Stark Law Overhaul: An In-Depth Review of the 2020 Rulemaking

White Paper No. 7
The Problem of the Square Peg and the Round Hole: When Fee for Service and Managed Care Collide

The Problem of the Square Peg and the Round Hole: **When Fee for Service and Managed Care Collide**

In December 2020, the Centers for Medicare & Medicaid Services (CMS) finalized its long-awaited changes to the agency's regulations governing the federal physician self-referral law, commonly known as the Stark Law (Final Rule).[1] Many of the changes had been proposed by the agency in an October 2019 proposed rulemaking (Proposed Rule).[2] The Final Rule represents the most significant Stark Law rulemaking in more than a decade. The Health Care Group at Dentons US is presenting a series of seven webinars, each with a companion white paper, addressing the principal components of the Final Rule. This is the seventh, and last, of these white papers, addressing three new exceptions created by CMS for certain so-called "value-based" compensation arrangements between physicians and entities that furnish designated health services (DHS Entities):

- The exception for arrangements with value-based full financial risk (Full Financial Risk Exception).[3]
- The exception for value-based arrangements with meaningful downside financial risk to the physician (Meaningful Downside Financial Risk Exception).[4]
- The exception for value-based arrangements more generally (Value-Based Arrangement Exception).[5]

We will refer to these, collectively, as the Value-Based Exceptions.

1 The Stark Law is codified at 42 U.S.C. § 1395nn, 1396b(s), and 42 C.F.R. § 411.350 *et seq.* The Final Rule was published at 85 Fed. Reg. 77492 (Dec. 2, 2020).

2 84 Fed. Reg. 55766 (Oct. 17, 2019).

3 42 C.F.R. § 411.357(aa)(1).

4 *Id.* § 411.357(aa)(2).

5 *Id.* § 411.357(aa)(3).


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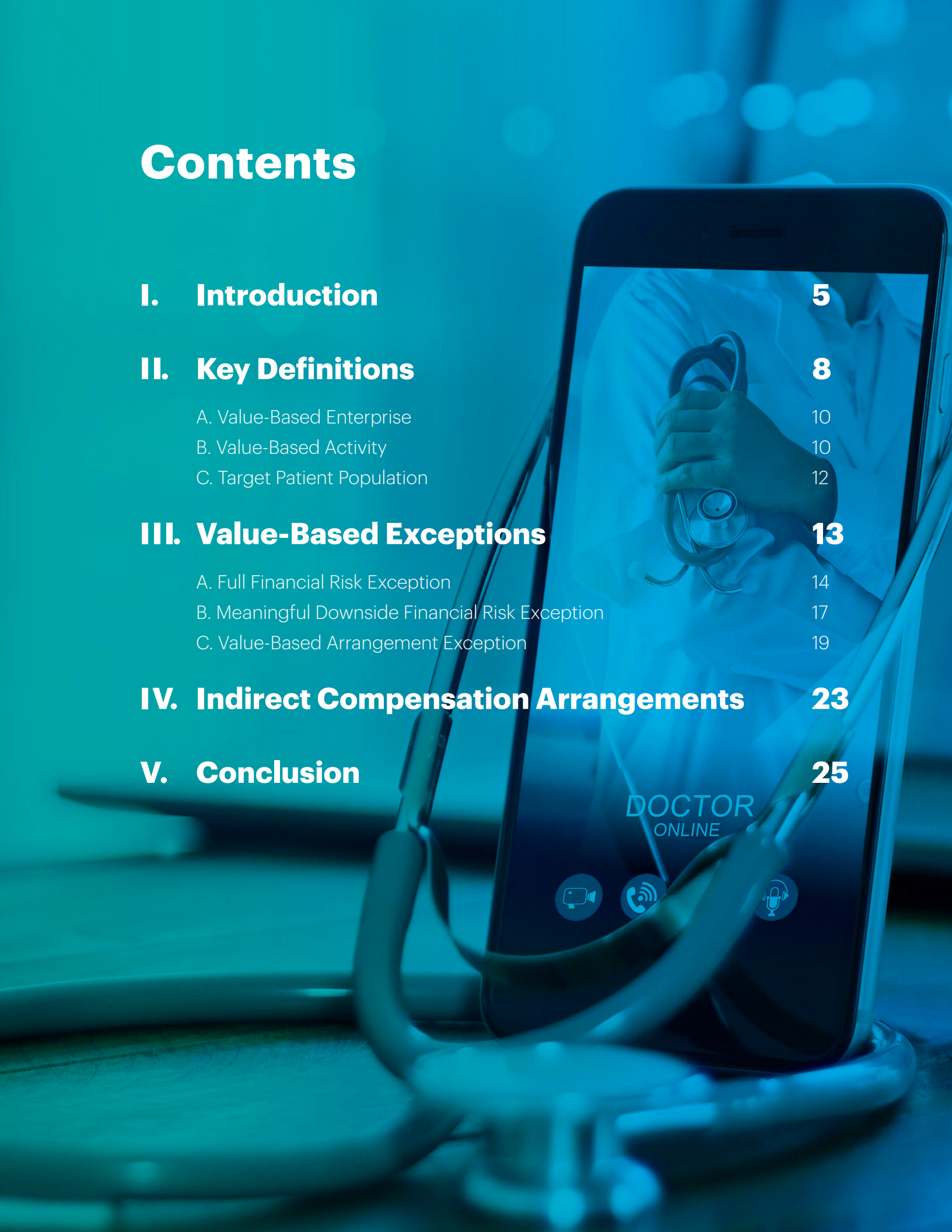


I. Introduction

As we've discussed in this series, the Stark Law was enacted in 1989, and amended in the early 1990s, to combat potential overutilization under the Medicare fee-for-service (FFS) program. At the time, the vast majority of items and services covered by Medicare—including, but not limited to, the "designated health services" (DHS) covered by the Stark Law—were paid based on volume. Simply put, the more lab tests, x-rays, drugs, physical therapy, and other items or services a provider or supplier ordered, the more Medicare payments it would receive.

Given this volume-driven reimbursement model, Congress was concerned that a physician who had a financial relationship with a DHS Entity would be motivated to make unnecessary referrals to that DHS Entity for the purpose of increasing its Medicare reimbursement. The substantive requirements commonly found in Stark Law exceptions—i.e., the FMV,[6] Commercial Reasonableness[7] and Volume/Value Standards[8]—were (and remain) specifically aimed at combating this potential for overutilization and increased Medicare program costs.

Over the past two decades, however, the health care industry has been gradually shifting toward value-based health care delivery and payment systems, in which payment is made based on value (e.g., improved patient outcomes or reduced total costs) rather than volume. For example, the 2010 Affordable Care Act established the Center for Medicare and Medicaid Innovation within CMS,[9] which has tested numerous alternative payment models aimed at improving care and lowering costs in the Medicare FFS program.[10] These have included, for example, payment models involving accountable care organizations (ACOs),[11] bundled payments for specific episodes of care (e.g., joint replacement)[12] and the recent Global and Professional Direct Contracting Model (pursuant to which health care organizations can enter into risk-sharing arrangements for Medicare FFS beneficiaries).[13] Commercial payors also have developed similar initiatives. These alternative payment models generally have included fraud and abuse waivers to avoid potential Stark Law compliance issues.

6 The FMV Standard generally requires that the compensation at issue be consistent with "fair market value." For an in-depth discussion of the FMV Standard, *see* Dentons US, *White Paper No. 4, Key Standards (Part II): "Fair Market Value" and "Commercial Reasonableness" Standards, and Indirect Compensation Arrangements*, at 5-11.

7 The Commercial Reasonableness Standard generally requires that the arrangement at issue be "commercially reasonable." For an in-depth discussion of the Commercial Reasonableness Standard, *see* Dentons US, *White Paper No. 4, Key Standards (Part II): "Fair Market Value" and "Commercial Reasonableness" Standards, and Indirect Compensation Arrangements*, at 12-18.

8 The Volume/Value Standard generally asks whether the compensation provided for under the arrangement at issue takes into account the volume or value of the physician's referrals to, or other business generated for, the DHS Entity. For an in-depth discussion of the Volume/Value Standard, *see* Dentons US, *White Paper No. 3, Key Standards (Part I): The "Volume or Value" Standard*, at 5-21.

9 Affordable Care Act § 3021, Social Security Act § 1115A.

10 CMS, *Innovation Models*, https://innovation.cms.gov/innovation-models#views=models (last visited June 10, 2021).

11 CMS, *Accountable Care Organizations (ACOs): General Information*, https://innovation.cms.gov/innovation-models/aco (last visited June 10, 2021).

