New Stark Law Exceptions for Value-Based Care

By Jennifer R. Breuer and Matthew Amodeo

On October 9, 2019, the U.S. Department of Health and Human Services released proposed changes to the Ethics in Patient Referrals Act (the “Stark Law”), as well as the Medicare and Medicaid Anti-Kickback Statute (the “Anti-Kickback Statute”) and the Beneficiary Inducement Civil Monetary Penalties Law (the “Beneficiary Inducement Statute”). These proposed changes are meant to ease the regulatory burden on healthcare providers and suppliers as the industry transitions from fee-for-service to value-based care. This Client Alert focuses on the proposed rules’ new Stark Law exceptions that permit certain remuneration among participants in certain value-based arrangements.

The Stark Law Proposed Rule (“Proposed Rule”) would create three new exceptions for compensation arrangements that qualify as “value-based arrangements” and that satisfy certain additional requirements, which vary based on the amount of financial risk shared among the participants to the arrangement. The exceptions would apply regardless of whether the arrangements relate to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both.

Examples of Protected Arrangements

We believe the proposed exceptions are helpful and may be used to protect common arrangements between value-based enterprises, such as ACOs, and their participating providers.

For example, the Full Financial Risk exception could be used protect an arrangement in which a hospital-sponsored ACO that contracts with payors on a capitated basis wants to embed care coordinators in the offices of certain of its contracted physician providers who provide care to diabetic patients. The hospital, at no cost to the providers, would pay the costs associated with the care coordinators. The physician providers would use the care coordinators to follow-up with their diabetic patient population on a routine basis, monitor their blood sugar levels, and recommend exercise and other programs to the population in an effort to reduce emergency room visits and improve certain additional measurable health outcomes. If the care coordination efforts result in reductions in the total cost of care to the diabetic patient population, the ACO would share with the physicians certain of the savings achieved.

Similarly, the Meaningful Downside Risk exception could be used to protect an arrangement in which a hospital enters into a bundled payment arrangement with a payor for hip replacements. The hospital then contracts with orthopedic surgeons to perform the professional component of the surgeries on a fee-for-service basis, but withholds at least 25% of the agreed upon compensation, subject to the physicians achieving certain quality metrics, such as decreasing the revision rate for the procedure over a set benchmark, seeing the patient within a certain number of days and weeks post-surgery, and assuring adherence to the rehabilitation plan. If the surgeons successfully achieve the quality metrics for at least a fixed portion of their patients, in addition to refunding the withhold amount, the hospital would pay the surgeons a bonus amount that had been agreed to at the time the arrangement was put in place.

Finally, the Value-Based Arrangements exception might be used to protect a gainsharing arrangement in which a hospital and certain of its surgical specialists agree to reduce costs by limiting the number and types of surgical implants and other products used at the hospital. The hospital would develop metrics to assure that neither the quality of patient care nor the minimum necessary services were reduced through the gainsharing program. If successful, the hospital would share with the surgical specialists all or some of the savings resulting from the gainsharing program.

In the Proposed Rule, the Centers for Medicare & Medicaid Services (CMS) explains that the new exceptions are dependent on the parties to a proposed arrangement satisfying both the requirements of the Proposed Rule’s new definitions applicable to the new exceptions as well as each element of the exceptions themselves. The new definitions include the following:

- **Value-based activity** would mean any of the following activities that are reasonably designed to achieve at least...
one value-based purpose of the value-based enterprise ("VBE"): (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. Making a referral is not a value-based activity.

- **Value-based arrangement** would mean 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** would mean 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 has an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that has a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

In the Commentary to the Proposed Rule, CMS clarifies that it intends the definition of “value-based enterprise” to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care system. An “enterprise” may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers. An “enterprise” also may consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement.

- **Value-based purpose** would mean (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.

An arrangement would need to meet at least one of the value-based purposes in order to qualify as a value-based arrangement. With respect to the second purpose, CMS is seeking comment as to whether to require that the purpose of the value-based enterprise is to improve quality or maintain the already-improved quality of care for the target patient population. If so, a VBE could not rely on this value-based purpose until after it has already achieved some improvement in the quality of care for the target patient population that is the subject of the value-based arrangement.

CMS is also seeking comment on whether it should define what is meant by “coordinating and managing care” and, if so, whether it should be defined to mean the deliberate organization of patient-care activities and sharing of information between two or more VBE participants, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population.

It also seeks comment regarding permissible ways to determine whether quality of care has improved, a methodology for determining whether costs are reduced or expenditure growth has been stopped, or what parties must do to show that they are 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.

CMS explains that it interprets “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 the target patient population” as a category that includes the integration of VBE participants in team-based coordinated care models; establishing the infrastructure necessary to provide patient-centered coordinated care; and accepting (or preparing to accept) increased levels of financial risk from payors or other VBE participants in value-based arrangements. CMS acknowledges, however, that this goal may lack the precision desired in Stark Law regulations.

