# CMS, OIG finalize Stark and AKS overhaul – paving the way for value-based care

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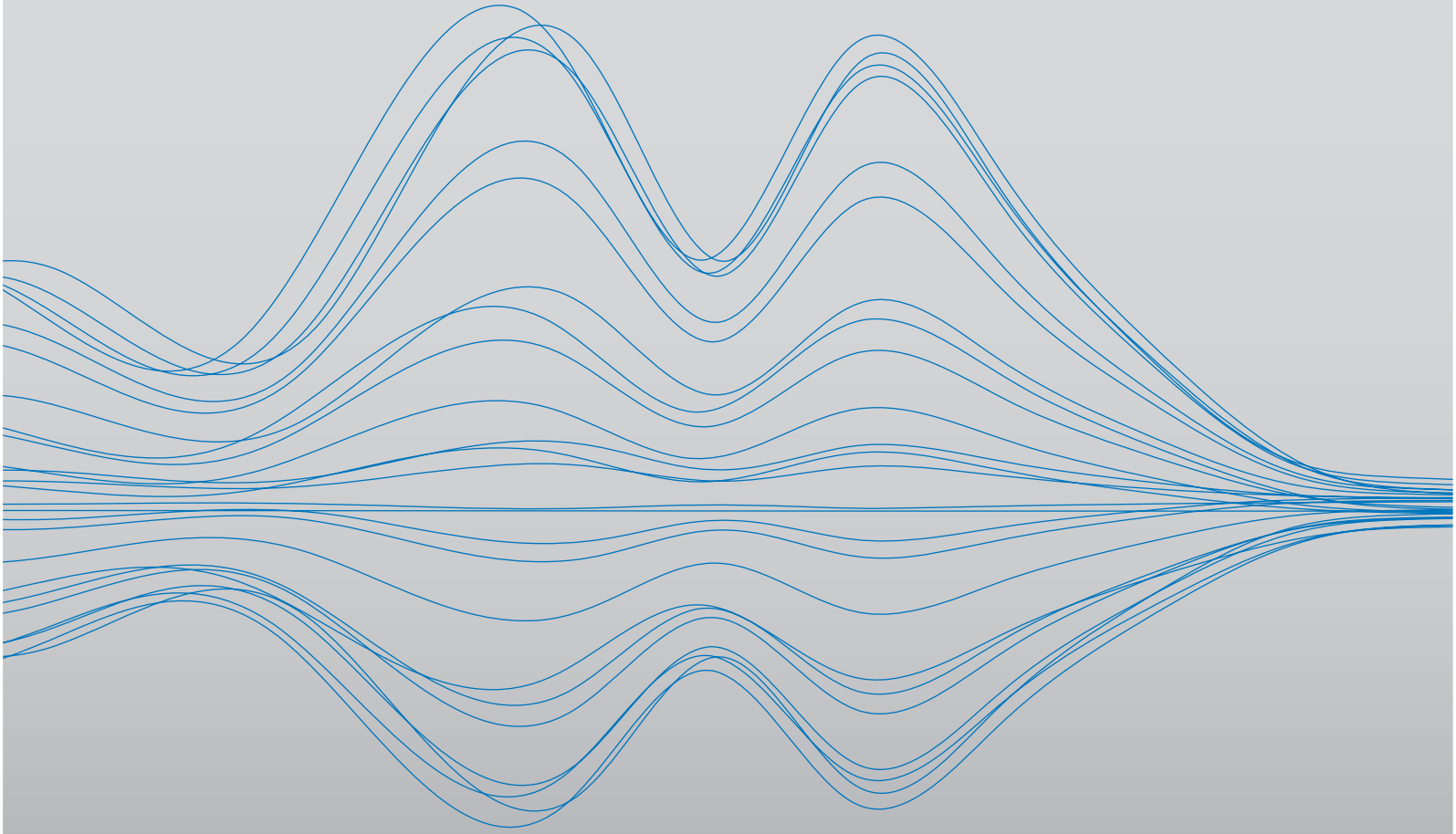

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HEALTHCARE

On Friday afternoon, November 20, 2020, the US Department of Health and Human Services (HHS) finalized two sweeping, interrelated rule change packages as part of the Department's "Regulatory Sprint to Coordinated Care." The Anti-Kickback Statute (AKS) and Medicare physician self-referral law (Stark Law) place different constraints on financial arrangements with sources of federal health care program (FHCP) referrals, but both statutes date back to the days when the vast majority of government health care funding flowed on a fee-for-service basis. As members of DLA Piper's health care regulatory team explained in detail last year when these rules were first proposed, the HHS Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) are attempting to grapple with the challenges of applying these statutory principles to an industry that has shifted dramatically over the years to focus more and more on value-based payment models. The agencies also took the opportunity to propose fixes to longstanding industry concerns regarding difficulties in interpreting and complying with the extensive and highly technical AKS and Stark Law regulations. In this alert – which is meant to be read in tandem with our complimentary analysis of the proposed rules – we highlight some of the most important ways in which HHS followed through on its ideas from last year or went in new directions based on public comments.

The regulations under these Final Rules will become effective January 19, 2021 unless otherwise indicated. As of the date of this alert, the final official text of the new rule announcements has not yet appeared in the Federal Register, so we have relied on the preliminary versions that the agencies have made available for public inspection. For purposes of this alert, citations in the form "CMS-F-[number]" refer to page numbers in the public inspection version of the new Stark Law final rule from CMS, and citations in the form "OIG-F-[number]" refer to the public inspection version of the new AKS final rule from OIG. Citations in this alert to the "SSA" refer to the Social Security Act, which contains the Stark Law and AKS. In addition, although the Stark Law and the AKS have each been the subject of numerous rounds of notice-and-comment rulemaking, mentions of "the proposed rule" in this alert generally refer to the October 17, 2019 Regulatory Sprint Rules from CMS, 84 FR 55766, or from OIG, 84 FR 55694, depending on the context.