12 CMS, *Comprehensive Care for Joint Replacement Model*, https://innovation.cms.gov/innovation-models/cjr (last visited June 10, 2021).

13 CMS, *Global and Professional Direct Contracting Model (GPDCM)*, https://innovation.cms.gov/innovation-models/gpdc-model (last visited June 10, 2021).

By their nature, value-based health care delivery and payment systems involve little (if any) risk of overutilization, since payment is tied to clinical and economic performance. Recognizing this, the US Department of Health and Human Services (HHS) launched a "Regulatory Sprint to Coordinated Care" in 2018 to accelerate the transition to a value-based health care delivery and payment system.[14] As part of this Regulatory Sprint, CMS sought to address aspects of the Stark Law that could serve as obstacles to coordinated care,[15] culminating in the new Stark Law Final Rule and, more specifically, the three new Value-Based Exceptions.

As recognized by CMS in the Final Rule, providers, suppliers and physicians may be discouraged from entering into value-based arrangements due to a concern about Stark Law noncompliance.[16] Specifically, industry stakeholders historically have been concerned that if a DHS Entity and a referring physician have a financial relationship arising from a value-based arrangement, it can be difficult to protect the physician's referrals of DHS furnished to Medicare FFS beneficiaries under an existing exception.

As discussed in White Paper No. 1, Stark Law exceptions fall into two categories: exceptions that apply to certain types of *services*,[17] and exceptions that apply to certain types of *financial relationships*.[18] With respect to the first category, the Stark Law has an exception at 42 C.F.R. § 411.355(c) for services furnished to enrollees of certain "prepaid health plans" (Prepaid Plan Exception).[19] The Prepaid Plan Exception is extremely broad, essentially protecting any services furnished by a DHS Entity to a Medicare Advantage enrollee. Importantly, however, the Prepaid Plan Exception will not protect a DHS Entity from potential Stark Law liability with respect to items or services that are furnished to a Medicare FFS beneficiary. That is, (i) if a value-based arrangement (or any other arrangement) gives rise to a financial relationship between a DHS Entity and a physician, and (ii) the physician refers both Medicare Advantage enrollees and Medicare FFS beneficiaries to the DHS Entity, the Prepaid Plan Exception will protect the DHS furnished to the Medicare Advantage enrollees, but *not* the DHS furnished to the Medicare FFS beneficiaries.

Historically, there has been only one exception under the Stark Law that might be used to protect a risk-sharing arrangement between a physician and DHS Entity so as to allow the physician to refer Medicare FFS beneficiaries to the DHS Entity: the exception for risk-sharing arrangements at 42 C.F.R. § 411.357(n) (Risk-Sharing Arrangements Exception). That Exception, however, applies only to direct or indirect compensation arrangements arising from a risk-sharing arrangement between a physician and a very limited subset of potential DHS Entities; specifically, managed care organizations (MCOs) and independent practice associations (IPAs).

In light of these limitations, to encourage innovation by removing (real or perceived) barriers to care coordination, and to avoid the need to continually rely on the ad hoc issuance of fraud and abuse waivers, CMS proposed the three new Value-Based Exceptions in the 2019 Proposed Rule,[20] all of which were adopted (with some modifications) in the Final Rule.[21]

14 83 Fed. Reg. 29524 (June 25, 2018).

15 *Id.*

16 85 Fed. Reg. at 77493.

17 42 C.F.R. § 411.355.

18 *Id.* § 411.356 (exceptions applicable to ownership interests) and § 411.357 (exceptions applicable to compensation arrangements).

19 *Id.* § 411.355(c).

20 84 Fed. Reg. at 55846-47 (proposing new 42 C.F.R. § 411.357(aa)).

21 85 Fed. Reg. at 77681-82 (adding new 42 C.F.R. § 411.357(aa)).

II. Key Definitions

While there are important distinctions (discussed below) among the new Value-Based Exceptions, all three share the following core feature: They apply to a *compensation arrangement* between a DHS Entity and a physician that arises from remuneration paid under a "*value-based arrangement*."[22] As reflected below, determining whether there is a "value-based arrangement"—separate and apart from whether the requirements of a Value-Based Exception are met—is complex and multifaceted.

Under the Final Rule, a "value-based arrangement" is defined as an arrangement for the provision of at least one "value-based activity" for a "target patient population" to which the only parties are (i) the "value-based enterprise" (VBE) and one or more of its "VBE participants" or (ii) "VBE participants in the same value-based enterprise."[23] For (relative) ease of discussion, we first will set forth the finalized definitions of each of these terms. We then will provide a high-level diagram that illustrates how (and where) these various entities and concepts fit together. Next, we will delve into some notable aspects of these definitions. Finally, we will turn to the Exceptions themselves.

Starting with the definitions, the key terms within the "value-based arrangement" definition are defined in the Final Rule as follows:

- A "***VBE participant"*** is defined as "a person or entity that engages in at least one value-based activity as part of a value-based enterprise."[24] In the preamble to the Final Rule, CMS clarified that, as used in this definition, "entity" refers to non-natural persons generally, as opposed to the term "entity" under 42 C.F.R. § 411.351 (i.e., a DHS Entity).[25]
- A "***value-based enterprise***" is defined as "two or more VBE participants" (i) "collaborating to achieve at least one value-based purpose," (ii) "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," (iii) "that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise," and (iv) "that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)."[26]
- A "***value-based purpose***" means any of the following: (i) "coordinating and managing the care of a target patient population," (ii) "improving the quality of care for a target patient population," (iii) "appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population," or (iv) "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."[27]
- A "***value-based activity***" is an activity that consists of (i) the "provision of an item or service," (ii) the "taking of an action," or (iii) the "refraining from taking an action," provided that the activity is "reasonably designed" to achieve at least one "value-based purpose" of the value-based enterprise.[28]
- A "***target patient population***" is an "identified patient population selected by a value-based enterprise or its VBE participants" based on "legitimate and verifiable" criteria that (i) are "set out in writing in advance of the commencement of the value-based arrangement" and (ii) "further the value-based enterprise's value-based purpose(s)."[29]

22 *Id. See also id.* at 77498 ("Effectively, the parties to a value-based arrangement must include an entity (as defined at § 411.351) and a physician; otherwise, the physician self-referral law's prohibitions would not be implicated. Also, because the exceptions at final § 411.357(aa) apply only to compensation arrangements (as defined at § 411.354(c)), the value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies.").

23 *Id.* at 77662 (adding the definition of "value-based arrangement" to 42 C.F.R. § 411.351).

24 *Id.* (adding the definition of "VBE participant" to 42 C.F.R. § 411.351).

25 *Id.* at 77505.

26 *Id.* (adding the definition of "value-based enterprise" to 42 C.F.R. § 411.351).

27 *Id.* at 77662 (adding the definition of "value-based purpose" to 42 C.F.R. § 411.351).

28 *Id.* at 77661-62 (adding the definition of "value-based activity" to 42 C.F.R. § 411.351).

29 *Id.* at 77661 (adding the definition of "target patient population" to 42 C.F.R. § 411.351).