- **VBE participant** would mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

CMS is considering whether to exclude the following providers, suppliers, and other persons from the definition of “VBE participant”: pharmaceutical manufacturers, manufacturers and distributors of DMEPOS, pharmacy benefit managers (PBMs), wholesalers, and distributors.

- **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 that further the value-based enterprise’s value-based purpose(s). In the commentary to the Proposed Rule, CMS explains that it is proposing to define the target patient population for which VBE participants undertake value-based activities to mean the identified patient population selected by a value-based enterprise or its VBE participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and that further the value-based enterprise’s value-based purpose(s). Legitimate and verifiable criteria could include medical or health characteristics (e.g., patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes), geographic characteristics (e.g., all patients in an identified county or set of zip codes), payor status (e.g., all patients with a particular health insurance plan or payor), or other defining characteristics. Selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as CMS...
would not consider the selection criteria to be legitimate (even if verifiable). Choosing a target patient population in a manner driven primarily by a profit motive or purely financial concerns would not be legitimate.

Assuming the arrangement in question meets the definitional elements of a value-based arrangement, it must then meet the requirements of at least one of the three new exceptions. The new exceptions would be included at 42 C.F.R. § 357(aa) under the title Arrangements that facilitate value-based health care delivery and payment and would except from the Stark Law’s general referral prohibition arrangements that meet the following requirements:

1. **Full financial risk**—Remuneration paid under a value-based arrangement, if the following conditions are met:

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

   “Full financial risk” is defined to mean 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.

   “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.

   In the commentary to the Proposed Rule, CMS explains that, for Medicare beneficiaries, it would interpret this requirement to mean, at a minimum, that the value-based enterprise is responsible for all items and services covered under Medicare Parts A and B. Further, CMS is seeking comment regarding whether a VBE should be considered to be at full financial risk if it is responsible for the cost of only a defined set of patient-care services for a target patient population and whether it should require a minimum period during which the value-based enterprise is at full financial risk (for example, 1 year).

   CME further explains that full financial risk may take the form of capitation payments (that is, a predetermined payment per patient per month or other period) or global budget payment from a payor that compensates the value-based enterprise for providing all patient-care items and services for a target patient population for a predetermined period. In addition, the proposed exception would not prohibit other approaches to full financial risk.

   CMS clarifies that this exception may be used even when downstream contractors are paid on something other than a full-risk basis. It explains that the VBE itself is incented to monitor for appropriate utilization, referral patterns and quality performance, which should reduce the risk of Medicare program or patient abuse.

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

   In the commentary to the Proposed Rule, CMS explains that it would not interpret the above requirement to mandate a one-to-one payment for an item or service or other value-based activity, and it acknowledges that gainsharing payments, shared savings distributions, and similar payments may result from value-based activities undertaken by the recipient of the payment for patients in the target patient population.

   CMS further explains that it intends this to be an objective standard: the remuneration must, in fact, be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. The proposed exception therefore would not protect payments for referrals or any other actions or business unrelated to the target patient population, such as general marketing or sales arrangements.

   With respect to in-kind remuneration, the remuneration must be necessary and not simply duplicate technology or other infrastructure that the recipient already has. Finally, although the remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, parties would not be prohibited from using the remuneration for the benefit of patients who are not part of the target patient population.

   - The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient

   - 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.

   By way of example, CMS explains that if the value-based enterprise is at full financial risk for the total cost of care for all of a commercial payor’s enrollees in a particular county, the exception would not protect a value-based arrangement between an entity and a physician that are VBE participants in the value-based enterprise if the entity required the physician to refer Medicare patients who are not part of the target patient population for designated health services furnished by the entity. Similarly, the exception would not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement required that the physician perform all his or her other orthopedic surgeries at the hospital.

   - If remuneration paid to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the value-based arrangement (a) is set out in writing and signed by the parties, and (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.

Note that unless referrals are required, no written agreement is required to document the VBE arrangement.

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 must be made available to the Secretary of HHS upon request.

2. Value-based arrangements with meaningful downside financial risk to the physician. Remuneration paid under a value-based arrangement, if the following conditions are met:

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

  “Meaningful downside financial risk” is defined to mean that the physician—(a) is responsible to pay the entity no less than 25 percent of the value of the remuneration that 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.

  In the commentary to the Proposed Rule, CMS explains that, although the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement, the remuneration to be protected under the exception could be paid to or from the physician.

  Further, it explains that the 25 percent risk requirement applies to the value of the remuneration to account for remuneration that may be provided in-kind, such as infrastructure or care-coordination services.

  Finally, CMS is seeking comment on whether the proposed 25 percent threshold is appropriate, and whether downside risk for 25 percent of only a nominal amount of remuneration would be sufficient to curb the influence of traditional FFS, volume-based payment.

- A description of the nature and extent of the physician’s downside financial risk is set forth in writing.

  CMS explains that the writing requirement, as well as the set-in-advance requirement described below, is intended to curtail manipulating a value-based arrangement to reward referrals.

- 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.

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

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

- 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.