## I. Expanding and Harmonizing CMS and OIG's Rules for Cybersecurity Technology, Electronic Health Records, and Related Services

OIG and CMS coordinated closely on proposed rules in these areas; we address their final rules together here.

*Safe Harbor and Stark Exception for Cybersecurity Technology and Related Services*

The OIG and CMS both finalized their companion regulations to protect donation of cybersecurity technology in an effort to foster beneficial cybersecurity arrangements to improve the cybersecurity of the healthcare industry – with modifications.

With respect to the AKS Safe Harbor, the OIG specifically chose not to finalize its alternative proposal to require parties to conduct a risk assessment prior to donating hardware. The proposed 42 C.F.R. §1001.952(JJ) included a limitation applying the cybersecurity safe harbor to technology and services necessary and used predominantly to implement, maintain, or reestablish cybersecurity. In the proposed 42 C.F.R. §1001.952(JJ), that limitation was located at 42 C.F.R. §1001.952(JJ)(1), but in the final rule it is included in the introductory paragraph to 42 C.F.R. §1001.952(JJ). This change in numbering will carry across the entire text of the final 42 C.F.R. §1001.952(JJ). After considering comments, the OIG decided to finalize 42 C.F.R. §1001.952(JJ) without any limitations on the type of individual or entity donating cybersecurity technology and services. OIG also considered whether additional safeguards should be implemented to protect recipients but chose to finalize 42 C.F.R. §1001.952(JJ) without modification, protecting all recipients without limitation and without additional safeguards.

OIG proposed to define "cybersecurity" broadly as the process of protecting information by preventing,

detecting, and responding to cyberattacks. This definition was derived from the NIST definition for "Framework for Improving Critical Infrastructure Cybersecurity." *See* NIST CSF, Version 1.1 (Apr. 2018) (collectively, the "NIST Framework"). OIG is finalizing the definition broadly and derived it from the NIST Framework, with certain clarifications at 42 C.F.R. §1001.952(jj)(5)(i). OIG proposed defining "technology" as any software or other type of information technology, other than hardware. OIG is finalizing their proposed definition, with modification at 42 C.F.R. §1001.952(jj)(5(ii). The modified final rule clarifies that multifunctional hardware falls outside the scope because it would not primarily be used for cybersecurity.

OIG originally included an alternate proposal allowing parties to donate hardware if such hardware is reasonably necessary based on a risk assessment by the donor and recipient. OIG has chosen not to finalize this alternate proposal as it did not want to create additional risk assessment requirements that may discourage donations.

OIG has altered the scope of the protected technology and services. In the proposed 42 C.F.R. §1001.952(jj), OIG proposed to protect a broad range of technology and services but excluded hardware. OIG is offering clarifications in the Final Rule stating that it covers a broad range of technology and services with the restrictions that the donations are constrained by the opening paragraph in 42 C.F.R. §1001.952(jj), which requires that the donation is necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. This constraint eliminates most multi-functional technology but does not specifically eliminate all hardware.

The OIG did not include a monetary value limit in their proposed 42 C.F.R. §1001.952(jj) but did solicit comments on the issue. After reviewing comments, the OIG determined it would not finalize any condition imposing monetary limits on donations. Similarly, the OIG solicited comments on whether to include a deeming provision to allow donors or recipients to demonstrate the donation satisfies 42 C.F.R. §1001.952(jj)(i). The OIG decided not to finalize any deeming provision. Nor did OIG finalize a contribution requirement for the recipient, even when hardware is included in the donation. The OIG also chose not to finalize any specific text related to patching and updates as it views these categories as generally included so long as they satisfy the other conditions of 42 C.F.R. §1001.952(jj).

The OIG is finalizing, without modification, their proposed volume and value conditions at 42 C.F.R. §1001.952(jj)(1) and (2) that eliminate the safe harbor if donors directly take into account the volume or value of referrals or other business generated between the parties. Similarly, the OIG proposed at 42 C.F.R. §1001.952(jj)(5) that the donor not shift the costs of the donated technology or services to any Federal healthcare program. The OIG is finalizing that requirement without modification at 42 C.F.R. §1001.952(jj)(4).

The OIG proposed at 42 C.F.R. §1001.952(jj)(4) a requirement for the donor and recipient to have a signed written agreement describing the technology and services provided. It is finalizing that requirement at 42 C.F.R. §1001.952(jj)(4) with modification including that it need not be a single document and that the signed document(s) must include a general description of the technology and services provided.

With respect to the Stark Law Exception, CMS modified its Final Rule to reorganize the text, more clearly establishing the requirements of necessity and predominant use as threshold elements of the exception. CMS-F-456-57. This modification maintains consistency with the text of the EHR exception at 42 C.F.R. §411.411.357(w)(1). Both CMS and the OIG deleted the phrase "certain types of" before "cybersecurity technology and services" in an effort to avoid any ambiguity in the provision's scope. CMS-F-456; OIG-F-652.

In response to comments about the bundling of hardware, software, and services into cybersecurity technology, CMS deleted the exclusion of hardware from its definition of "technology" in the Final Rule. 42 C.F.R. §411.411.357(bb)(2). CMS acknowledged that certain hardware, such as encrypted servers and drives, may be an integral component of a cybersecurity program, but cautioned that the exception applies only if that hardware is necessary

and used predominantly to implement, maintain, or reestablish cybersecurity. CMS-F-476.

