



**Education & Events**  
**Practice Groups & Communities**  
**Publications & Resources**      **About AHLA & Membership**

Education & Events  
Practice Groups & Communities  
Publications & Resources  
About AHLA & Membership

**Back to Current Issue**



10/11/2019

## **Fraud and Compliance**

### **Extensive Changes to the Stark and Anti-Kickback Statute Regulations Are Designed to Remove Barriers to Innovation and Create Clarity**

*By Julie E. Kass and Kristin M. Bohl, BakerOber Health Law, practice group of Baker Donelson*

The Department of Health and Human Services (HHS) continued its efforts to have a major impact on innovation in health care by releasing extensive and significant proposed rules governing the Stark Self-referral prohibition<sup>[1]</sup> (Stark) and the Medicare Anti-Kickback Statute<sup>[2]</sup> (AKS) on October 9. The proposed regulations are part of HHS' Regulatory Sprint to Coordinated Care and are intended to remove regulatory barriers to coordinated care and value-based care to improve the quality of care, health outcomes, and efficiency, all allowing for significant innovation in our country's health care system. These proposed regulations, issued by the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG), consider comments received in response to Requests for Information (RFI) from OIG and CMS published in the summer of 2018. The proposed rules currently are on display at the *Federal Register*. Comments to the regulations will be due 75 days after the proposed rules are published in the *Federal Register*.

#### **Anti-Kickback Statute**

The OIG proposes both new safe harbors and modifications to existing safe harbors. The OIG indicates that it drafted the rules with the

following principles in mind: (1) to allow for beneficial innovations in health care delivery; (2) to avoid regulations that limit innovation to certain arrangements that may not reflect the most current understanding in medicine, science, and technology; and (3) to provide safe harbor protection that will be useful for a wide range of provider types and sizes. The OIG goals are ambitious, trying to balance the competing challenges of the flexibility needed for change and innovation versus the safeguards necessary to protect federal health care programs and patients. The OIG indicates that it has endeavored to create rules that are clear, objective, flexible, and easy to implement while at the same time that also include adequate safeguards. The OIG stresses that it has not made a final determination that the regulations strike the right balance. The proposed safe harbors are prospective only and subject to possible material change until a final rule is issued. Indeed, much of the preamble to the proposed rules is made up of requests by the OIG for further feedback on the proposed rules or potential alternatives.

#### *Value-Based Enterprise Safe Harbors*

The proposed rule includes three new safe harbors encompassing a variety of arrangements for "value-based enterprises" (VBE) intended to "foster better care at lower cost through improved care coordination for patients." VBEs can take many forms. They are generally networks of individuals or entities (at least two) that collaborate to achieve a value-based purpose. VBEs include all the entities that would participate in arrangements that would be eligible for safe harbor protection. The VBE is also the body that is accountable for making sure that all of the criteria of the safe harbor are met.

The VBE safe harbors are:

1. Care coordination arrangements to improve quality, health outcomes, and efficiency (1001.952(ee));
2. Value-based arrangements with substantial downside financial risk (1001.952(ff)); and
3. Value-based arrangements with full financial risk (1001.9529gg))

Each of these safe harbors protects a variety of arrangements. They share a common terminology, such as VBE Participant, Value-Based Arrangement, and Value-Based Activity. While the OIG has stated that the definitions will be similar to those in the Stark proposed rules, whenever appropriate, the OIG has also indicated that the proposed safe harbors are more restrictive than the CMS proposals in various respects. A key example of this is the definition of VBE Participant. The safe harbor definition excludes pharmaceutical manufacturers, manufacturers, distributors, DMEPOS suppliers, and laboratories. The

parallel CMS preamble defines a VBE Participant as an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. Rather than excluding certain types of entities, CMS merely considers whether to exclude pharmaceutical manufacturers; manufacturers and distributors of DMEPOS; pharmacy benefit managers (PBMs); wholesalers; and distributors from the VBE Participant definition. Notably, laboratories are not included in this list.

The Care Coordination safe harbor protects only in-kind remuneration, does not require the participants to take on risk, but does require that the arrangement be measured based on at least one evidence-based outcome measure, along with several other safeguards that ensure transparency. Notably, the recipient must pay at least 15% of the offeror's cost of the in-kind remuneration.