- If remuneration paid to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the value-based arrangement (a) is set out in writing and signed by the parties; and (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.

- 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 must be made available to the Secretary upon request.

3. Value-based arrangements—Remuneration paid under a value-based arrangement, if the following conditions are met:

- The arrangement is set forth in writing and signed by the parties. The writing includes a description of—
  1. The value-based activities to be undertaken under the arrangement;
  2. How the value-based activities are expected to further the value-based purpose(s) of the value-based
3. The target patient population for the arrangement;
4. The type or nature of the remuneration;
5. The methodology used to determine the remuneration; and
6. The performance or quality standards against which the recipient will be measured, if any.

As proposed, the exception would permit both monetary and nonmonetary remuneration between the parties. CMS is considering whether to limit the scope of the proposed exception to nonmonetary remuneration only and seeks comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system.

- The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.

In the commentary to the Proposed Rule, CMS explains that it recognizes that performance or quality standards may not be applicable to all value-based arrangements—for example, an arrangement under which a hospital provides needed infrastructure to a physician in the same value-based enterprise may not require the physician to achieve specific performance or quality goals in order to receive or keep the infrastructure items or services. However, if the value-based arrangement does include performance or quality standards that relate to the receipt of the remuneration—for example, an arrangement to share the internal cost savings achieved if the physician meaningfully participates in the hospital’s quality and outcomes improvement program and reaches or exceeds predetermined benchmarks for his or her personal performance or quality measurement—such performance or quality standards must be determined in advance of their implementation. The exception would not protect arrangements for which the performance or quality standards are set retrospectively.

Moreover, any performance or quality standards against which the recipient of the remuneration will be measured should not simply reflect the status quo. CMS is considering whether to require that performance or quality standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery.

- 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.

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

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

- 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.

As an alternative to the above requirement, CMS is considering a requirement that remuneration is not conditioned on the volume or value of referrals of any patients to the entity or the volume or value of any other business generated by the physician for the entity.

Under either formulation, the exception would not protect a “side” arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise of which they are participants, even if the side arrangement itself serves a value-based purpose.

- 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 (a) is set out in writing and signed by the parties; and (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.

- 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.

With respect to arrangements that would qualify for protection under the third proposed exception for value-based arrangements, there would also exist an implicit ongoing obligation to monitor for compliance with the exception. If, at any time the arrangement no longer qualifies as a “value-based arrangement” as defined above, or any of the other elements of the exception are not met, the arrangement would no longer qualify for protection under the exception.

CMS is considering whether to require that (1) the value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise, and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, the physician must cease referring designated health services to the entity, either immediately upon the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such
CMS is also seeking comment regarding whether to require that monitoring should occur at specified intervals and, if so, what the intervals should be. Recognizing that cost savings in particular may take an extended period to achieve, it is also seeking comment regarding whether to impose time limits with respect to a value-based enterprise’s or VBE participant’s determination that the value-based purpose of the enterprise will not be achieved through the value-based activities required under the arrangement and, if it is not, the value-based purpose would be deemed not achievable through the value-based activities requirement under the arrangement.

CMS is also considering whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor’s cost of the nonmonetary remuneration. CMS would require that the 15 percent contribution be made (1) within 90 calendar days of the donation of the nonmonetary remuneration if the donation is a one-time cost to the donor; and (2) at reasonable, regular intervals if the donation of the nonmonetary remuneration is an ongoing cost to the donor. CMS explained that requiring financial participation by a recipient of nonmonetary remuneration under a value-based arrangement would help ensure that the nonmonetary remuneration is appropriate and beneficial for the achievement the value-based purpose(s) of the value-based enterprise and that the recipient will actually use the nonmonetary remuneration. However, it is also concerned that such a requirement could inhibit the adoption of value-based arrangements.

The Proposed Rule would allow indirect compensation arrangements in which the link in the chain closest to the physician is a value-based arrangement to qualify as a “value-based arrangement” for purposes of applying the proposed exceptions described above. In this way, physicians who participate in indirect compensation arrangements will not be disqualified by those value-based arrangements qualifying for protection under the Proposed Rule. In the alternative, CMS is proposing to define an “indirect value-based arrangement,” and to make the proposed exceptions applicable to indirect value-based arrangements as well.

In furtherance of its objectives to improve price transparency, CMS also is considering whether to add to all of the proposed value-based arrangement exceptions a requirement that physicians provide notice or have a policy requiring physicians to alert patients that their out-of-pocket costs for items and services referred by their physicians may vary based on the site where the services are furnished and based on the type of insurance they have.

CMS is also seeking comment regarding the availability of pricing information and out-of-pocket costs to patients, the appropriate timing for dissemination of that information to patients, and the burden of adding a price transparency requirement in an exception to the Stark Law.

The Proposed Rules are scheduled for publication in the Federal Register on October 17, 2019. Comments on the Proposed Rules will be due 75 days from the date of publication.

Stakeholders considering comments should contact any member of Drinker Biddle’s Health Care Group or District Policy Group.