There are variations between the CMS and the OIG regulations that reflect differences in the enabling statutes. CMS-F-484. For example, the OIG rule requires that the cybersecurity technology be "effective." CMS declined to take this approach because the Stark Law is a strict liability statute, and CMS was concerned that this qualification could have a chilling effect on otherwise beneficial cybersecurity donations. CMS-F-466-67.

Unlike the OIG Safe Harbor, the CMS Stark Law Exception does not require a signature or description of services in the written documentation of the arrangement. The Stark Law Exception does not contain cost-shifting prohibitions, and it does not define the term "cybersecurity." Finally, whereas the OIG Safe Harbor applies the recipient condition to the physician and any affiliated individuals or entities, the Stark Law Exception applies more narrowly to physicians, their employees and staff members.

*Updated Safe Harbor and Stark Exception for Electronic Health Record Items and Services*

The OIG and CMS both proposed changes to their provisions in this area. The OIG proposed the following changes to the EHR safe harbor at 42 C.F.R. §1001.952(y), which protects certain arrangements involving donation of interoperable EHR software or information technology and training: *(1)* Amending the safe harbor to expand the safe harbor's potential protection of cybersecurity software donations; *(2)* Proposed updating the condition at 42 C.F.R. §1001.952(y)(2) to specify that for software to be deemed interoperable, it must be certified by a certifying body on the date it is donated; *(3)* Proposed modifying 42 C.F.R. §1001.952(y)(3) to align with the proposed information blocking definition and related exceptions in the Office of the National Coordinator for Health Information Technology ("ONC"), HHS Notice of Proposed Rulemaking "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program"; *(4)* Proposed eliminating (i) the condition at 42 C.F.R. §1001.952(y)(7) that prohibits the donation of equivalent items or services to allow donations of replacement technology and (ii) the sunset provision at 42 C.F.R. §1001.952(y)(13) to make the safe harbor permanent; *(5)* OIG also proposed to revise the definitions of "interoperable" and "electronic health record" and add a definition of "cybersecurity" as well as other definitions contained in the proposed 42 C.F.R. §1001.952(y)(14).

OIG is finalizing the proposed changes, with certain modifications, to 42 C.F.R. §1001.952(y). OIG is finalizing its proposal to eliminate the sunset provision and the section that prohibits the donation of equivalent EHR items and services. It is also finalizing the language protecting cybersecurity software and services and the definition of "cybersecurity." OIG also finalized its revision to 42 C.F.R. §1001.952(y)(2) to update the deeming provision with a minor clarification. The Final Rule also revises 42 C.F.R. §1001.952(y)(1)(i)(A) to expand the scope of protected donors to certain entities such as accountable care organizations and health systems. It also clarifies that the EHR safe harbor specifically excludes hardware.

However, neither the OIG nor CMS finalized the information blocking provisions of 42 C.F.R. §1001.952(y)(3) and 42 C.F.R. §411.411.357(y)(3) as originally proposed, determining that those provisions would now be duplicative of the existing information blocking rules. Whereas the existing provisions of 42 C.F.R. §1001.952(y)(3) will remain unchanged, CMS withdrew its proposal entirely, as well as its existing rule language, and marked subsection (3) as "Reserved."

Moreover, CMS agreed with commenters who complained that the EHR Stark proposed rule created risk exposure for donors and vendors who may have no knowledge of or control over actions taken by the other. CMS-F-386-87.

Both Final Rules withdrew the proposed changes to the definition of "electronic health record" with identical language. The OIG recodified its existing definition in new subparagraph 42 C.F.R. §1001.952(y)(14)(iv), and CMS withdrew the proposed changes to its cross-referenced definition in 42 C.F.R. §411.411.351. Although CMS originally intended to create consistency with ONC rules,

commenters complained that the proposed ONC definitions were too broad and CMS conceded that the proposed revisions could inadvertently complicate the subsection (w) exception. After the comment period for this regulation closed, ONC finalized its definition, which differed substantively from its proposed rule. Because CMS was concerned about preserving the original intent of this Stark exception and avoiding confusion, it retained the existing definition. CMS-F-396-97.

CMS also adopted identical language in 42 C.F.R. §411.411.351 to redefine the term "interoperable" in accordance with the OIG revisions. The new definition in the Final Rule omits the information blocking prohibition of the EHR Stark proposed rule. Moreover, CMS clarified that it deleted the phrase "without special effort on the part of the user" from the Final Rule because that is a condition of certification by the ONC. CMS reiterated that ONC certification is not required for compliance with this exception and deleted the language in an effort to avoid any inference otherwise. CMS-F-400.

The CMS Final Rule added a provision affording some relief for physician contributions toward donations occurring after the initial gift or donations of replacement items or services. Rather than paying 15 percent of the donor's cost prior to receipt, as is required for the initial donation, physicians must pay the 15 percent contribution toward these subsequent donations "at reasonable intervals." 42 C.F.R. §411.411.357(w)(4)(ii). CMS advises that physicians who are unable to contribute 15 percent toward the cost of these donations might still receive donated items or services in accordance with the value-based exception at 42 C.F.R. §411.411.357(aa) or the standalone cybersecurity exception at 42 C.F.R. §411.411.357(bb). CMS-F-391,404-05.

## II. Modernizing and Clarifying the Physician Self-Referral Regulations – Stark Final Rule

The Stark Law is a strict liability statute that prohibits referrals from a physician to an entity for certain Medicare-covered "designated health services" (DHS), if the entity and the physician have a financial relationship – unless the relationship or services fully satisfy one or more of dozens of highly technical exceptions. The revisions to the Stark Law under this Final Rule seek to remove regulatory barriers that impede care coordination, clarify and streamline terminology, and establish new exceptions for non-abusive arrangements. CMS-F-14.

