**Redline Comparing *Final* CMS Physician Self-Referral Value-Based Exceptions to *Proposed* Value-Based Exceptions**

*Provided by Baker Donelson*

*Target patient population* means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

*Value-based ~~activity—(1) Means~~ activity* 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~~(1) The provision of an item or service;

~~(ii~~(2) The taking of an action; or

(~~iii~~3) The refraining from taking an action.

~~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~~ valuebased activity for a target patient population ~~between or among—Start Printed Page 55841~~to which the only parties are—

(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 the 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—~~*means any of the following:

(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~~ a person or entity that engages in at least one value-based activity

as part of a value-based enterprise.

*  *  *

(aa) *Arrangements that facilitate value-based health care delivery and payment*—

(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined ~~in § 411.351~~at §411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the ~~6~~ 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary ~~items or~~ itemsor services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement ~~satisfies the requirements of § 411.354(d)(4)(iv).~~complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the ~~physician.~~ ~~Remuneration~~ physician.* Remuneration paid under a value-based arrangement, as defined ~~in § 411.351~~at §411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the ~~value~~ value- based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is ~~paid.Start Printed Page 55847~~paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement ~~satisfies the requirements of § 411.354(d)(4)(iv).~~complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the ~~physician—(A) Is~~ physician is responsible to ~~pay the entity~~ repay or forgo no less than ~~25~~ 10 percent of the total value of the remuneration the physician receives under the value-based arrangement~~; or~~.

~~(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.~~

(3) *Value-based ~~arrangements.~~ ~~Remuneration~~ arrangements.* Remuneration paid under a value-based arrangement, as defined ~~in § 411.351~~at §411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;
(D) The type or nature of the remuneration;
(E) The methodology used to determine the remuneration; and
(F) The ~~performance or quality standards~~ outcome measures against which the recipient ~~will be measured, if~~ of the remuneration is assessed, if
any.

(ii) The ~~performance or quality standards~~ outcome measures against which the recipient ~~will be measured~~of the remuneration is assessed, if any, are objective ~~and~~ , measurable, and selected based on clinical evidence or credible medical support.

~~any~~ (iii) Any changes to the ~~performance or quality standards must be~~ outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing.

~~(iii~~(iv) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(~~iv~~v) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(vi) The arrangement is commercially reasonable.

(vii)(A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor:

*(1)* Whether the parties have furnished the value-based activities required under the arrangement;
*(2)* Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and
*(3)* Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed.

(B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise—

*(1)* For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or
*(2)* For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity.

(C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring.

~~(v~~(viii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(~~vi~~ix) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

~~(vii~~(x) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement ~~satisfies the requirements of § 411.354(d)(4)(iv).~~complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

~~(viii)~~ (xi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(xii) For purposes of this paragraph (aa)(3), "outcome measure" means a benchmark that quantifies:

(A) Improvements in or maintenance of the quality of patient care; or

(B) Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.