Redline Comparing *Final* AKS Value-Based Safe Harbor Regulations to *Proposed* Value-Based Safe Harbor Regulations

Provided by Baker Donelson

(ee) *Care coordination arrangements to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, "remuneration" does not include the exchange of anything of value between a VBE and VBE participant or between VBE participants pursuant to a value-based arrangement if all of the standards in paragraphs (ee)(1) through ~~(12~~(13) of this section are met:

~~(1) The VBE participants establish one or more specific evidence-based, valid outcome measures against which the recipient will be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target patient population.~~

(1) The remuneration exchanged:

(i) Is in-kind;

(ii) Is used predominantly to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population and does not result in more than incidental benefits to persons outside of the target patient population; and

(iii) Is not exchanged or used:

(A) More than incidentally for the recipient's billing or financial management services; or

(B) For the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

(2) The value-based arrangement is commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE.

(3) ~~In~~ The terms of the value-based arrangement are set forth in writing and signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement ~~or~~ and any material change to the value-based arrangement~~, the offeror of the remuneration and any recipient(s) of such remuneration have set forth the terms of the value-based arrangement in a signed writing. The writing states,~~. The writing states at a minimum:

(i) The value-based purpose(s) of the value-based activities provided for in the value-based arrangement;

~~(i)~~ (ii) The value-based activities to be undertaken by the parties to the value-based arrangement;

(~~ii~~iii) The term of the value-based arrangement;

(~~iii~~iv) The target patient population;

(~~iv~~v) A description of the remuneration;

(~~v~~vi) ~~The~~ Either the offeror's cost for the remuneration and the reasonable accounting methodology used by the offeror to determine its cost, or the fair market value of the remuneration;

(~~vi~~vii) The percentage ~~of the offeror's cost~~ and amount contributed by the recipient;

(~~vii~~viii) If applicable, the frequency of the recipient's contribution payments for ongoing costs; and

(~~viii~~ix) The ~~specific evidence-based, valid~~ outcome or process measure(s) against which the recipient will be measured.

~~(4) The remuneration exchanged:~~

~~(i) Is in-kind;~~

(4) The parties to the value-based arrangement establish one or more legitimate outcome or process measures that:

~~(ii) Is used primarily~~ (i) The ~~to engage in value-based activities that are directly connected to~~ parties reasonably anticipate will advance the coordination and management of care for the target patient population based on clinical evidence or credible medical or health sciences support;

~~(iii) Does not induce VBE participants to furnish medically unnecessary items or services or reduce or limit medically necessary items or services furnished to any patient; and~~

~~(iv) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the applicable VBE.~~

(ii) Include one or more benchmarks that are related to improving or maintaining improvements in the coordination and management of care for the target patient population;

(iii) Are monitored, periodically assessed, and prospectively revised as necessary to ensure that the measure and its benchmark continue to advance the coordination and management of care of the target patient population;

(iv) Relate to the remuneration exchanged under the value-based arrangement; and

(v) Are not based solely on patient satisfaction or patient convenience.

(5) The offeror of the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

(6) The recipient pays at least 15 percent of the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration. If it is a one-time cost, the recipient makes such contribution in advance of receiving the in-kind ~~Start Printed Page~~

~~55762remuneration. If~~ remuneration. If it is an ongoing cost, the recipient makes such contribution at reasonable, regular intervals.

(7) The value-based arrangement does not:

~~(i) Is directly connected to the coordination and management of care of the target patient population;~~

~~(ii) Does not place any limitation on VBE participants'~~ (i) Limit the VBE participant's ability to make decisions in the best ~~interest of their~~ interests of its patients;

(~~iii~~ii) ~~Does not direct~~ Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law ~~or regulations~~ under titles XVIII and XIX of the Act; ~~and(iv) Does not include marketing to patients of items or services or engaging in~~ or

(iii) Induce parties ~~patient recruitment activities.~~ to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient.

(8) The exchange of remuneration by a limited technology participant and another VBE participant or the VBE must not be conditioned on any recipient's exclusive use or minimum purchase of any item or service manufactured, distributed, or sold by the limited technology participant.