*Untangling Key Concepts: FMV, Commercial Reasonableness, and Volume or Value (various provisions)*

In the new Stark Final Rule, CMS followed through on its proposal to create what it calls objective, bright-line rules defining these concepts, while emphasizing that its new rules have no bearing on OIG's interpretation of the same or similar terms in AKS and CMP rules. CMS-F-125.

For *commercial reasonableness*, CMS reiterated that arrangements need not be designed to achieve a profit, but could address other legitimate goals such as "community need, timely access to health care services, fulfillment of licensure or regulatory obligations..., the provision of charity care, and the improvement of quality and health outcomes." CMS-F-127. However, CMS declined to say that profitability is categorically irrelevant to a determination of commercial reasonableness. CMS-F-139. CMS codified the following at 42 C.F.R. §411.351: "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty." Notably, CMS confirmed that if a Stark exception requires commercial reasonableness even in the absence of referrals, this means referrals for Medicare-covered DHS. CMS-F-138. An arrangement could theoretically satisfy one of these exceptions even if its reasonableness depends in part on referrals for services other than DHS (though such an arrangement might have difficulty satisfying the "volume or value" standard that appears in many exceptions).

The elements of various exceptions that prohibit taking into account *volume or value of referrals* and *other business generated* came up as a major source of confusion and perceived risk leading up to the Proposed Rule. *See* CMS-F-144. The new Stark Final Rule follows through on CMS's proposal to establish

that compensation varies with the volume or value of referrals or other business if and only if the compensation is determined using a formula where referrals are a variable and physician compensation correlates directly with that variable. *See* new 42 C.F.R. §411.357(d)(5) and (6). One significant change from the Proposed Rule is that CMS clarified that the new volume or value special rules "do not apply for purposes of applying the exceptions at §411.357(m), (s), (u), (v), and (w), or ... (bb)" (the existing exceptions for medical staff incidental benefits, professional courtesy, community-wide health information systems, electronic prescribing items and services, and electronic health records items and services, or the new exception for cybersecurity, respectively). CMS-F-147.

CMS did *not* finalize a proposal to define by regulation when compensation that is fixed over the term of an arrangement would also be deemed to take into account the volume or value of referrals or other business generated; instead, the CMS modified its rule at 42 C.F.R. §411.354(d)(4) to note that "neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the volume or value of... referrals." *See* CMS-F-153.

CMS reiterated its rejection of the position taken by the Fourth Circuit in the *Tuomey Healthcare* case that compensation may vary with referrals where a hospital pays a physician for personally performed services, but those services correlate directly with opportunities for the hospital to bill for technical components of the same procedures. CMS declined to write this clarification into the "volume or value" special rule but did insert a clarification into the definition of an "indirect compensation arrangement" at 42 C.F.R. §411.354(c)(2). CMS-F-154-55.

*Volume or Value and Indirect Compensation*

Until now, a wide range of "indirect compensation arrangements" involving unbroken chains of financial arrangements connecting DHS entities with referring physicians were considered "financial arrangements." *See* prior version of 42 C.F.R. §411.354(c)(2). But CMS had also created an exception for a large subset of those indirect compensation arrangements. *See* prior version of 42 C.F.R. §411.357(p). In the new Final Rule, CMS purports to simplify this framework: with certain exceptions, no indirect compensation arrangement exists at all unless, among other conditions, the physician receives compensation that (i) correlates with the volume or value of DHS referrals or other business generated, or (ii) is not fair market value. *See* new 42 C.F.R. §411.354(c)(2). One significant practical consequence is that arrangements that previously relied on an exception at 42 C.F.R. §411.375(p) but are now completely carved out of the Stark Law at the definitional stage will no longer need to meet the writing requirement in that exception. CMS-F-175-77.

*Patient Choice and Other Safeguards*

CMS has finalized its proposal to broaden the applicability of certain protections for patient choice, payor network coverage, and clinical judgment when physicians are required to direct referrals to a particular target (typically their employer). CMS-F-181. "The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier" without violating the new version of 42 C.F.R. §411.354(d)(4). CMS-F-183. This is in place of a proposed special rule that would have applied the Stark Law to arrangements where a fixed rate of compensation is directly correlated to prior referrals. Specific permutations such as termination for failure to hit referral targets or tying bonus pool allocations to directed referral percentages are addressed in the new Final Rule. *See* CMS-F-187-89.

*Fair Market Value (FMV)*

The Final Rule rolls back the portion of the definition of FMV that prohibits taking into account the volume or value of referrals or other business generated, in recognition that these are separate statutory requirements and should be addressed separately in the regulations. *See* new 42 C.F.R. §411.351; CMS-F-197. FMV is defined in both statute and regulation by reference to the concept of "general market value," and CMS proposed a definition for the latter in 2019. However, in light of various comments

regarding valuation methods, CMS departed from the proposed definition of general market value in favor of a set of context-specific definitions. *See* CMS-F-202. Notably, although the Proposed Rule considered dropping the requirement that comparables used to calculate general market value exclude entities and physicians in a position to refer or generate business for each other, the Final Rule keeps that requirement in place. CMS-F-206. The Final Rule also walks back some commentary in the Proposed Rule about the term "market value," which commenters stated CMS had confused with the valuation industry's concept of "investment value." CMS-F-208.

