U.S.C. 256b](#)), and part B of title XVIII of the Social Security Act ([42 U.S.C. 1395j et seq.](#)), including compliance with such programs; and

(2) using data submitted pursuant to clause (vi) of section 1927(b)(3)(A) of the Social Security Act ([42 U.S.C. 1396r–8\(b\)\(3\)\(A\)](#)), as added by section 3 of this Act, analyze all the types of value-based purchasing arrangement pricing structures, which structures are working well (as measured by price and ease of implementing), and which need improvement.

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

SEC. 8. SUNSET.

The provisions of, and the amendments made by, this Act shall have no effect beginning 5 years after the date of the enactment of this Act. The preceding sentence shall not apply to any value-based purchasing arrangement in effect as of the date that is 5 years after such date of enactment.