~~(8~~(9) The VBE, a VBE participant in the value-based arrangement acting on the VBE's behalf, or the VBE's accountable body or responsible person reasonably monitors and assesses~~,~~ the following and reports ~~such~~ the monitoring and assessment of the following to the VBE's accountable body or responsible person~~,~~, as applicable, no less frequently than annually or at least once during the term of the value-based arrangement for arrangements with terms of less than 1 year:

(i) The coordination and management of care for the target patient population in the value-based arrangement;

(ii) Any deficiencies in the delivery of quality care under the value-based arrangement; and

(iii) Progress toward achieving the ~~evidence-based, valid~~ legitimate outcome or process measure(s) in the value-based arrangement.

(~~9~~10) ~~The parties terminate the arrangement within 60 days if~~ If the VBE's accountable body or responsible person determines~~,~~ based on the monitoring and assessment conducted pursuant to paragraph (ee)(9) of this section, that the value-based arrangement~~:(i) Is~~ has resulted in material deficiencies in quality of care or is unlikely to further the coordination and management of care for the target patient population~~;~~, the parties must within 60 days either:

(i) Terminate the arrangement; or

(ii) Develop and implement a corrective action plan designed to remedy the deficiencies within 120 days, and if the corrective action plan fails to remedy the deficiencies within 120 days, terminate the value-based arrangement.

~~(ii) Has resulted in material deficiencies in quality of care; or~~

~~(iii) Is unlikely to achieve the evidence-based, valid outcome measure(s).~~

(~~10~~11) The offeror does not~~,~~ and should not~~,~~ know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose.

(~~11~~12) ~~The~~ For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ee).

(13) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) Except to the extent the entity is a limited technology participant, a manufacturer of a device or medical supply;

(vi) Except to the extent the entity or individual is a limited technology participant, an entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

(~~12~~14) For purposes of this paragraph (ee), the following definitions apply:

(i) *Coordination and management of care (or coordinating and managing care)* means~~, for purposes of the anti-kickback statute safe harbors at § 1001.952,~~ the deliberate organization of patient care activities and sharing of information between two or more VBE participants ~~or~~, one or more VBE participants and the VBE, or one or more VBE participants and patients, ~~tailored to improving~~ that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population~~, in order to achieve safer and more effective care for the target patient population.~~.

(ii) *Digital health technology* means hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care; such term includes any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose.

(iii) *Limited technology participant* means a VBE participant that exchanges digital health technology with another VBE participant or a VBE and that is:

(A) A manufacturer of a device or medical supply, but not including a manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year (for purposes of this paragraph, the terms "ownership or investment interest," "physician," and "immediate family member" have the same meaning as set forth in 42 CFR 403.902); or

(B) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services).

(iv) *Manufacturer of a device or medical supply* means an entity that meets the definition of applicable manufacturer in 42 CFR 403.902 because it is engaged in the production, preparation, propagation, compounding, or conversion of a device or medical supply that meets the definition of covered drug, device, biological, or medical supply in 42 CFR 403.902, but not including entities under common ownership with such entity.

~~(ii~~(v) *Target patient population* means an identified patient 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).

(~~iii~~vi) *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~~.~~; and

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

~~(iv~~(vii) *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population ~~between or among~~to which the only parties are:

(A) The value-based enterprise and one or more of its VBE participants; or

(B) VBE participants in the same value-based enterprise.

~~(v~~(viii) *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~~ toachieve its value-based purpose(s).

(~~vi~~ix) *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~~.other than a patient acting in their capacity as a patient.

~~(vii~~(x) *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~~ 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.

(ff) *Value-based arrangements with substantial downside financial risk.* As used in section 1128B of the Act, "remuneration" does not include the exchange of payments or anything of value between a VBE and a VBE participant pursuant to a value-based arrangement if all of the following standards in paragraphs (ff)(1) through (8) of this section are met:

(1) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

~~(1~~(2) The VBE (directly or through a VBE participant~~-~~, other than a payor, acting on the VBE's behalf) has assumed through a written contract or a value-based arrangement (or ~~is contractually obligated~~ has entered into a written contract or a value-based arrangement to assume in the next 6 months) substantial downside financial risk ~~(as defined in this paragraph (ff))~~ from a payor for ~~providing or arranging for the provision of items and services for a target patient population~~a period of at least 1 year.