*Group Practices and Value-Based Care*

Certain Stark Law exceptions are only available in the context of a "group practice" that adheres to limitations on physician compensation and other requirements. The Final Rule discusses how the updated conceptions of FMV, volume or value, and commercial reasonableness fit into the group practice framework, and it finalizes a provision that allows certain profit distributions attributable to specific physicians' participation in value-based arrangements (even if such payments take into account the volume or value of DHS referrals). *See* CMS-F-218-21; new 42 C.F.R. §411.357(aa); amended 42 C.F.R. §411.352(i). The final rule also contains certain "clarifying revisions" related to group practices but the substance is largely as proposed. *See* CMS-F-223-25.

Notably, while group practices have long been able to pay profit distributions based on aggregated DHS from subgroups of five or more physicians each, the Final Rule clarifies that, beginning in 2022, any such subgroup must aggregate **all** of its DHS profits for distribution – the services subject to this treatment cannot, for example, be limited to diagnostic testing if the same physicians also refer other DHS to the group. *See* CMS-F-225-26.

*Decoupling AKS and Stark*

Many Stark Law regulatory exceptions have long required that an arrangement not violate the AKS. CMS finalized its proposal to strip this requirement out, except that CMS decided to keep in place an AKS compliance requirement as part of the Stark exception for certain "fair market value compensation" arrangements. *See* CMS-F-244-52; new 42 C.F.R. §411.357(l)(5).

*"Referral" Definition Updates*

CMS largely followed through on its proposal to clarify the DHS definition so as to exclude certain inpatient referrals that do not change the entity's compensation (such as when a specialist treats a patient who has already been admitted to a hospital as an inpatient for additional inpatient hospital services and the additional services do not affect the hospital's Inpatient Prospective Payment System rates). CMS-F-252-57. The Final Rule emphasizes that this logic extends to other hospital prospective payment systems such as the Long-Term Care Hospital Prospective Payment System but does **not** extend to outpatient hospital services. Separately, the FMV compensation exception permits certain compensation for items and services, and CMS finalized its proposal to update the definition of "referral" at 42 C.F.R. §411.351 to clarify that referrals are not items or services for which FMV compensation can be protected. CMS-F-263.

*"Remuneration" Definition: Specimen Tools*

Under the Stark statute, certain specimen collection items can be provided to physicians without being considered a form of financial arrangement with the physician. SSA 1877(h)(1)(C)(ii). CMS's rules previously made this exception unavailable for surgical items because they could be used other than for specimen collection for the furnishing entity. Now CMS is finalizing a proposal to protect items that are "in fact" used solely for specimen collection and transport. CMS-F-268.

*Isolated Transactions*

The exception for isolated transactions, 42 C.F.R. §411.357(f), cannot be used to cover multiple services simply because the services are paid for in a single lump sum, per a clarification finalized in the Final Rule. CMS-F-274. The new regulatory text also clarifies how certain settlement payments can be considered "isolated transactions" (but cannot be used to bring the arrangement underlying the dispute into conformity with another Stark exception). CMS-F-277-78.

*Periods of Disallowance*

CMS finalized its proposal to repeal the regulations at 42 C.F.R. §411.353(c)(1) that set forth outer bounds on how long the referral- and bill-invalidating effects of certain non-compliant arrangements last. CMS-F-289. CMS also created a special rule that gives parties to a compensation arrangement 90 days after the conclusion of the arrangement to reconcile their actual compensation with the terms of their arrangement. *See* CMS-F-299; new 42 C.F.R. §411.353(h).

*Titular Ownership*

In some jurisdictions that prohibit the corporate practice of medicine, entities that are subject to physician ownership and control but that do not offer the full financial benefits of ownership are common. CMS finalized a proposal to codify its longstanding policy that "titular" ownership and investment interests (that is, interests in name only without access to the financial benefits of ownership) do not constitute financial relationships under the rules at 42 C.F.R. §411.354(b). CMS-F-310.

*Ownership and Investment Through Retirement Plans*

CMS finalized a proposal to adjust the rules around entity ownership through an "employee stock ownership plan" retirement investment structure, to allow for certain indirect interests in the physician's employer while still prohibiting abuse of retirement arrangements to circumvent the prohibition on investments in other referral targets. *See* CMS-F-314; new 42 C.F.R. §411.354(b)(3)(vii).

*Special Rules on Compensation (411.354(e))*

Over the years, CMS used its regulatory authority to establish certain alternative methods of compliance with respect to Stark Law exceptions, including those for temporary noncompliance, delayed signatures, and clarification that a collection of writings together could be used to satisfy the exceptions' writing requirement. CMS extends further flexibility by codifying changes proposed by CMS in the Proposed Rule relating to the writing and signature requirements for compensation arrangements. CMS-F-321. CMS adopted, without modification, its proposed changes to Section 411.354(e)(4), allowing parties up to 90 days after the initiation of a compensation arrangement that otherwise, apart from the writing or signature requirements, satisfies an applicable exception, to put in place a signed writing to meet the requirements of the exception. CMS-F-322. CMS is also codifying its special rule for electronic signatures under 411.354(e), confirming longstanding CMS policy that electronic signatures are valid so long as the signature constitutes a valid signature under state or Federal law. CMS-F-342.

CMS is also codifying its modifications to the special rule at 411.354(d)(1) to allow for certain modifications to a compensation arrangement during the term, provided that the modified compensation is set out in writing before the furnishing of items or services to which the modified compensation is to be paid. CMS-F-322. Notably, §411.354(d)(1)(ii) does not contain a signature requirement, so the modified compensation formula, while set out in writing, need not be signed by the parties. There is no prohibition on the number of times the parties may modify the compensation, provided that the conditions of §411.354(d)(1)(ii) are met each time the compensation is modified. CMS-F-333.