Given that these definitions are complex and interlocking, we believe it would be helpful to illustrate their relationship through a hypothetical and corresponding diagram. For purposes of illustration, Diagram 1 below assumes the following:

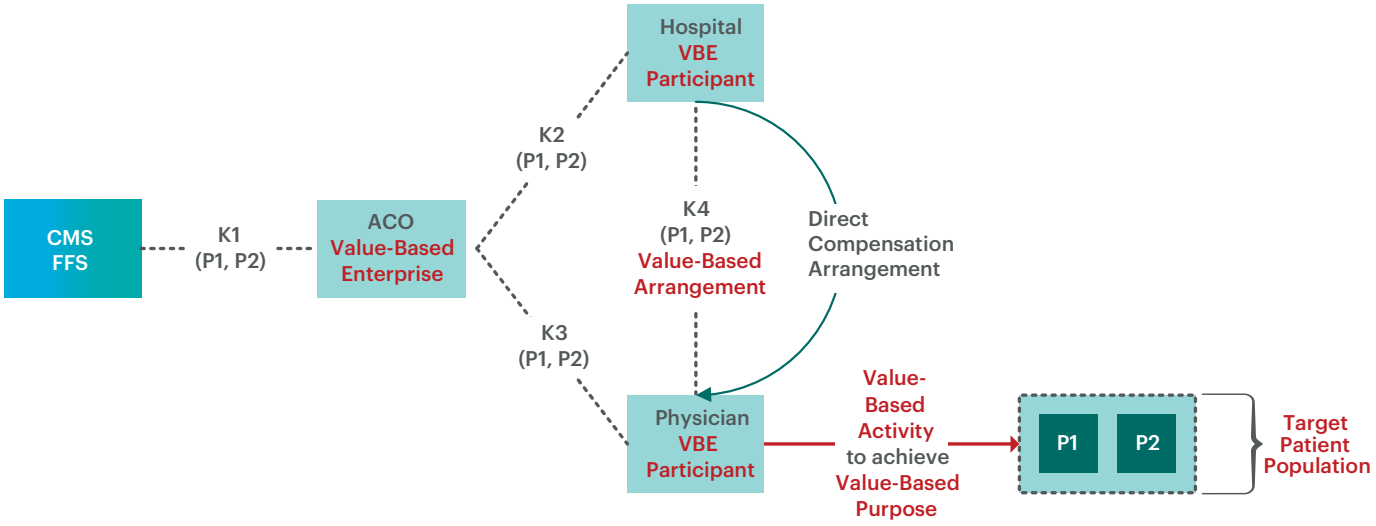
- ACO has entered into an agreement with CMS (K1), pursuant to which ACO has agreed to manage and coordinate the care for all Medicare FFS beneficiaries within a specific county (ACO Aligned Beneficiaries). The ACO Aligned Beneficiaries are P1 and P2.
- ACO's participating providers include Hospital (i.e., a DHS Entity) and Physician. ACO contracts with these providers pursuant to K2 and K3, respectively.
- Our ACO Aligned Beneficiaries (P1 and P2) are patients of both Physician and Hospital.
- Hospital and Physician, acting in their capacities as ACO participants, enter into an agreement (K4), pursuant to which:
  - Physician agrees to implement a new care protocol (Care Protocol) for the ACO Aligned Members under her care (i.e., P1 and P2); and
  - Hospital agrees to pay Physician in connection with her implementation of the Care Protocol.

Putting all of this together, for Stark Law purposes, K4 creates a direct compensation arrangement between Hospital (a DHS Entity) and Physician arising from the compensation paid by Hospital to Physician. That direct compensation arrangement, in turn, arises from remuneration paid under a "value-based arrangement" because:

- Hospital and Physician are both VBE participants of the same value-based enterprise (i.e., the ACO);
- Hospital and Physician (i.e., the VBE participants) are engaging in a value-based activity (i.e., implementing the Care Protocol) on behalf of a target patient population (i.e., the two ACO Aligned Members under Physician's care);
- the value-based activity is reasonably designed to achieve a value-based purpose of the ACO (i.e., coordinating and managing the care of the target patient population); and
- the remuneration paid by Hospital to Physician under K4 is compensation for that value-based activity.

We can illustrate this value-based arrangement, and the direct compensation arrangement arising from it, as follows:

Diagram 1



Having illustrated the relationship between the various components of a "value-based arrangement," we now will take a deeper dive into some of those terms.

A. Value-Based Enterprise

Fundamental to the definition of a "value-based arrangement," and several of its component terms, is the existence of a "value-based enterprise." As noted above, the definition of a "value-based enterprise" requires two or more VBE participants (i) "collaborating to achieve at least one value-based purpose," (ii) "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," (iii) "that have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise," and (iv) "that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)."[30]

As reflected in prongs 3 and 4 of the definition, a "value-based enterprise" will not exist unless, from the outset, there is in place an accountable body or person responsible for the financial and operational oversight of the enterprise,[31] and a governing document. In the preamble to the Final Rule, CMS makes clear that it does not intend to "dictate or limit the appropriate legal structures" that could qualify as a value-based enterprise.[32] To illustrate, CMS notes that a value-based enterprise could consist of 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" or, alternatively, only "the two parties to a value-based arrangement with the written documentation recording the arrangement serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s)."[33]

B. Value-Based Activity

As noted above, a "value-based arrangement" must involve the provision of at least one "value-based activity"—i.e., (i) the "provision of an item or service," (ii) the "taking of an action," or (iii) the "refraining from taking an action," provided the activity is "reasonably designed" to achieve at least one value-based purpose of the value-based enterprise.

In the Final Rule, CMS declined to provide a list of items, services, actions or ways to refrain from taking an action that would qualify as value-based activities, due to a concern that "even a non-exhaustive list of common value-based activities could unintentionally limit innovation and inhibit robust participation in value-based health care delivery and payment systems."[34]

Further, in the 2019 Proposed Rule, CMS had proposed forbidding "[t]he making of a referral" as qualifying as a "value-based activity."[35] In the Final Rule, however, CMS changed its mind. First, the agency noted that the definition of a "referral" at 42 C.F.R. § 411.351 includes the establishment of a plan of care that includes the provision of DHS.[36] Second, CMS conceded that "referrals are an integral part of a value-based health care delivery and payment system, especially with respect to care planning" and, as such, excluding the making of a referral from the definition of ''value-based activity'' would "significantly limit the utility" of the new Value-Based Exceptions.[37]

30 *Id.* at 77662 (adding the definition of "value-based enterprise" to 42 C.F.R. § 411.351).

31 In the preamble to the Final Rule, CMS states that the accountable body or person could be, for example, a "governing board," a "committee of the governing board," a "corporate officer of the legal entity that is the value-based enterprise," or "the party to a value-based arrangement that is designated as being responsible for the financial and operational oversight of the arrangement between the parties." *Id.* at 77498.

32 *Id.*

33 *Id.*

34 *Id.* at 77500.

35 84 Fed. Reg. at 55840 (proposed 42 C.F.R. § 411.351, definition of "value-based activity," paragraph (2)).

36 85 Fed. Reg. at 77500.

37 *Id.* That said, as discussed in White Paper No. 1, CMS has revised the definition of "referral" at § 411.351 to affirm the agency's policy that, as a general matter, referrals are not items or services for which a physician may be compensated under the Stark Law. For an in-depth discussion of the definition of a "referral," *see* Dentons US, *White Paper No. 1, Rolling Up Our Sleeves: A Stark Law Refresher*, at 17.

As noted above, the definition of a value-based activity requires that the activity be "reasonably designed" to achieve at least one value-based purpose. In the preamble to the Final Rule, CMS states that this is a "fact-specific determination,"[38] and "[n]othing in our final regulations requires that the value-based purpose(s) must be achieved in order for a value-based arrangement to be protected" under a Value-Based Exception.[39]

That said, CMS cautions that parties to the value-based arrangement must have a "good faith belief" that the activity "will achieve or lead to the achievement of at least one value-based purpose of the value-based enterprise in which the parties to the arrangement are VBE participants."[40] Thus, for example, "if [and when] the parties are aware that the provision of the item or service, the taking of the action, or the refraining from taking the action will not further the value-based purpose(s) of the value-based enterprise," the activity "will cease to qualify as a value-based activity and the parties may need to amend or terminate their arrangement."[41]

This requirement of a "good faith" belief raises the question whether, for an activity to be "reasonably designed" to achieve a value-based purpose, the relevant parties have an affirmative duty to periodically monitor the effectiveness of the activity over time. On the one hand, only one of the three Value-Based Exceptions includes an explicit requirement that the parties monitor whether and how the continuation of a value-based activity is expected to further the value-based purpose(s) of the value-based enterprise. On the other hand, all three Value-Based Exceptions require at least one value-based activity, and CMS may take the position that if parties to a value-based arrangement never assess the effectiveness of that activity, they may—at least at some point in time, and at least under some circumstances—cease having a "good faith belief" that the activity at issue is "reasonably designed" to achieve a value-based purpose.

Indeed, in discussing value-based activities, CMS suggests that, depending on the value-based purpose, monitoring might be inherent in the activity being "reasonably designed." For example, "if the value-based purpose of the enterprise is to reduce the costs to or growth in expenditures of payors while improving or maintaining the quality of care for the target patient population, providing patient care services (the purported value-based activity) without monitoring their utilization would not appear to be reasonably designed to achieve that purpose."[42]

CMS also repeatedly emphasizes in the preamble of the Final Rule that, under the Stark Law, a DHS Entity has the burden of ensuring that its claims for DHS submitted to Medicare do not arise from a prohibited financial relationship,[43] and thus there is an "implicit ongoing obligation to monitor each of its financial relationships with a physician for compliance with an applicable exception."[44] To the extent a DHS Entity relies on one of the Value-Based Exceptions, this implicit obligation to monitor presumably would extend to monitoring compliance with the various components of the definition of a "value-based arrangement," including whether the underlying value-based activity is "reasonably designed" to achieve at least one value-based purpose of the value-based enterprise.