(~~2~~3) ~~Under the value-based arrangement, the~~ The VBE participant ~~meaningfully shares in~~ (unless the VBE participant is the payor from which the VBE is assuming risk) is at risk for a meaningful share of the VBE's substantial downside financial risk for providing or arranging for the provision of items and services for the target patient population.~~For purposes of this paragraph (ff), a VBE participant meaningfully shares in the VBE's substantial downside financial risk if the value-based arrangement provides that the VBE participant is subject to risk under one of the following three methodologies:~~

~~(i) A risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor;~~

~~(ii) A partial or full capitation payment or similar payment methodology, excluding the Medicare inpatient prospective payment system or other like payment methodology; or~~

~~(iii) In the case of a VBE participant that is a physician, a payment that meets the requirements of the regulatory exception for value-based arrangements with meaningful downside financial risk at § 411.357(aa)(2) of this title.Start Printed Page 55763~~

~~(3~~(4) The remuneration provided by, or shared among, the VBE and VBE participant:

~~(i) Is used primarily~~ (i) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be a value-based purpose defined in §1001.952(ee)(14)(x)(A), (B), or (C);

(ii) Unless exchanged pursuant to risk methodologies defined in paragraph (ff)(9)(i) or (ii) of this section, is used predominantly to engage in value-based activities that are directly connected to the items and services for which the VBE ~~is at~~ has assumed (or has entered into a written contract or value based arrangement to assume in the next 6 months) substantial downside financial risk~~ and that are set forth in writing pursuant to paragraph(ff)(4) of this section~~;

~~(ii) Is directly connected to one or more of the VBE's value-based purposes, at least one of which must be the coordination and management of care for the target patient population;~~

~~(iii) Does not induce VBE participants to reduce or limit medically necessary items or services furnished to any patient;~~

~~(iv~~(iii) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

~~(v) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE.~~

(iv) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

~~(4) In~~ (5) The value-based arrangement is set forth in writing, is signed by the parties in advance of, or contemporaneous with, the commencement of the value-based arrangement ~~or~~ and any material change to the value-based arrangement, ~~the VBE and VBE participant set forth in a signed writing the terms of the value-based arrangement. The writing states~~ and specifies all material terms ~~of the value-based arrangement, including: A description of the nature and extent~~ including:

(i) Terms evidencing that the VBE is at substantial downside financial risk or will assume such risk in the next 6 months ~~of the VBE's substantial downside financial risk for the target patient population; a description of the manner in which the recipient meaningfully shares in the VBE's substantial downside financial risk; the value-based activities; the target patient population; and the type and the offeror's cost of the remuneration.~~ for the target patient population;

(ii) A description of the manner in which the VBE participant (unless the VBE participant is the payor from which the VBE is assuming risk) has a meaningful share of the VBE's substantial downside financial risk; and

(iii) The value-based activities, the target patient population, and the type of remuneration exchanged.

(~~5~~6) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

~~(6~~(7) The value-based arrangement does not:

(i) ~~Place any limitation on VBE participants'~~ Limit the VBE participant's ability to make decisions in the best ~~interest of their~~ interests of its patients;

(ii) Direct or restrict referrals to a particular provider, practitioner, or supplier if:

(A) A patient expresses a preference for a different practitioner, provider, or supplier;

(B) The patient's payor determines the provider, practitioner, or supplier; or

(C) Such direction or restriction is contrary to applicable law ~~or regulations~~ under titles XVIII and XIX of the Act; or

(iii) ~~Include marketing to patients of~~ Induce parties to reduce or limit medically necessary items or services ~~or engaging in~~ furnished to any patient ~~recruitment activities~~.

(~~7~~8) ~~The~~ For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish compliance with the conditions of this paragraph (ff).

~~(8~~(9) For purposes of this paragraph (ff), the following definitions apply:

(i) *Substantial downside financial risk* means ~~risk, for the entire term of the value-based arrangement, in the form of~~:

~~(A) Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;~~

~~(B) A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures;~~

~~(C) A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures; or~~

~~(D) A partial capitated payment from the payor for a set of items and services for the target patient population, where such capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangement.~~

(A) Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care;

(B) Financial risk equal to at least 20 percent of any loss, where:

(*1*) Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a *bona fide* benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and

(*2*) The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or

(C) The VBE receives from the payor a prospective, per patient payment that is:

(*1*) Designed to produce material savings; and

(*2*) Paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services.

(ii) *Meaningful share* means the VBE participant:

(A) Assumes two-sided risk for at least 5 percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or

(B) Receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services.

~~(ii) *Coordination and management of care*~~(iii) *Manufacturer of a device or medical supply*, *target patient population*, *value-based activity*, *value-based arrangement*, *value-based enterprise*, *value-based purpose*, and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(gg) *Value-based arrangements with full financial risk.* As used in section 1128B of the Act, "remuneration" does not include the exchange of payments or anything of value between the VBE and a VBE participant pursuant to a value-based arrangement if all of the standards in paragraphs (gg)(1) through (~~8~~9) of this section are met:

(1) The remuneration is not exchanged by:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

(v) A manufacturer of a device or medical supply;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); or

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supplies.