Commenters proposed alternative methodologies under the special rule, including (1) an attestation in the subsequently signed writing whereby the parties attest that the compensation arrangement was set in advance, even if there were no contemporaneous writings to support it; or (2) an agreement by the parties to determine, in the future, compensation in an arms-length transaction, consistent with fair market value. CMS-F-338-339. CMS declined to adopt these suggested deeming provisions, noting that the "set in advance" requirement is statutory and noting concerns regarding abuse. CMS-F-339. CMS directed commenters to the new exception for limited remuneration to a physician at §411.357(z), which does not contain a set in advance requirement, to provide greater flexibility to address commenters' concerns. CMS-F-400.

*Exceptions for Rental of Office Space and Rental of Equipment (§411.357(a) and (b))*

CMS codified, without modification, its position in the Proposed Rule with respect to the "exclusive

use" requirement under the exceptions for rental of office space and rental of equipment, that the lessor is the only party excluded from use of the space or equipment, respectively. CMS-F-344. One commenter suggested "that, if a hospital leases space to a physician practice, the practice should be permitted to sublease back an exam room to the hospital for use by a hospital-employed physician or technician, in order to coordinate care." CMS-F-345. CMS rejected that suggestion as it would "render the statutory 'exclusive use' requirement meaningless", however, CMS referenced its amendment to the exception for fair market value compensation at §411.357(l) which now may be used for office space and equipment lease arrangements. CMS-F-346.

*Exception for Physician Recruitment (§411.357(e))*

CMS is codifying, without modification, its proposal *not* to require a physician practice to sign the writing documenting a recruitment arrangement (whereby a physician is recruited by a hospital to join an existing practice), *if* the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital. CMS-F-349. Therefore, physician practices that realize no financial benefit from a recruitment arrangement need not sign the recruitment agreement.

*Exception for Payments by a Physician (§411.357(i))*

CMS is finalizing without modification, its proposal at §411.357(i) to treat the statutory Payments by a Physician exception as a catch-all for other statutory exceptions (that is, it would not apply to arrangements implicating other statutory exceptions) but not for CMS's regulatory exceptions created under 1877(b)(4). CMS-F-363. Therefore, the Payments by a Physician exception has effectively been returned to the industry to cover compensation paid by a physician to a DHS entity for items and services.

*Exception for Fair Market Value Compensation (§411.357(l))*

CMS is finalizing modifications to §411.357(l) to permit parties to rely on the exception for fair market value compensation to protect arrangements for the rental or lease of office space; however, CMS decided not to remove the requirement at §411.357(l)(5) that the arrangement must not violate the Anti-Kickback Statute. CMS-F-370. CMS noted that it believed that the requirement functions as an important safeguard that substitutes for requirements included in certain statutory exceptions but omitted from §411.357(l), including the exclusive use requirement in the exceptions for the rental of office space and equipment. CMS is also retaining §411.357(l)(6), which requires that any services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. Further, due to concerns regarding per click arrangements for office space, CMS is including under §411.357(l)(3), prohibitions on percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for the lease of office space, similar to the restrictions found in §411.357(a)(5)(ii) and §411.357(p)(1)(ii). CMS-F-369. CMS is also reorganizing the exception as follows: §411.357(l)(1) will require the arrangement to be in writing and signed by the parties; while §411.357(l)(i) through §411.357(l)(iii) will list the information that must be specified in writing, as follows: the items, services, office space, or equipment covered by the arrangement (§411.357(l)(1)(i)); the compensation that will be provided under the arrangement (§411.357(l)(1)(ii)); and timeframe of the arrangement (§411.357(l)(1)(iii)). CMS-F-371. Finally, CMS is requiring at §411.357(l)(7) that any arrangement that includes a directed referral requirement must satisfy all the conditions of §411.354(d)(4). CMS-F-372.

*Exception for Assistance to Compensate a Nonphysician Practitioner (§411.357(x))*

The exception at §411.357(x) applies to remuneration provided by a hospital to a physician to compensate an NPP to provide patient care services. CMS is finalizing the proposed revisions to §411.357(x) without modification. CMS-F-418. Importantly, ''NPP patient care services'' shall is defined to mean "direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any

task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement." CMS-F-415. CMS did not expand this exception to additional NPP specialty practice areas, noting that "commenters that requested the expansion of the exception to any other specialty services provided no documentation or other evidence of the compelling need for such an expansion." CMS-F-419.

### III. Stark and Value-Based Payment

The proposed Stark regulatory changes had a significant focus on removing impediments to Value-Based Arrangements.

*Key Definitions*

CMS is defining *value-based activity* to mean any of the following activities, provided that the activity is reasonably designed to achieve at least one *value-based purpose* of the *value-based enterprise (VBE)*: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action.

CMS had proposed to expressly state in the definition of "value-based activity" that making a referral is not a value-based activity. While CMS decided not to finalize this part of the definition, the agency reiterated that referrals are not items or services for which a physician may be compensated. Care planning activities that meet the definition of "referral" at §411.351 will qualify as "the taking of an action." CMS declined to provide a list of value-based activities noting that a non-exhaustive list could unintentionally limit innovation and inhibit robust participation in value-based systems.

The final exceptions apply only to arrangements that qualify as *value-based arrangements*. A "value-based arrangement" is defined to mean "an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are: (1) a value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise." CMS revised its proposed language to make clear that all parties must be VBE participants in the same value-based enterprise. CMS also clarified that the value-based arrangement must be a compensation arrangement and not another type of financial relationship.

*Value-based enterprise* means "two or more VBE participants: (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s)." CMS declined to dictate particular legal or other structural requirements for a value-based enterprise. Rather, the definition of "value-based enterprise" is intended to encompass a wide range of structures.