For all of these reasons, then, parties seeking to rely on any of the three Value-Based Exceptions should strongly consider monitoring their value-based activities on a regular basis as a way to mitigate against potential Stark Law non-compliance, even if such monitoring is not explicitly required under the Value-Based Exception upon which the parties are relying.

38 85 Fed. Reg. at 77500.

39 *Id.* (emphasis added).

40 *Id.*

41 *Id.*

42 *Id.* at 77497.

43 *Id.* at 77500.

44 *Id.* at 77520. *See also id.* at 77523.

C. Target Patient Population

As noted above, for the definition of a "value-based arrangement" to be met, the "value-based activity" must be for a "target patient population," which must be selected based on "legitimate and verifiable" criteria that are "set out in writing in advance of the commencement of the value-based arrangement" and "further the value-based enterprise's value-based purpose(s)."[45] In the preamble to the Final Rule, CMS states that "legitimate and verifiable" criteria could include, for example:

- "medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes),"
- "geographic characteristics (for example, all patients in an identified county or set of zip codes)," or
- "payor status (for example, all patients with a particular health insurance plan or payor)."[46]

While CMS provided these criteria as examples, CMS specifically declined to provide a comprehensive list of permissible and impermissible selection criteria, and stated that whether selection criteria are "legitimate and verifiable" will depend on the "facts and circumstances."[47]

With respect to assessing whether selection criteria are "legitimate," CMS expressed concerns about "cherry-picking" (i.e., selecting a targeted population "consisting of only lucrative or adherent patients") and "lemon-dropping" (i.e., "avoiding costly or noncompliant patients" in the target population).[48] Even with these parameters, however, it is unclear what makes selection criteria "legitimate." For example, if the criteria have the *effect* of including only lucrative or adherent patients, but there is no evidence that the parties chose the selection criteria for that *purpose*, are the criteria "legitimate"? What if the parties are motivated in part by financial considerations but that is not their *primary* purpose in choosing the selection criteria?

CMS equivocates somewhat on these questions in the preamble to the Final Rule. On the one hand, CMS states that "[i]f the criteria are selected *primarily* for their effect on the parties' profits or *purely* financial concerns, they will not be considered legitimate and, therefore, are impermissible."[49] Similarly, CMS states that "[c]hoosing a target patient population *solely* because it appears likely to reduce the costs to one of the parties to a value-based arrangement would be suspect."[50] These statements would appear to support the proposition that selection criteria are "legitimate" as long as financial considerations are not the sole or primary purpose of the arrangement.

Elsewhere in the preamble, however, CMS states that "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."[51] This statement appears to focus on the *effect* of the selection criteria, and not the parties' *motives*, and thus may suggest a broader range of selection criteria could be considered illegitimate by CMS.

45 *Id.* at 77661-62 (adding definitions to 42 C.F.R. § 411.351).

46 *Id.* at 77499.

47 *Id.* at 77504.

48 *Id.* at 77499.

49 *Id.* at 77504 (emphasis added).

50 *Id.* at 77505 (emphasis added).

51 *Id.*

III. Value-Based Exceptions

Assuming there is a "value-based arrangement" between a DHS Entity and a physician that meets the relevant definitions/requirements discussed above, that compensation arrangement may be protected under one of three new Value-Based Exceptions. As a threshold matter, all of these Exceptions share the following five requirements (collectively, the "Common Requirements"):

- "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."[52]
- "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 the remuneration *is* conditioned on referrals of patients who *are* part of the target patient population, the conditions of the Required Referrals Special Rule[53] must be met. That is, the referral requirement must be "set out in writing and signed by the parties," and must include certain safeguards (i.e., the referral requirement 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 [of HHS] upon request."[54]

In the preamble to the Final Rule, CMS notes that some of the "traditional" safeguards commonly found in Stark Law exceptions—such as the FMV and Volume/Value Standards—may be difficult to satisfy under a value-based health care delivery-and-payment system, and thus might have a "chilling effect" on the transition to value-based care.[55] For this reason, the three Value-Based Exceptions do not include a requirement that the remuneration paid under the value-based arrangement be (i) consistent with fair market value or (ii) not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician for the DHS Entity.[56] While the omission of these conditions certainly is helpful, the numerous remaining requirements in these Exceptions (discussed below)—together with the half-dozen interlocking definitions discussed above—may ultimately make these Exceptions less useful, as a practical matter, than CMS intends.

52 As illustrated by the body of case law analyzing the "inducement" element of the federal health care program anti-kickback statute, 42 U.S.C. § 1320a-7b(b), whether something is an "inducement" inherently involves an analysis of a party's state of mind. This appears to be another instance of CMS improperly injecting a normative, intent-based condition into an objective, strict liability statute. *See also* Dentons US, *White Paper No. 4, Key Standards (Part II): "Fair Market Value" and "Commercial Reasonableness" Standards, and Indirect Compensation Arrangements*, at 17.

53 The Required Referrals Special Rule is a special rule found at 42 C.F.R. § 411.354(d)(4) that protects arrangements pursuant to which a physician is required to refer patients to a particular provider as a condition of payment, as long as certain safeguards are implemented. For an in-depth discussion of the Required Referrals Special Rule, *see* Dentons US, *White Paper No. 3, Key Standards (Part I): The "Volume or Value" Standard*, at 11, 14, and 20.

54 85 Fed. Reg. at 77680-82 (adding new 42 C.F.R. § 411.357(aa)). CMS also considered, but ultimately rejected, including certain price transparency requirements as a Common Requirement for the Value-Based Exceptions. In the 2019 Proposed Rule, CMS stated that it was considering whether to require that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out-of-pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and the type of insurance they have. The agency's proposal to incorporate price transparency into the new Exceptions was based, in part, on a June 24, 2019, Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First, which executive order directs federal agencies (including CMS) to make meaningful price and quality information more broadly available so that consumers can make well-informed about their health care. 84 Fed. Reg. at 55788. In the Final Rule, CMS opted not to include any price transparency requirements in the new Value-Based Exceptions. 85 Fed. Reg. at 77529.

55 85 Fed. Reg. at 77506-07.

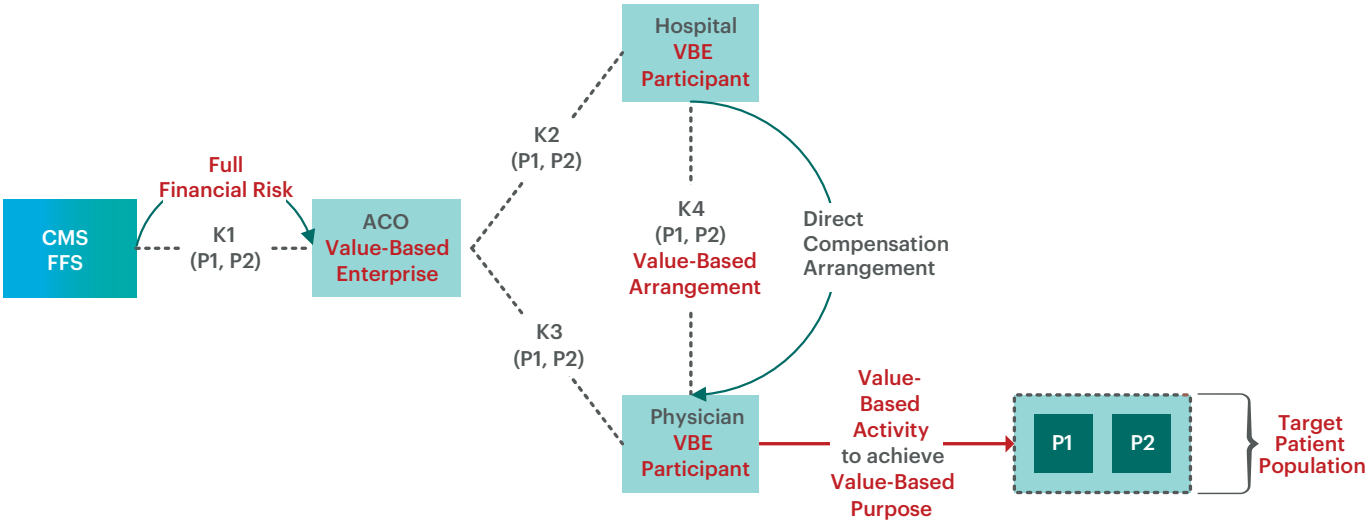
56 *Id.* at 77507.