~~(1~~(2) The VBE (directly or through a VBE participant~~-~~, other than a payor, acting on behalf of the VBE) has assumed ~~(or is contractually obligated to assume in the next 6 months) full financial risk from a payor and has a signed writing with the payor that specifies the target patient population and contains terms evidencing that the VBE is at~~ through a written contract or a value-based arrangement (or has entered into a written contract or a value-based arrangement to assume in the next 1 year) full financial risk ~~for that population for a period of at least 1 year~~from a payor.

(~~2~~3) The value-based arrangement is set ~~out in a~~ forth in writing~~-~~, is signed by the parties ~~that~~ , and specifies ~~the~~ all material terms ~~of the value-based arrangement~~, including the value-based activities ~~to be undertaken by the parties, and is for a period of at least 1 year~~and the term.

(~~3~~4) The VBE participant (unless the VBE participant is a payor) does not claim payment in any form ~~directly or indirectly~~ from ~~a~~ the payor for items or services covered under the contract or value-based arrangement~~.~~ between the VBE and the payor described in paragraph (2).

~~(4~~(5) The remuneration ~~exchanged between~~ provided by, or shared among, the VBE and ~~a~~ VBE participant:

~~(i) Is used primarily to engage in the value-based activities set forth in writing pursuant to paragraph (gg)(2) of this section;~~

~~(ii)~~ (i) Is directly connected to one or more of the VBE's value-based purposes~~, at least one of which must be the coordination and management of care for the target patient population;~~;

(ii) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and

(iii) Is not exchanged or used for the purpose of marketing items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities.

~~(iii) Does not induce the VBE or VBE participants~~ (6) The value-based arrangement does not induce parties to reduce or limit medically necessary items or services furnished to any patient~~;~~.

~~(iv) Does not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and~~

~~(v) Is not funded by, and does not otherwise result from the contributions of, any individual or entity outside of the VBE.~~

~~(5) The VBE or VBE participant~~ (7) The VBE or VBE participant offering the remuneration does not take into account the volume or value of, or condition the remuneration on:

(i) Referrals of patients who are not part of the target patient population; or

(ii) Business not covered under the value-based arrangement.

~~(6~~(8) The VBE provides or arranges for

~~:(i) An operational utilization review program; and~~

~~(ii) A~~ a quality assurance program for services furnished to the target patient population that:

~~that protects~~ (i) Protects against underutilization ~~and specifies patient goals, including measurable outcomes, where appropriate.~~; and

(ii) Assesses the quality of care furnished to the target patient population.

~~(7) The value-based arrangement does not include marketing to patients of items or services or engaging in patient recruitment activities.~~

~~(8) The~~ (9) For a period of at least 6 years, the VBE or VBE participant makes available to the Secretary, upon request, ~~Start Printed Page 55764all~~ all materials and records sufficient to establish compliance with the conditions of this paragraph (gg).

(~~9~~10) For purposes of this paragraph (gg), the following definitions apply:

(i) *Full financial risk* means the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population ~~and is prospectively paid by the applicable payor;~~for a term of at least 1 year.

(ii) *Prospective basis* means that the VBE has assumed financial responsibility for the cost of all items and services covered by the applicable payor prior to the provision of items and services to patients in the target patient population.

~~(ii)~~ (iii) *Items and services* ~~shall have the meaning set forth in § 1001.952(t)(2)(iv); and~~means health care items, devices, supplies, and services.

~~(iii) *Coordination and management of care*~~(iv) *Manufacturer of a device or medical supply*, *target patient population*, *value-based activity*, *value-based arrangement, value-based enterprise, value-based purpose*, and *VBE participant* shall have the meaning set forth in paragraph (ee) of this section.