The safe harbor for Value-Based Arrangements with Substantial Downside Risk protects both in-kind and monetary remuneration. In this safe harbor, VBE Participants are required to "meaningfully share" in downside risk; participants must be at risk for at least 8% of the amount for which the VBE is at risk; the arrangement must be a partial or full capitation payment; or for physicians, must meet the Stark exception for valued-based arrangements with meaningful downside risk. The safe harbor also requires VBE arrangements to meet many of the same requirements as the Care Coordination safe harbor.

The final VBE safe harbor for Value-Based Arrangements with Full Financial Risk also protects in-kind and monetary remuneration. Full Financial Risk is defined as responsibility for all the costs of care for a specific patient population. The OIG states that this safe harbor provides the greatest flexibility, as the parties to the arrangements have taken on full financial risk.

In addition to the VBE safe harbors, the OIG has added a separate safe harbor to protect CMS-sponsored models, such as those designed by the CMS Innovation Center. This safe harbor is intended to replace the current model-by-model fraud and abuse waiver process for each new CMS innovation program.

A related new safe harbor provides protection for certain patient engagement tools (1001.952(hh)). The Patient Engagement and Support safe harbor protects arrangements with beneficiaries from both the Anti-Kickback Statute and the Civil Money Penalty (CMP) for Patient Inducement. This proposed safe harbor is intended to address medically necessary care and other non-medical, but health-related items and services that patients might need to adhere to treatment regimens. Its protection is limited to in-kind remuneration provided by VBE Participants to patients to assist with patient engagement in their

care. Covered patient engagement tools are limited to "in-kind, preventative items, goods or services such as health related technology, patient health-related monitoring tools and services and supports or services designed to identify and address a patient's social determinants of health that have a direct connection to the coordination and management of care of the target patient population." Excluded are gift cards, cash, and any cash equivalent.

#### *Personal Services and Management Safe Harbor*

The OIG also proposes to modify the personal services and management contracts safe harbor to include the protection of certain outcomes-based payment arrangements, such as payments from a hospital to a physician who improves certain clinical measures, such as infection rates. The safe harbor requires that payments for any such arrangement must be for measurably improving care and materially reducing costs. Outcomes-based payments that relate only to internal cost savings for the party paying the remuneration are excluded from safe harbor protection. Payments from a pharmaceutical company, manufacturer, distributor, DMEPOS supplier, or laboratory are also excluded.

In addition, the OIG removes the current safe harbor requirement that the *aggregate* payment be set out in advance and replaces it with the requirement that the methodology need only be set in advance. This is consistent with the parallel Stark exception. Further the OIG removes the criteria that if an arrangement is part-time, the schedule of services be specifically set out in the written agreement.

#### *Cybersecurity and Electronic Health Record Donation Safe Harbors*

The OIG acknowledges the increased use of technology in patient care and the need for the safe protection of patient information. Therefore, the proposed rule includes a new safe harbor for the provision of cybersecurity technology to potential referral sources. It also modifies the safe harbor for donation of electronic health records safe harbor, most notably removing any sunset of the safe harbor and updating provisions to create consistency with Office of National Coordinator for Health Information Technology proposed rules related to interoperability.

#### *Modification to the Warranty Safe Harbor*

The OIG proposes changes to the Warranty safe harbor to allow protection for one or more items and related services; exclude beneficiaries from the reporting requirements for buyers and directly define warranty rather than relying on the reference to 15 U.S.C. § 2301(6). The changes to the safe harbor do not extend protection to

warranty of service-only arrangements. Moreover, there are additional safe harbor criteria that must be met for protection of bundled warranties.

#### *Modification to Local Transportation Safe Harbor*

The OIG proposes to modify the local transportation safe harbor to expand the distance allowed for residents in rural areas as well as remove any distance requirement for inpatients on discharge. The OIG also clarifies that ride-sharing arrangements are permissible under the safe harbor.

#### *ACO Beneficiary Incentive Program Safe Harbor*

The Balanced Budget Act of 2018 included a statutory provision excluding from remuneration incentive payments made to a beneficiary who receives such payments as part of the ACO Beneficiary Incentive Program under Section 1899(m) of the Statute. The OIG is codifying the Balanced Budget Act provision as a new safe harbor without any modification from the statute.

### **Civil Money Penalty Exception**

#### *Statutory Exception for Telehealth Technologies for In-Home Dialysis*

The Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2018 included a provision to permit individuals with end-stage renal disease that receive home dialysis treatment to be provided monthly clinical assessments through telehealth and created an exception from the definition of remuneration under the CMP for telehealth technologies provided to those patients. The OIG proposes certain safeguards for such telehealth technologies to implement the statutory provision.