A. Full Financial Risk Exception

Assuming each and every one of the (i) definitions and (ii) Common Requirements discussed above are met, the Full Financial Risk Exception will protect the remuneration paid under a value-based arrangement if a single condition is satisfied: "The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement."[57]

Note that as reflected in Diagram 2 below—which tracks the hypothetical in Diagram 1 above except that instead of an ACO, we have a Direct Contracting Entity (DCE)—the "full financial risk" test applies to *K1,* which is the arrangement between the value-based enterprise and CMS, and not to *K4,* which is the value-based arrangement between the two VBE participants (even though K4 is the arrangement actually being protected under the Full-Financial Risk Exception).

Diagram 2



In the preamble to the Final Rule, CMS explains that full financial risk inherently acts as a safeguard against overutilization and related federal health care program costs, since, "[w]hen a value-based enterprise is at full financial risk for the cost of all patient care services, the incentives to order unnecessary services or steer patients to higher-cost sites of service are diminished," and "the value-based enterprise itself is incented to monitor for appropriate utilization, referral patterns, and quality performance."[58]

Before unpacking the sole condition set forth above, it should be emphasized that although the Full Financial Risk Exception does not include an explicit writing requirement:

- To meet the definition of a "value-based arrangement," the selection criteria for the target population must be set out in writing in advance of the commencement of the value-based arrangement, and the value-based enterprise must have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

57 *Id.* at 77680-81 (adding new 42 C.F.R. § 411.357(aa)(1)).

58 *Id.* at 77511.

- Further, if the remuneration under the value-based arrangement is conditioned on referrals, the referral requirement must be set out in a writing signed by the parties, consistent with the Required Referrals Special Rule.[59]

1. "Full Financial Risk" Defined

Under the final regulations, "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."[60]

In the preamble to the Final Rule, CMS emphasizes that it is not "prescribing a specific manner for the assumption of full financial risk," noting that such risk could take the form of "capitation payments (that is, a predetermined payment per patient per month or other period of time) or global budget payment from a payor," provided the other elements of the definition of "full financial risk" are met.[61]

As noted, "full financial risk" requires, among other things, that the value-based enterprise be financially responsible, on a prospective basis, for the cost of *all* patient care items and services covered by the applicable payor for the target patient population. (Where the payor is Medicare, CMS notes, this requirement means that "the value-based enterprise, at a minimum, is responsible for all items and services covered under Parts A and B" that are furnished to the target patient population.[62]) In the preamble to the Final Rule, CMS rejected requests from commenters to permit coverage for smaller, defined sets of patient care items or services—similar to "episode-based" bundled payment models—on the ground that this would be counter to the "policy goals of moving more health care providers and practitioners into two-sided risk payment structures."[63] CMS also rejected requests from commenters to carve out certain "high-cost or specialty items or services" (e.g., organ transplants, pharmacy benefits) from the definition of "full financial risk."[64]

With respect to the requirement that the assumption of financial risk be on a "prospective basis," the final regulations define "prospective basis" to mean "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."[65] In the preamble to the Final Rule, CMS clarifies that this means "the contract between the value-based enterprise and the payor may not allow for any additional payment to compensate for costs incurred by the value-based enterprise in providing *specific* patient care items and services to the target patient population," and no VBE participant may "claim payment from the payor for such items or services."[66] That said, CMS notes that the definition of "full financial risk" does not prohibit an arrangement between a value-based enterprise and a payor from including "risk mitigation terms such as risk corridors, global risk adjustments, reinsurance, or stop-loss provisions to protect against significant and catastrophic losses," provided the risk mitigation terms do not effectively "shift material financial risk back to the payor."[67]

59 *Compare id.* at 77680-81 (adding new 42 C.F.R. § 411.357(aa)(1)) *with id.* at 77681-82 (adding new 42 C.F.R. § 411.357(aa)(2)-(3)). *See also id.* at 77515.

60 *Id.* at 77680-81 (adding new 42 C.F.R. § 411.357(aa)(1)(vii)) (emphasis added).

61 *Id.* at 77510.

62 *Id.*

63 *Id.* at 77512.

64 *Id.* at 77513.

65 *Id.* at 77680-81 (implementing 42 C.F.R. § 411.357(aa)(1)(vii)) (emphasis added).

66 *Id.* at 77511 (emphasis in original).

67 *Id.* at 77513.

2. Methods for Assuming "Full Financial Risk"

The Full Financial Risk Exception requires that full financial risk be assumed by the *value-based enterprise*. If the value-based enterprise is a separate legal entity (like the DCE in Diagram 2 above), the enterprise presumably would assume full financial risk through an agreement with the relevant payor. However, where the value-based enterprise is not a separate legal entity, the method for assuming full financial risk is less clear.

In the preamble to the Final Rule, CMS emphasizes that a value-based enterprise "need not be a separate legal entity with the power to contract on its own," and offers several examples of how a value-based enterprise could assume full financial risk through the VBE participants' contractual arrangements.[68] According to CMS:

- "[A]ll VBE participants in a value-based enterprise could each sign the contract for the value-based enterprise to assume full financial risk from a payor."[69]
- "[T]he VBE participants in a value-based enterprise could have contractual arrangements among themselves that assign risk jointly and severally."[70]
- "[S]imilar to physicians in an independent practice association (IPA), VBE participants could vest the authority to bind all VBE participants in the value-based enterprise with a designated person that contracts for the assumption of full financial risk on behalf of the value-based enterprise and its VBE participants."[71]

Arguably, the above examples could be read to suggest that where a value-based enterprise is not a separate legal entity, the VBE participants must be jointly and severally liable for the full financial risk at issue. However, in the preamble to the Final Rule, CMS suggests that it would be permissible for *each* VBE participant to assume full financial risk for a *subset* of items and services, provided that, in the aggregate, the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population is assumed.[72] To illustrate, CMS provides the following example:

> [A]ssume a value-based enterprise has as its VBE participants a hospital, skilled nursing facility, physicians, and a full complement of providers and suppliers that, together, provide all the patient care services covered by an applicable payor. . . . [T]he hospital could assume full financial risk for hospital services, the skilled nursing facility could assume full financial risk for skilled nursing services, the physicians could assume full financial risk for physician services, etc. As long as there are no services covered by the applicable payor for which the VBE participants have not assumed full financial risk, the value-based enterprise will be at full financial risk for purposes of [the Full Financial Risk Exception].[73]

3. Protection for Value-Based Arrangements During Pre-Risk Period

In recognition of the fact that assuming full financial risk can require extensive preparation, CMS included a "pre-risk period" in the final Full Financial Risk Exception.[74] Specifically, the Exception will protect remuneration paid under a value-based arrangement prior to the value-based enterprise assuming full financial risk, provided (among other things) the value-based enterprise is "contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement."[75]

68 *Id.* at 77510.

69 *Id.*

70 *Id.*

71 *Id.* at 77510-11.

72 *Id.* at 77514.

73 *Id.*

74 *Id.* at 77513.

75 *Id.* This represents a change from the Proposed Rule, in which the pre-risk period was proposed to be only six months. 84 Fed. Reg. at 55846 (proposed 42 C.F.R. § 411.357(aa)(1)(i)).

4. "Entire Duration" Requirement

The Full Financial Risk Exception protects remuneration paid under a value-based arrangement only if, during the "entire duration" of the value-based arrangement, the value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement).[76] In the preamble to the Final Rule, CMS states that due to this "entire duration" requirement, the Full Financial Risk Exception "will not protect arrangements that begin at some point during a period when the value-based enterprise has assumed full financial risk, but that continue into a timeframe when the safeguards intrinsic to full financial risk payment, such as the disincentive to overutilize or stint on medically necessary care, no longer exist."[77]

At least in theory, this "entire duration" requirement could have significant compliance implications. Ordinarily, if a particular requirement of a Stark Law exception is not met for a specific period of time, a physician's referrals of DHS (and the associated collections by the DHS Entity) will be tainted *only* for that period. Historically, for example, if a one-year personal services arrangement was not set out in writing for the first month of the arrangement, but all the other requirements of the Stark Law exception for personal service arrangements were met during the entire term of the agreement, only that one-month period would be considered out-of-compliance. CMS has not yet made it clear whether it will treat the "entire duration" requirement similarly. Assume, for example, the following:

- As of January 1, 2022, a DHS Entity and physician are participants in a value-based enterprise that has assumed full financial risk.
- On February 1, 2022, the DHS Entity and physician enter in a two-year value-based arrangement (running through January 31, 2024), pursuant to which there is an exchange of remuneration.
- Effective January 1, 2024, one month before the end of the parties value-based arrangement, the value-based enterprise modifies its contract with the applicable payor, such that the value-based enterprise is no longer at full financial risk.
- The DHS Entity and physician continue their value-based arrangement for the remainder of the month (i.e., through January 31, 2024).