*Value-based purpose* means: "(1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population." "Coordinating and managing" are not defined in the regulation. CMS does not believe that permitting a value-based enterprise to exist solely for the purpose of *reducing costs* to VBE participants would adequately protect the Medicare program and its beneficiaries from abuse. Nothing in the Final Rule requires that the value-based purpose(s) must be *achieved* for a value-based arrangement to be protected under an applicable exception; however, *post hoc* scrutiny will certainly include an analysis of the reasonableness of the purposes selected.

At final 42 C.F.R. §411.351, *VBE participant* is defined to mean "a person or entity that engages in at least one value-based activity as part of a value-based enterprise." CMS considered disqualifying labs and DMEPOS suppliers but ultimately did not do so. The definition of "VBE participant" finalized here

does not exclude any specific persons, entities, or organizations from qualifying as a VBE participant.

At final 42 C.F.R. §411.351, *target patient population* means "an identified patient population selected by VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s)." With respect to commenters' requests for lists of impermissible and permissible selection criteria, CMS determined that is was not feasible to provide an exhaustive list of unacceptable selection criteria. Deeming provisions sometimes have a chilling effect because they are, in practice, interpreted by the regulated industry as mandatory or otherwise prescriptive rules. Although CMS sought comment on whether to incorporate a requirement that patients in the target patient population have at least one chronic condition in order to align with OIG's proposals, CMS is not including that requirement in the definition of "target patient population" at §411.351.

*Three New Exceptions for Arrangements that Facilitate Value-Based Health Care Delivery and Payment*

Using the Secretary's authority under section 1877(b)(4) of the Act, CMS is adding three exceptions applicable to compensation arrangements. Consistent in these new exceptions is the abandonment of common Stark Law requirements that compensation be *set in advance, reflect fair market value, and not take into account the volume or value* of a physician's referrals or other business generated by the physician. CMS was concerned that the inclusion of such requirements in the new exceptions for value-based arrangements at 42 C.F.R. §411.357(aa) would conflict with the goal of addressing regulatory barriers to value-based care transformation.

Also consistent across these new exceptions is a focus on the *beneficiary's right to choose*. CMS is finalizing in all three exceptions a fortified requirement to ensure that, regardless of the nature of the value-based arrangement and its value-based purposes, the regulation adequately protects a patient's choice of health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. Under final §411.357(aa)(2)(vii), if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement must comply with both of the following conditions: (1) the requirement to make referrals to a particular provider, practitioner, or supplier must be set out in writing and signed by the parties; and (2) the requirement to make referrals to a particular provider may not apply if the patient expresses a preference for a different provider; 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.

*Exception for Full Financial Risk (§411.357(aa)(1))*

CMS had proposed an exception at 42 C.F.R. §411.357(aa)(1) that 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 period of time. CMS's intent was for this requirement to mean that the value-based enterprise, at a minimum, is responsible for all items and services covered under Medicare Parts A and B.

CMS is finalizing the exception with one modification. At §411.357(aa)(2), CMS is finalizing an exception that extends the period of time during which the exception will be available prior to the value-based enterprise's financial responsibility for the cost of all patient care items. Under the regulation as finalized, the value-based enterprise must be financially responsible within the 12 months following the commencement date of the value-based arrangement 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. Extending this pre-risk period from the proposed six months to 12 months should, according to CMS, allow parties sufficient time to work together in preparation for taking on full financial risk.

*Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician (§411.357(aa)(2))*

CMS proposed a definition of "meaningful downside financial risk" set at the 25 percent threshold. Upon consideration of the public comments, CMS is revising the definition to mean that the physician is responsible to repay or in the regulation at §411.357(aa)(2)(ix) to explicitly state that the physician must be 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. CMS believes that the assumption by a physician of 10 percent downside financial risk is sufficient to curb the influence of traditional FFS payment systems.

CMS reiterated that, for purposes of the exception at §411.357(aa)(2), the downside financial risk threshold relates to remuneration from an entity to a physician. Withholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures are all permissible options for structuring the financial terms of a value-based arrangement between an entity and a physician, provided that the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise. CMS does not believe that it is appropriate to link this threshold to the level of risk related to payments for services from a payor, for example, by linking to risk levels under MIPS or MACRA.

*Value-Based Arrangements (§411.357(aa)(3))*

To encourage robust participation in a value-based health care delivery and payment system, CMS proposed an exception at 42 C.F.R. §411.357(aa)(3) for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise. The value-based arrangement exception would permit both monetary and nonmonetary remuneration between the parties; and CMS sought comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system. 84 FR 55783.

The requirements are: 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 methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided; and records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

Because the exception at proposed §411.357(aa)(3) would be applicable even to value-based arrangements where neither party, but especially not the physician, has undertaken any downside financial risk, CMS stated that safeguards beyond those included in the meaningful downside financial risk exception are necessary. To address this, CMS will require that remuneration not be conditioned on the volume or value of referrals of any patients, including patients in the target patient population, to the entity or the volume or value of any other business generated, including business covered by the value-based arrangement, by the physician for the entity. As noted above, CMS is not including in the final exceptions at §411.357(aa) the traditional requirements that compensation is set in advance, consistent with fair market value, and 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 entity. However, CMS is requiring that the compensation arrangement be commercially reasonable, the arrangement must be set forth in writing and signed by the parties, and the parties must monitor the arrangement 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 Final Rule replaces the Proposed Rule's requirement that "performance or quality standards against which the recipient of the remuneration will be measured be objective and measurable", with evaluation of "outcome measures", which are defined as "a benchmark that quantifies: (A) improvements in or maintenance of the quality of patient care; or (B) reductions in the costs to or reductions in growth in expenditures of payors while

maintaining or improving the quality of patient care."