### **Physician Self-Referral (Stark) Law**

In this proposed rule, CMS not only created new exceptions for value-based arrangements, but also addressed many areas in the existing regulations that have prompted requests for clarification and guidance. CMS notes that many of its proposals are intended to reduce the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties. While responding to the concerns raised by respondents to the RFI, CMS was intentional in establishing proposals that not only maintain program integrity, but also ensure compliance with the Stark Law is achievable, as well as offer the flexibility required by participants in value-based health care delivery and payment systems.

#### *Value-Based Enterprise Proposed Exceptions*

The proposed exceptions were drafted with a focus on several corresponding goals: to remove regulatory barriers, real or perceived; to create space and flexibility for industry-led innovation in the delivery of better and more efficient coordinated health care for patients and improved health outcomes; and in support of the Secretary's priorities. CMS noted the historical trend toward improving health care through better care coordination and the increasing adoption of value-based models in the health care industry, and sought to propose exceptions that will create incentives for the industry to move away from volume-based health care delivery and payment and toward population health and other non-fee-for-service payment models.

To support expansion of value-based arrangements, CMS proposed three new exceptions as well as new definitions, that when read together provide the requirements for protection from the Stark Law's prohibition on referrals and claims submission. CMS notes that these proposed exceptions would apply regardless of whether the arrangement includes care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. Additionally, CMS notes that the proposal of the new exceptions is not intended to imply that any existing value-based arrangements that currently satisfy an exception are in danger of noncompliance.

The new definitions for the proposed value-based exceptions include: value-based activity; value-based arrangement; value-based enterprise (VBE); value-based purpose; VBE participant; and target patient population. The proposed exceptions would apply only to compensation arrangements that qualify as value-based arrangements, that is between a VBE and one or more of its VBE participants or between parties in the same VBE. CMS notes that a determination of whether one of the new exceptions applies to an arrangement will be based on the activities that serve as the basis for the compensation arrangements. Although identifying those activities that are specifically responsible for a value-based outcome can be challenging, CMS explicitly states that the act of referring patients for designated health services is itself not a value-based activity.

The proposed exceptions include:

- Full Financial Risk § 411.357(aa)(1)
- Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician § 411.357(aa)(2)
- Value-Based Arrangements Proposed § 411.357(aa)(3)

The Full Financial Risk exception applies to value-based arrangements between VBE participants in a value-based enterprise that has assumed "full financial risk" 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 time period. The VBE 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. CMS explained that full financial risk may take the form of capitation payments or global budget payments 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 of time but is not limited to only these approaches. This exception is similar to the risk-sharing arrangements exception but is not limited to "risk-sharing compensation." CMS does not propose a writing requirement for this exception.

The Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician exception would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise (the "meaningful downside financial risk exception"). CMS proposes to define "meaningful downside financial risk" as the physician is responsible to pay the entity no less than 25% of the value of the remuneration the physician receives under the value-based arrangement. The proposal requires the nature and extent of the physician's financial risk to be set forth in writing.

The proposed Value-Based Arrangements exception addresses compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise or any of its VBE participants (the "value-based arrangement exception") and would permit both monetary and nonmonetary remuneration between the parties. This proposed exception has additional safeguards, including the requirement of a signed writing that the other two value-based exceptions do not have.

CMS did not include a separate proposed exception to protect CMS-sponsored models like the OIG did. CMS believes that the exceptions proposed at § 411.357(aa) would be applicable to the compensation arrangements between parties in a CMS-sponsored model, program, or other initiative (provided that the compensation arrangement at issue qualifies as a "value-based arrangement"). Although CMS hopes that the new value-based exceptions would eliminate the need for any new waivers of Section 1877 of the Act for value-based arrangements, parties may elect to use the waivers applicable to the CMS-sponsored models.

*Indirect Compensation Arrangements to which the Exceptions at Proposed § 411.357(aa) Are Applicable (Proposed § 411.354(c)(4))*

Under the current regulations, if an indirect compensation arrangement exists, the only exception available for protection under the Stark Law is the indirect compensation exception at § 411.357(p), although parties to an arrangement may opt to apply an applicable exception in § 411.355 to protect individual referrals of and claims for designated health services. CMS raised the issue of indirect compensation arrangements that are part of an unbroken chain of financial relationships in a value-based arrangement. The newly proposed exceptions at § 411.357(aa) are less restrictive than the current indirect compensation exception and an arrangement could be an indirect value-based compensation arrangement and not be able to meet the existing indirect compensation exception because value-based arrangements do not have to meet certain of the criteria of the existing exception. To address this, CMS proposes that, when the value-based arrangement is the link in the chain closest to the physician—that is, the physician is a direct party to the value-based arrangement—the indirect compensation arrangement would qualify as a "value-based arrangement" for purposes of applying the proposed exceptions at § 411.357(aa) and would not have to satisfy the indirect compensation exception.