Because the value-based enterprise was not at full financial risk during the last month of the value-based arrangement—i.e., during the "entire duration" of the arrangement—CMS could, at least conceivably, take the position that the entire two-year period of the value-based arrangement (i.e., from February 1, 2022, through January 31, 2024) does not qualify for protection under the Full Financial Risk Exception. In that case, unless the parties have structured their arrangement, from the inception, to comply with a different Stark Law exception (e.g., one of the other Value-Based Exceptions), all of the physician's referrals to the DHS Entity during this two-year period (and the DHS Entity's associated collections) would violate the Stark Law. Hopefully, CMS will confirm, sooner rather than later, that this is *not* the result the agency intends, as it would not be consistent with the position it has taken in analogous circumstances.

B. Meaningful Downside Financial Risk Exception

Assuming all of the definitions and Common Requirements discussed above are met, the Meaningful Downside Financial Risk Exception will protect remuneration paid under a value-based arrangement if the following three conditions are satisfied:

- "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."
- "A description of the nature and extent of the physician's downside financial risk is set forth in writing."
- "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."[78]

76 85 Fed. Reg. at 77680-81 (adding new 42 C.F.R. 411.357(aa)(1)).

77 *Id.* at 77511.

78 *Id.* at 77681 (adding new 42 C.F.R. § 411.357(aa)(2)).

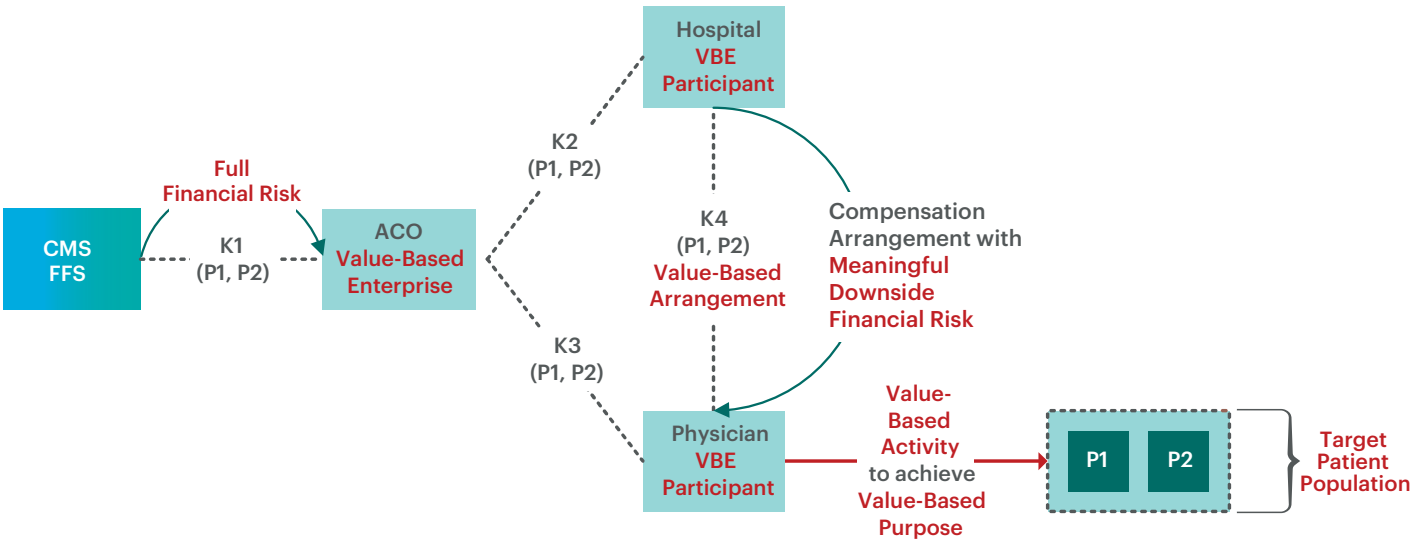
Before turning to each of these conditions, we note that like the Full Financial Risk Exception, the Meaningful Downside Financial Risk Exception is premised on the notion that the form of financial risk required under the Exception inherently will serve as a safeguard against overutilization and any associated increase in Medicare program costs. In the preamble to the Final Rule, CMS explains that "[f]inancial risk assumed directly by a physician will likely affect [their] practice and referral patterns in a way that curbs the influence of traditional FFS, volume-based payment," and that tying this financial risk to the achievement (or failure to achieve) value-based purpose(s) "incents the type of behavior-shaping necessary to transform our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces the costs to or growth in expenditures of payors."[79]

1. "Meaningful Downside Financial Risk" Defined

Under the Final Rule, "meaningful downside financial risk" means "the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement."[80] As a threshold matter, this definition differs from the definition of "full financial risk" in terms of both the relevant parties and the type of financial risk they are assuming.

- As reflected in Diagram 2 above, under the Full Financial Risk Exception, the financial risk is assumed by the *value-based enterprise* (under K1) and consists of the financial responsibility for the cost of all patient care items and services covered by the applicable payor for the target patient population.
- As reflected in Diagram 3 below, which tracks the hypothetical in Diagram 1 above, under the Meaningful Downside Financial Risk Exception, the financial risk is assumed by a *physician* (under K4), and the financial risk consists of the value of the remuneration received by the physician under the value-based arrangement.[81]

Diagram 3



79 *Id.* at 77515.

80 *Id.* at 77681 (adding new 42 C.F.R. § 411.357(aa)(2)(ix)). This represents a change from the Proposed Rule, in which the required percentage was a more demanding 25 percent. 84 Fed. Reg. at 55846-47 (proposed 42 C.F.R. § 411.357(aa)(2)(ix)(A)).

81 85 Fed. Reg. at 77516.

In the preamble to the Final Rule, CMS notes that the Meaningful Downside Financial Risk Exception, like the other Value-Based Exceptions, "does not limit the type of remuneration that may be provided."[82] Thus, the Meaningful Downside Financial Risk Exception requires the physician to be responsible to repay or forgo no less than 10 percent of the total "value" of the remuneration at issue, thereby ensuring that the Exception "account[s] for remuneration that may be provided in-kind, such as infrastructure or care coordination services."[83]

Also notable is the definition's inclusion of the word "forgo." Under the Proposed Rule, "meaningful downside financial risk" was defined, in pertinent part, to require the physician to be "responsible to pay the entity" the required minimum value of the remuneration received under the value-based arrangement.[84] In the preamble to the Final Rule, CMS explains that it changed this language to "repay or forgo" to make clear that the Meaningful Downside Financial Risk Exception is "not limited to value-based arrangements under which a physician is required to repay remuneration already received from the entity."[85] Rather, "[w]ithholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures" would all be "permissible options" for meeting this requirement, provided the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise.[86]

2. Writing and Set in Advance Requirements

The Meaningful Downside Financial Risk Exception includes two "traditional" safeguards not found in the Full Financial Risk Exception—namely, that (i) the "description of the nature and extent of the physician's downside financial risk is set forth in writing," and (ii) "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."[87]

- With respect to the set in advance requirement, in the preamble to the Final Rule, CMS clarifies that it is requiring merely that the *methodology* used to determine the amount of the remuneration be set in advance; the parties "need not know the ultimate *amount* of remuneration under the value-based arrangement."[88]
- With respect to the writing requirement, it bears repeating that, in addition to a description of the nature and extent of the physician's downside financial risk, to meet the definition of a "value-based arrangement," the selection criteria for the target population must be set out in writing, and the value-based enterprise must have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve the enterprise's value-based purpose(s). Further, if the remuneration under the value-based arrangement is conditioned on referrals, the referral requirement must be set out in a writing signed by the parties, consistent with the Required Referrals Special Rule.