(hh) *Arrangements for patient engagement and support to improve quality, health outcomes, and efficiency.* As used in section 1128B of the Act, "remuneration" does not include a patient engagement tool or support furnished by a VBE participant to a patient in ~~a~~ the target patient population of a value-based arrangement to which the VBE participant is a party if all of the conditions in paragraphs (hh)(1) through (~~6~~9) of this section are met:

(1) The VBE participant is not:

(i) A pharmaceutical manufacturer, distributor, or wholesaler;

(ii) A pharmacy benefit manager;

(iii) A laboratory company;

(iv) A pharmacy that primarily compounds drugs or primarily dispenses compounded drugs;

~~(1) The~~ (v) A manufacturer of a device or medical supply, unless the patient engagement tool or support is ~~furnished directly to the patient by a VBE participant.~~digital health technology;

(vi) An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies covered by a Federal health care program (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services);

(vii) A medical device distributor or wholesaler that is not otherwise a manufacturer of a device or medical supply; or

(viii) A manufacturer of a device or medical supply that was obligated under 42 CFR 403.906 to report one or more ownership or investment interests held by a physician or an immediate family member during the preceding calendar year, or that reasonably anticipates that it will be obligated to report one or more ownership or investment interests held by a physician or an immediate family member during the present calendar year, even if the patient engagement tool or support is digital health technology (for purposes of this paragraph, the terms ownership

or investment interest," "physician," and "immediate family member" have the same meaning as set forth in 42 CFR 403.902).

(2) The patient engagement tool or support is furnished directly to the patient (or the patient's caregiver, family member, or other individual acting on the patient's behalf) by a VBE participant that is a party to the value-based arrangement or its eligible agent.

~~(2) No individual or entity outside of the applicable VBE funds or otherwise contributes to the provision of the patient engagement tool or support.~~

(3) The patient engagement tool or support:

~~(i) Is an in-kind preventive item, good, or service, or an in-kind item, good, or service such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health;~~

(i) Is an in-kind item, good, or service;

(ii) That has a direct connection to the coordination and management of care of the target patient population;

(iii) Does not include any ~~gift card, cash~~, or cash equivalent;

~~(iv) Does not include any in-kind item, good, or service used for patient recruitment or marketing of items or services to patients;~~

~~(v)~~ (iv) Does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program;

~~(vi~~(v) Is recommended by the patient's licensed ~~healthcare provider~~health care professional; and

(~~vii~~vi) Advances one or more of the following goals:

(A) Adherence to a treatment regimen determined by the patient's licensed ~~healthcare provider~~health care professional.

(B) Adherence to a drug regimen determined by the patient's licensed ~~healthcare provider~~health care professional.

(C) Adherence to a ~~follow-up~~ followup care plan established by the patient's licensed ~~healthcare provider~~health care professional.

(D) ~~Management~~ Prevention or management of a disease or condition as directed by the patient's licensed ~~healthcare provider~~health care professional.

~~(E) Improvement in measurable evidence-based health outcomes for the patient or for the target patient population.~~

~~(F) Ensuring~~ (E) Ensure patient safety.

(4) The ~~offeror does not, and should not, know that the remuneration is likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the~~ patient engagement tool or support is ~~provided.~~not funded or contributed by:

(i) A VBE participant that is not a party to the applicable value-based arrangement; or

(ii) An entity listed in paragraph (hh)(1) of this section.

(5) The aggregate retail value of patient engagement tools and supports furnished to a patient by a VBE participant on an annual basis does not exceed $500 ~~unless such patient engagement tools and supports are furnished to patients based on a good faith, individualized determination of the patient's financial need.~~. The monetary cap set forth in this paragraph (hh)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index - Urban All Items (CPIU) for the 12-month period ending the preceding September 30. OIG will publish guidance after September 30 of each year reflecting the increase in the CPI-U for the 12-month period ending September 30 and the new monetary cap applicable for the following calendar year.

(6) The VBE participant or any eligible agent does not exchange or use the patient engagement tools or supports to market other reimbursable items or services or for patient recruitment purposes.

~~(6) The~~ (7) For a period of at least 6 years, the VBE participant makes available to the Secretary, upon request, all materials and records sufficient to establish that the patient engagement tool or support was distributed in a manner that meets the conditions of this paragraph (hh).

(8) The availability of a tool or support is not determined in a manner that takes into account the type of insurance coverage of the patient.

~~(7~~(9) For purposes of this paragraph (hh), the following definitions apply:

(i) *Eligible agent* means any person or entity that is not identified in paragraphs (hh)(1)(i) through (viii) of this section as ineligible to furnish protected tools and supports under this paragraph.

~~*coordination*~~ (ii) *Coordination and management of care, target patient population*, *value-based* ~~*purpose*~~*arrangement*, *VBE*, ~~and~~ *VBE participant*~~.~~*, manufacturer of a device or medical supply,* and *digital health technology* shall have the meaning set forth in paragraph (ee) of this section.