*Price Transparency*

CMS sought comments on price transparency in the RFI and received mixed responses regarding the role of transparency in the context of the Stark Law. While CMS continues to support patient access to price information, the agency is seeking additional comments on how to incorporate price transparency objectives while overcoming the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the physician self-referral regulations.

*Fundamental Terminology Requirements*

In addition to the proposed value-based arrangement exceptions, definitions, and related changes, CMS responded to many of the concerns and questions raised in the RFI and through self-referral disclosure protocol (SRDP) submissions, as well as other sources.

*Commercially Reasonable*

Several statutory and regulatory exceptions include a requirement that the compensation arrangement is "commercially reasonable." In considering a clarifying definition for the term, CMS considered whether the arrangement makes sense as a means to accomplish the parties'



goals. As the specific facts to an arrangement matter, this consideration must be made based on the perspective of the particular parties involved in the arrangement. CMS highlights that a commercial reasonableness determination is not one of valuation and it is *not* based on whether the arrangement is profitable. CMS provides helpful explicit clarification that arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable.

The proposal includes two alternative definitions for the term "commercially reasonable": (1) that the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, or (2) that the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.

#### *Volume or Value Standard and the Other Business Generated Standard*

CMS proposes two separate special rules for the volume or value standard and two special rules for the other-business-generated standard. To provide the bright-line test requested by commenters, CMS proposes to define when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties rather than deeming compensation under certain circumstances not to have been determined in a manner that takes into account the volume or value of referrals or takes into account other business generated between the parties.

CMS reaffirmed its position from the Phase II regulations:

With respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We are also clarifying that our guidance extends to compensation arrangements that do not rely on the exception for *bona fide* employment relationships at § 411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule at § 411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula—even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value

of the physician's referrals if the compensation meets the conditions of the special rule at § 411.354(d)(2) (see 69 FR 16067).

#### *Patient Choice and Directed Referrals*

In an effort to ensure that patient choice and physicians' professional medical judgment are protected and to avoid interference in the operations of a managed care organization, even with proposed changes to the volume or value standard, CMS proposes to add an element to certain exceptions that would require the compensation arrangement to meet the conditions of the special rule at § 411.354(d)(4). Under the special rule, an entity is permitted to direct referrals to a particular provider, practitioner, or supplier for a physician who is a *bona fide* employee, independent contractor, or party to a managed care contract, as long as the compensation arrangement meets specified conditions designed to preserve patient choice, comply with insurer's determinations, and protect the physician's judgment as to the patient's best medical interests. The exceptions CMS is considering for this additional element include: § 411.355(e) for academic medical centers, § 411.357(c) for bona fide employment relationships, § 411.357(d)(1) for personal service arrangements, § 411.357(d)(2) for physician incentive plans, § 411.357(h) for group practice arrangements with a hospital, § 411.357(l) for fair market value compensation, and § 411.357(p) for indirect compensation arrangements.

#### *Fair Market Value*

CMS proposed to define fair market value to mean the value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction. Additionally, CMS proposed to change the definition of "general market value," currently included within the definition of fair market value at § 411.351 to equate it to "market value," the term used uniformly in the valuation industry.

#### *Modifications to Group Practice*

In addressing comments received related to clarification of the group practice rules, CMS focused on changes that apply to the purposes of the proposed rule—the proposed definitions and special rules for "commercially reasonable" compensation arrangements, "fair market value" compensation, and the volume or value standard applicable throughout the physician self-referral law and regulations; and the transition from a volume-based to a value-based health care system. The proposed changes apply to clarifying the application of the "volume or value standard" and revisions to the special rules for profit shares

and productivity bonuses. CMS proposed to clarify that where § 411.352(i) states that a physician in a group practice may be paid a share of overall profits of the group practice, provided that the share is not determined in any manner that is *directly related* to the volume or value of referrals by the physician, is interpreted to mean "takes into account" the volume or value of referrals. For the special rules for profit shares and productivity bonuses, CMS proposes to add a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. This distribution would be deemed not to directly take into account the volume or value of the physician's referrals and would enable physicians in a group practice who are participating in value-based arrangements to be rewarded for their participation in such models in compliance with these special rules.

