To amend titles XI, XVIII, and XIX of the Social Security Act to promote value-based arrangements.

IN THE SENATE OF THE UNITED STATES

Mr. CASSIDY (for himself and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend titles XI, XVIII, and XIX of the Social Security Act to promote value-based arrangements.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “Patient Affordability Value and Efficiency Act”.
SEC. 2. EXCLUSION OF CERTAIN VALUE-BASED ARRANGEMENTS FROM ANTI-KICKBACK AND PHYSICIAN SELF-REFERRAL PROHIBITIONS.

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

(1) in subparagraph (J)—

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

(B) by striking “and” at the end;

(2) in subparagraph (K)—

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

(B) by striking the period at the end and inserting a semicolon; and

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

“(L) a value-based arrangement pursuant to a written agreement in which each participant agrees to assume varying levels of financial risk relative to a participant’s contribution to the achievement of the targeted outcomes (including but not limited to rebates, discounts, price reductions, contributions, reimbursements, guarantees, patient care, shared savings pay-
ments, withholds, or bonuses or anything of value) based on—

“(i) the future performance of the goods or services described in the arrange-
ment;

“(ii) the achievement of preidentified clinical or economic target metrics that are specifically tailored to improve patient outcomes or reduce the costs of health care delivery without negatively affecting patient outcomes;

“(iii) implementation of processes or procedures that otherwise optimize the delivery, efficiency, or quality of patient-centered care; and

“(iv) any other evidence-based outcome or circumstance as defined by the Secretary through notice-and-comment rulemaking; and

“(M) a medication adherence support program pursuant to a written agreement (including a program that is part of a value-based arrangement and any agreement with respect to the collection and use of derived adherence data and information) that establishes the protocol
for a patient’s substantial compliance with a covered medication regimen prescribed by the patient’s health care provider under title XVIII, a Federal health care program, or a State health care program.”.

(b) PHYSICIAN SELF-REFERRAL.—Section 1877(h)(1)(C) of the Social Security Act (42 U.S.C. 1395nn(h)(1)(C)) is amended by adding the following subclause:

“(iv) Any amounts determined under a value-based arrangement described in section 1128(b)(3)(L).”.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect [ ].

SEC. 3. EXCLUSION OF DRUGS PURCHASED THROUGH VALUE-BASED ARRANGEMENTS FROM MEDICAID BEST PRICE AND AVERAGE MANUFACTURER PRICE DETERMINATIONS.

(a) IN GENERAL.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (c)(1)(C)(i)—

(A) in subclause (V), by striking “and” after the semicolon;

(B) in subclause (VI), by striking the period at the end and inserting “; and”; and
(C) by adding at the end the following:

“(VII) any prices charged under a value-based purchasing arrangement.”; and

(2) in subsection (k)—

(A) in paragraph (1)(B)(i)—

(i) in subclause (IV), by striking “and” after the semicolon;

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

(iii) by adding at the end the following:

“(VI) any prices charged under a value-based purchasing arrangement.”; and

(B) by adding at the end the following:

“(12) VALUE-BASED PURCHASING ARRANGE-

MENT.—The term ‘value-based purchasing arrangement’ means any arrangement documented in writ-

ing under which the price of a covered outpatient drug (net of any discounts under the arrangement) is based in whole or in part on—

“(A) the achievement of measurable and defined evidence-based patient outcomes;
“(B) clinical circumstances or measures;

“(C) the relative values of multiple indications; or

“(D) any other measure of value as specified by the Secretary through notice-and-comment rulemaking.”.

(b) Effective Date.—The amendments made by subsection (a) shall apply with respect to rebate periods beginning on or after the first day of the first calendar year beginning after the date of the enactment of this section.