C. Value-Based Arrangement Exception

Unlike the other two Value-Based Exceptions, and provided a host of conditions are satisfied, the Value-Based Arrangement Exception applies to remuneration paid under a value-based arrangement even if *no* financial risk is assumed by *any* party.[89] Like the other two Value-Based Exceptions, the Value-Based Arrangement Exception does not have FMV or Volume/Value Standards. Due to the Exception's lack of downside financial risk, however—and, therefore, its lack of inherent safeguards against overutilization—the Value-Based Arrangement Exception includes the most "traditional"—and other—safeguards.[90] Specifically, assuming all of the definitions and Common Requirements discussed above are met, the Value-Based Arrangement Exception will protect remuneration paid under a value-based arrangement if the following conditions are satisfied:

82 *Id.* at 77515.

83 *Id.*

84 84 Fed. Reg. at 55847.

85 85 Fed. Reg. at 77517.

86 *Id.*

87 *Id.* at 77681 (adding new 42 C.F.R. § 411.357(aa)(2)(ii)-(iii)). *See also id.* at 77515.

88 *Id.* at 77518 (emphasis in original).

89 *Id.* at 77681-82 (adding new 42 C.F.R. § 411.357(aa)(3)). *See also id.* at 77518.

90 *Id.* at 77519.

- The arrangement must be "set forth in writing and signed by the parties," and the "writing" must include a description of:
  - the "value-based activities to be undertaken under the arrangement,"
  - "[h]ow the value-based activities are expected to further the value-based purpose(s) of the alue-based enterprise,"
  - the "target patient population for the arrangement,"
  - the "type or nature of the remuneration,"
  - the "methodology used to determine the remuneration," and
  - the "outcome measures against which the recipient of the remuneration is assessed, if any."
- The "outcome measures" against "which the recipient of the remuneration is assessed, if any," must be "objective, measurable, and selected based on clinical evidence or credible medical support," and any changes to the measures must be "made prospectively and set forth in writing."
- "The methodology used to determine the amount of the remuneration" must be "set in advance of the undertaking of value-based activities for which the remuneration is paid."
- "The arrangement" must be "commercially reasonable."
- "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" must "monitor":
  - "[w]hether the parties have furnished the value-based activities required under the arrangement,"
  - "[w]hether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise," and
  - "[p]rogress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed."
- If this 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." Under such circumstances, however:
  - the "value-based activity" will be "deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise" for (i) "30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement," or (ii) "90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity"; and
  - "[i]f 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."

1. Writing Requirement

As reflected in the first condition above, the writing requirement in the Value-Based Arrangement Exception is *far* more extensive than anything to be found in the other two Value-Based Exceptions. Importantly, however, in the preamble to the Final Rule, CMS confirms that, as with the "writing" requirement in other Stark Law exceptions, the "writing" requirement under the Value-Based Arrangement Exception does not require a "single formal contract," but instead can met through any number of contemporaneous documents that *collectively* include all of the various descriptions/components listed above.[91] The governing document of the relevant value-based enterprise, for example, might be a document that would be included in such a collection.

2. Outcome Measure Requirements

The second condition above requires that the outcome measures against which the recipient of the remuneration is assessed "if any" must be (i) "objective, measurable, and selected based on clinical evidence or credible medical support," and (ii) set forth in a signed writing. Further, "any changes to the outcome measures against which the recipient of the remuneration will

91 *Id.* at 77522.

be assessed" must be "made prospectively and set forth in writing."[92] The Final Rule defines an "outcome measure" as a "benchmark" that "quantifies" either (i) "improvements in or maintenance of the quality of patient care" or (ii) "reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care."

As evidenced by the "if any" language in the regulations, and as explicitly recognized by CMS in the preamble to the Final Rule, "outcome measures may not be available for or applicable to certain value-based activities."[93] CMS notes, for example, that "the adoption of the same EHR [electronic health record] system or the completion of training on the EHR system are potential value-based activities that likely would not have an associated outcome measure."[94]

An open question is whether the failure to include outcome measures where they *could* be "available for or applicable to" a value-based activity would preclude the value-based arrangement from meeting the requirements of the Value-Based Arrangement Exception. CMS may take the position, for example, that for certain types of value-based arrangements, *other* requirements in the Exception (e.g., commercial reasonableness) or the definition of a "value-based arrangement" (e.g., that a value-based activity must be "reasonably designed" to achieve at least one value-based purpose of the value-based enterprise) *effectively* require the use of outcome measures. This might be one way to address what otherwise seems to create a disincentive for parties to a value-based arrangement to include outcome measures in their arrangement (a prospect that, at least under certain circumstances, would seem to be antithetical to the goal of improving quality of care and reducing expenditures).

3. Commercial Reasonableness Requirement

Interestingly, in discussing the three new Value-Based Exceptions in the preamble to the Final Rule, CMS explicitly rejected requests by commenters to exclude a Commercial Reasonableness Standard, noting that while it was not including the FMV and Volume/Value Standards, the agency was still "requiring that the compensation arrangement [be] commercially reasonable."[95] In the regulations themselves, however, a commercial reasonableness condition appears *only* in the Value-Based Arrangement Exception.[96]

Whether and when CMS will reconcile the apparent disconnect between the agency's statements in the preamble and the text of the Final Rule as it relates to the Full-Financial Risk and Meaningful Downside Financial Risk Exceptions remains to be seen. In the interim, however, since this same disconnect does *not* exist as it relates to the Value-Based Arrangement Exception—where the preamble and regulations align—parties wishing to protect their compensation arrangement under the Value-Based Arrangement Exception will need to be sure that "[t]he arrangement is commercially reasonable."

4. Monitoring Requirement

As discussed above, the definition of a "value-based activity"—specifically, the requirement that the activity must be "reasonably designed" to achieve at least one value-based purpose of the value-based enterprise—may, in and of itself, create an affirmative duty to monitor the effectiveness of a value-based activity, regardless of the Value-Based Exception at issue. Separate and apart from that, however, and unlike the other two Value-Based Exceptions, the Value-Based Arrangement Exception includes a specific (and quite detailed) set of monitoring requirements and associated grace periods.

92 *Id.* at 77681 (adding new 42 C.F.R. § 411.357(aa)(3)(ii)-(iii)).

93 *Id.* at 77524.

94 *Id.*

95 *Id.* at 77508-09.

96 *Id.* at 77681 (adding new 42 C.F.R. § 411.357(aa)(3)(vi)).

Although the Proposed Rule did not include a monitoring requirement in the Value-Based Arrangement Exception,[97] CMS did indicate it was considering such a requirement and sought comment on whether monitoring should be required at "specified intervals" and, if so, what those intervals should be.[98] As noted above, the condition that CMS ultimately adopted generally requires that on at least an annual basis, the value-based enterprise monitor:

- "[w]hether the parties have furnished the value-based activities required under the arrangement,"
- "[w]hether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise," and
- "progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed."[99]

Recall that for the definition of a "value-based activity" to be met, the activity must be "reasonably designed" to achieve at least one value-based purpose of the value-based enterprise.[100] Because the Value-Based Arrangement Exception requires extensive monitoring, parties may learn that a particular value-based activity has not been effective and, therefore, can no longer be expected to further a value-based purpose of the value-based enterprise. If and when this happens, does the arrangement immediately cease to qualify for protection under the Value-Based Arrangement Exception?

According to CMS, the answer is "no." Under the Final Rule, "[i]f 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 either (i) terminate the *value-based arrangement* within 30 consecutive calendar days after completion of the monitoring, or (ii) terminate the ineffective *value-based activity* within 90 consecutive calendar days after completion of the monitoring.[101] The regulations further provide that, as long as either of these termination provisions are satisfied during the 30- or 90-day period in question, the value-based arrangement will be deemed to comply with the "reasonably designed" requirement during that period.[102]

In the preamble to the Final Rule, CMS explains that this deeming provision is designed to provide a "grace period," such that the discovery that a value-based activity is not effective would not *immediately* cause the activity to fail the "reasonably designed" requirement and, thus, *immediately* fall out of compliance with the definition of a "value-based arrangement."[103] Absent this deeming provision, the period between (i) the discovery of an ineffective value-based activity and (ii) the effective termination of the activity might not be protected by the Value-Based Arrangement Exception (and thus could lead to violations the Stark Law's referral and billing prohibitions).[104] Notably, this deeming provision is not included in the regulatory text of the other two Value-Based Exceptions, which raises the question whether a similar grace period is available under those Exceptions where monitoring reveals that a value-based activity is ineffective.

