

New Definitions: Stark Act (Exhibit A)

Value-Based Activity:

- (1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:
 - (i) The provision of an item or service;
 - (ii) The taking of an action; or
 - (iii) The refraining from taking an action.
- (2) The making of a referral is not a value-based activity.

Value-Based Arrangement: means an arrangement for the provision of at least one value-based activity for a target patient population between or among—

- (1) The value-based enterprise and one or more of its VBE participants; or
- (2) VBE participants in the same value-based enterprise.

Value-Based Enterprise (VBE): means two or more VBE participants—

- (1) Collaborating to achieve at least one value-based purpose;
- (2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
- (3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
- (4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-Based Purpose: means—

- (1) Coordinating and managing the care of a target patient population;
- (2) Improving the quality of care for a target patient population;
- (3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
- (4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

VBE Participant: means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

Target Patient Population: would mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

New Definitions: Anti-Kickback Safe Harbors (Exhibit B)

Value-based activity

(A) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

- (1) The provision of an item or service;
- (2) The taking of an action; or
- (3) The refraining from taking an action.

(B) Does not include the making of a referral.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population between or among:

- (A) The value-based enterprise and one or more of its VBE participants; or
- (B) VBE participants in the same value-based enterprise.

Value-based enterprise or VBE means two or more VBE participants:

- (A) Collaborating to achieve at least one value-based purpose;
- (B) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;
- (C) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and
- (D) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based enterprise participant or VBE participant means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. VBE participant does not include a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies; or a laboratory.

Value-based purpose means:

- (A) Coordinating and managing the care of a target patient population;
- (B) Improving the quality of care for a target patient population;
- (C) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
- (D) Transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Target Patient Population means an identified population selected by the VBE or its VBE participants using legitimate and verifiable criteria that:

- (A) Are set out in writing in advance of the commencement of the value-based arrangement; and
- (B) Further the value-based enterprise's value based purpose(s).