#### *Recalibrating the Scope and Application of the Regulations*

CMS noted it has reconsidered its position and no longer believes that it is necessary or appropriate to include requirements pertaining to compliance with the AKS and federal and state laws or regulations governing billing or claims submission as requirements of the exceptions to the physician self-referral law. CMS proposes to remove from the exceptions in 42 C.F.R. pt. 411, subpt. J the requirement that the arrangement does not violate the AKS or any federal or state law governing billing or claims submission wherever such requirements appear.

CMS also proposes clarifications to several definitions including: (i) designated health services (clarifying that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS)), (ii) physician, (iii) referral, (iv) remuneration, and (v) transaction. CMS also proposes to delete in their entirety the rules on the period of disallowance.

#### *Electronic Health Records (EHR)*

CMS and OIG are both proposing changes to the EHR exception and safe harbor, respectively. These proposals focus on interoperability and the "deeming provision," information blocking, and data lock-in. They clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the sunset provision, and modify the definitions of "electronic health record" and "interoperable" to ensure consistency with the 21st Century Cures Act.

### *Flexibility for Non-abusive Business Practices*

To address other arrangements that CMS believes do not raise a risk of program or patient abuse, CMS proposes two new exceptions. The first is an exception for limited remuneration to a physician. This would permit the provision of limited remuneration to a physician if certain requirements are met including instances when the amount of, or a formula for, calculating the remuneration is not set in advance of the provision of items or services and the remuneration does not exceed an aggregate of \$3,500 per calendar year.

Another proposed exception addresses the donation of cybersecurity technology and related services which would protect nonmonetary remuneration in the form of certain types of cybersecurity technology and related services.

### **Conclusion**

The proposed rules from CMS and OIG contain a great deal to consider. As they have done in the past, CMS and OIG worked cooperatively with each other in drafting the proposed regulations and have produced a thoughtful and far-reaching proposal. The proposed rules recognize the inherent overlap of the Stark Law with the AKS and highlight some of those areas where CMS and OIG align with each other in their proposals, and where, due to the focus and application of the different laws, the analysis differs. It is critical that the industry takes the time to study the proposals and the potential impacts on existing value-based arrangements and take advantage of the opportunity to respond to these proposals.

### **About the Authors:**

**Julie Kass**, the co-chair of the Health Law Practice Group at BakerOber, is a recognized authority in the field of Medicare and Medicaid fraud and abuse. Her practice deals with the regulatory aspects of structuring arrangements under the Stark and Anti-Kickback laws. She often serves as defense counsel in DOJ and OIG matters and has worked on a variety of voluntary disclosures to CMS and OIG. Julie's clients involve the full spectrum of health care providers across the U.S. Julie is a former Senior Counsel in the U.S. Department of Health and Human Services, Office of Inspector General. Julie was the recipient of the Baker Donelson Susan E. Rich Award for excellence in the promotion of and commitment to women in the legal profession in 2018. She is listed in *Best Lawyers in America*® in Health Care Law (2018, 2019) and as a top lawyer Nationwide and in Maryland by *Chambers USA: America's Leading Business Lawyers* in

Healthcare (2017 – 2019). Julie is a Member of the Board of Directors of the Jewish Federations of North America and Co-Chair of the Health and Long-Term Care Subcommittee.

**Kristin Bohl** is a Shareholder in the Health Law Practice Group at BakerOber. Ms. Bohl advises hospitals, health care systems, and providers in compliance and regulatory issues with particular emphasis on fraud and abuse matters as well as recently implemented Medicare payment models. Drawing on her experience in the federal government, she counsels clients on actual and potential compliance concerns that arise on a day-to-day basis as well as offers assistance navigating more serious concerns that require a more extensive plan of action to address. She regularly assists clients with analysis of issues involving the Stark physician self-referral statute, the anti-kickback statute, and Medicare payment policy. Ms. Bohl advises clients on arrangements among health care providers, internal compliance issues, communication with the federal government related to compliance issues—including the submission and resolution of voluntary disclosures to the OIG and CMS self-disclosure protocols when necessary. She provides guidance on the legal aspects of health systems operations and drafts and implements compliance programs and policies.

**Endnotes:**

[1] 42 U.S.C. § 1395nn.

[2] 42 U.S.C. § 1320a-7b(b).

© 2018 American Health Lawyers Association. All rights reserved.

1620 Eye Street NW, 6th Floor, Washington, DC 20006-4010

P. 202-833-1100 F. 202-833-1105