Finally, and similarly, the Value-Based Arrangement Exception also provides that "[i]f 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.[105]

97 *See* 84 Fed. Reg. at 55847 (proposing new 42 C.F.R. § 411.357(aa)(3)).

98 *Id.* at 55785.

99 85 Fed. Reg. at 77861 (adding new 42 C.F.R. § 411.357(aa)(3)(vii)).

100 42 C.F.R. § 411.351 (defining "value-based activity").

101 85 Fed. Reg. at 77861 (adding new 42 C.F.R. § 411.357(aa)(3)(vii)).

102 *Id.* (adding new 42 C.F.R. § 411.357(aa)(3)(vii)).

103 *Id.* at 77520-21.

104 *Id.*

105 *Id.* at 77861 (adding new 42 C.F.R. § 411.357(aa)(3)(vii)) (emphasis added).

IV. Indirect Compensation Arrangements

In the Final Rule, CMS also finalized a new "special rule" making the Value-Based Exceptions available to protect certain indirect compensation arrangements.[106] As previously noted, Stark Law exceptions fall into two categories: exceptions that apply to certain types of services,[107] and exceptions that apply to certain types of financial relationships.[108] The exceptions that apply to financial relationships in the form of direct and indirect compensation arrangements (ICAs) are found at 42 C.F.R. § 411.357.

Prior to the Final Rule, only two exceptions in § 411.357 applied to ICAs: the exception for indirect compensation arrangements at 42 C.F.R. § 411.357(p) (ICA Exception), and the Risk-Sharing Arrangements Exception at 42 C.F.R. § 411.357(n).[109] Recognizing that these exceptions might not protect many value-based arrangements—the ICA Exception, for example, includes FMV and Volume/Value Standards—CMS adopted a new "special rule" confirming that the new Value-Based Exceptions are "applicable" to an ICA if, in the chain of financial relationships between the DHS Entity and the referring physician, the physician (or their physician organization) is a "direct party" to a "value-based arrangement."[110] We will refer to this as the "ICA Exception Special Rule."

In the preamble to the Final Rule, CMS clarifies that this "direct party" requirement means that, in the chain of financial relationships, "the link closest to the physician may not be an ownership interest"; rather, "it must be a compensation arrangement that meets the definition of value-based arrangement."[111] Thus, if there is a chain of financial relationships that gives rise to an ICA and the link in the chain closest to the physician is an ownership interest, the Value-Base Exceptions are not available to protect the ICA.

Unfortunately, while CMS clarifies that the Value-Based Exceptions can, in theory, be applied to certain types of ICAs, the regulations do not explain how, in practice, to apply these Exceptions. The Value-Based Exceptions, by their terms, apply only to remuneration paid "under a value-based arrangement," but the value-based arrangement is only a *subset* of the financial relationships (and corresponding exchanges of remuneration) that give rise to the ICA between a DHS Entity and the physician.

In the preamble to the Final Rule, CMS states that in order to determine whether the ICA between the physician and DHS Entity is protected, the parties need to "determine whether the value-based arrangement to which the physician [or physician organization] is a direct party satisfies all the requirements" of a Value-Based Exception.[112] Thus, it would appear that the ICA will be deemed protected if the value-based arrangement *within* the ICA meets the requirements of a Value-Based Exception.

In the preamble to the Final Rule, CMS seeks to clarify the application of the new ICA Exception Special Rule through the following example:

106 *Id.* at 77666 (adding new 42 C.F.R. § 411.354(c)(4)).

107 42 C.F.R. § 411.355.

108 *Id.* § 411.356 (exceptions applicable to ownership interests) and § 411.357 (exceptions applicable to compensation arrangements).

109 In the Proposed Rule, CMS mistakenly stated that, other than the ICA Exception, there was "no other exception in § 411.357" that was applicable to ICAs. 84 Fed. Reg. at 55786. In the Final Rule, CMS confirmed that the Risk-Sharing Arrangements Exception also is applicable to an ICA, provided that the DHS Entity therein is a MCO or IPA. 85 Fed. Reg. at 77527-28.

110 85 Fed. Reg. at 77666 (adding new 42 C.F.R. § 411.354(c)(4)).

111 *Id.* at 77526.

112 *Id.* at 77527.

- Assume that there is the following chain of relationships between a hospital and a physician: "Hospital—(owned by)—parent organization—(owns)—physician practice—(employs)—physician."[113]
- Assume also that "the compensation paid to the physician under her employment arrangement varies with the volume or value of her referrals to the hospital because she is paid a bonus for each referral for designated health services furnished by the hospital, provided that she adheres to redesigned care protocols intended to further one or more value-based purposes."[114]
- Finally, assume that "the hospital has actual knowledge that the physician receives aggregate compensation that varies with the volume or value of her referrals to the hospital."[115]

According to CMS, the above example would meet the definition of an ICA. The agency then goes on to state, somewhat confusingly, that if the compensation arrangement "between the physician practice and the physician qualifies as a value-based arrangement," the Value-Based Exceptions "would be available to protect *the value-based arrangement (that is, the indirect compensation arrangement) between the hospital and the physician*."[116] This is confusing, of course, because while the *ICA* may be between the *hospital* and the physician, the *value-based arrangement* is clearly between the *physician practice* and the physician.

In all events, what CMS *appears* to be saying—and hopefully will clarify in a future rulemaking—is that if (i) there is an ICA between a physician and a DHS Entity, (ii) the link in the chain of financial relationships closest to the physician is a compensation arrangement, (iii) this compensation arrangement meets the definition of a "value-based arrangement," and (iv) the value-based arrangement meets the requirements of a Value-Based Exception, then the ICA between the DHS Entity and the physician will be protected.

113 *Id.* at 77526.

114 *Id.*

115 *Id.*

116 *Id.* (emphasis added).

V. Conclusion

On the one hand, there is a certain elegance and efficiency to the cascading, interlocking definitions, Common Requirements and exception-specific conditions that, collectively, constitute CMS's new Value-Based Exceptions. Further, it may be that that these Exceptions will, in fact, serve to protect substantially more risk-sharing, gainsharing and other types of value-based arrangements than the patchwork of model-specific fraud and abuse waivers and Stark Law exceptions that existed prior the Final Rule. In particular, this may be the case where the compensation arrangement at issue—i.e., the compensation arrangement between the DHS Entity and physician—is downstream of a risk-sharing arrangement between a VBE and a commercial insurer.

On the other hand, it is not clear how many arrangements will in fact qualify for the Full Financial Risk Exception; and although elegant and efficient, after accounting for all of their overlapping and individual component parts, the Meaningful Downside Financial Risk and Value-Based Arrangement Exception are quite complicated. Further, as reflected above—and to be expected with any new exceptions meant to address a rapidly evolving reimbursement landscape—a number of important questions remain unanswered, and many more will arise over time.

In sum, while the three new Value-Based Exceptions represent an admirable attempt by CMS to encourage the transition to value-based care, it is obvious from the complexity of the Exceptions that CMS struggled—and likely will continue to struggle—to find just the right balance of safeguards for arrangements that exist somewhere between fully fee-for-service and fully managed care.

Stark Law Overhaul Series: An In-Depth Review of CMS's Final Rule

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Date	Time	Topic*
March 18	12:30-1:45 pm ET	Rolling Up Our Sleeves: A Stark Law Refresher and Clearing the Brush
April 1	12:30-1:45 pm ET	Separating the Wheat From the Chaff: Providing Greater Flexibility for Technical and Low-Dollar Violations
April 15	12:30-1:45 pm ET	Key Standards (Part I): Distinguishing and Defining the 'Volume or Value' Requirement
April 29	12:30-1:45 pm ET	Key Standards (Part II): 'Fair Market Value' and 'Commercial Reasonableness' Standards, and Indirect Compensation Arrangements
May 13	12:30-1:45 pm ET	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	12:30-1:45 pm ET	What's Past is Prologue: Technology Subsidies Part Deux
June 10	12:30-1:45 pm ET	The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide

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Key Contacts

The Dentons lawyers presenting this series, including Gadi Weinreich, Chris Janney and Ramy Fayed, are widely recognized as Stark Law thought leaders. They and other members of Dentons' US Health Care practice group have assisted countless clients in navigating this unforgiving law since its enactment in 1989, lectured extensively on its challenges and pitfalls, and authored multiple articles as well as two editions of *The Stark Law: A User's Guide to Achieving Compliance*.

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