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

As noted above, for Stark purposes, a compensation arrangement is any arrangement involving direct or indirect remuneration between a physician (or an immediate family member of the physician) and an entity. If an indirect compensation arrangement exists, the exception for indirect compensation arrangements at §411.357(p) is available to protect the compensation arrangement.

Because compensation to the physician under a value-based arrangement could take into account the volume or value of referrals or other business generated by the physician for the entity or may not be fair market value for specific items or services provided by the physician, an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships that forms the indirect compensation arrangement may be unable to satisfy the requirements of the exception as it existed previously.

The Proposed Rule noted that an unbroken chain of financial relationships that includes a value-based arrangement could form an "indirect compensation arrangement" for purposes of the physician self-referral law if the circumstances described in §411.354(c)(2)(ii) and (iii) also exist. To avoid a blanket prohibition on indirect compensation arrangements that enhance value-based health care delivery and payment, CMS makes additional exceptions available to certain indirect compensation arrangements. CMS is finalizing regulations at §411.354(c)(4)(iii) to address when an unbroken chain described in §411.354(c)(2)(i) includes a value-based arrangement to which the physician (or the physician organization in whose shoes the physician stands) is a direct party.

In the Proposed Rule, CMS sought comments on how to pursue price transparency and overcome the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the Stark regulations. Commenters supported patients' access to clear, accurate, and actionable cost-sharing, but many supportive commenters also asserted that requiring price transparency disclosures as a requirement of an exception to the Stark Law is not an appropriate mechanism for promoting price transparency objectives given the strict liability nature of the law. CMS did not finalize any price transparency provisions in this rulemaking.

*Limited Remuneration to a Physician*

At CMS-F-447-93, CMS adopts a new exception, 42 C.F.R. §411.357(z), which authorizes certain limited compensation arrangements with physicians for short-term, infrequent, or exigent services. (OIG did not propose or adopt a companion safe harbor.)

The EHR Stark Proposed Rule provided that compensation from an entity to a physician for the provision or items of services that do not exceed an aggregate of $3,500 per calendar year does not constitute remuneration for purposes of the Stark Law as long as certain safeguards are satisfied. The proposed safeguards generally prohibited compensation based on the volume or value of referrals or other business generated by the parties, compensation in excess of fair market value, commercially unreasonable arrangements, percentage of revenue, or per-unit rental charges for the use or lease of office space or equipment.

The Final Rule adopts these safeguards with some modifications and increases the amount of permissible compensation from $3,500 to $5,000 per calendar year. 42 C.F.R. §411.143.357(z)(1). CMS clarified that this exception may be used in conjunction with the personal service arrangement and the fair market value exceptions, and it also adopted corresponding conforming changes to subsections (d)(1) and (l). The annual $5,000 dollar limit does not accrue unless or until the other exceptions do not apply. CMS-F-428-30.

The Final Rule clarified that the arrangement must be commercially reasonable "even if no referrals were made between the parties." CMS adopted this modification in order to ensure consistency with other exceptions and prevent any inference that this exception requires a lesser standard. CMS-F-441.

The Final Rule also adds a sixth condition for satisfying this exception. If the remuneration is condition on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement must satisfy the special rules on compensation from a bona fide employer or under a managed care contract. Specifically, the compensation must be set in advance for the term of the arrangement, be consistent with fair market value and not take into account the volume or value of anticipated referrals, and otherwise comply with this or another applicable exception. 42 C.F.R. §411.143.354(d)(4); 42 C.F.R. §411.143.357(z)(1)(vi).

The revision to subparagraph (z)(1)(v) was modified in the Final Rule to clarify that the prohibited per-click and percentage-based compensation provisions only apply to timeshare arrangements for the use of premises or equipment. Although the EHR Proposed Rule also prohibited timeshare arrangements for the use of personnel, items, supplies, and services, CMS deleted those provisions from the Final Rule in response to comments about overbreadth. CMS-F-443-44.

The Final Rule adds a new subsection (2), which provides that a physician may provide items or services through employees whom the physician has hired for the purpose of performing the services; through a wholly-owned entity; or through *locum tenens* physicians, except that the regular physician need not be a member of the group practice. 42 C.F.R. §411.143.357(z)(2). Any amounts paid to such individuals will be counted toward the physician's annual dollar limit. CMS-F-432. CMS clarifies that the physician may not engage an independent contractor to perform these services. CMS-F-431.

## IV. Revisions to Safe Harbors under the Anti-Kickback Statute

The revisions to the AKS under this Final Rule seek to strike the right balance between flexibility for beneficial innovation and better coordinated patient care with necessary safeguards to protect patients and Federal health care programs. OIG-F-7. Furthermore, many of the new safe harbors support outcomes-based payments that facilitate care coordination, encourage provider engagement across care settings, and advance the transition to value. OIG-F-784.

While requested by commenters, the Final Rule Safe Harbors do not completely align with the Stark Final Rule Exceptions because of fundamental differences in the statutory structures of the two regulations and the sanctions across the two laws.

*Personal Services and Management Contracts Safe Harbor Revisions (42 CFR 1001.952(d))*

OIG proposed to modify the safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), to substitute the aggregate compensation requirement with a requirement that the *methodology* for determining compensation be set in advance (similar to the requirement under the Stark Law's Personal Services Arrangement exception). OIG further proposed to eliminate the requirement that if an agreement provides for the services of an agent on a periodic, sporadic, or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals. OIG is finalizing these changes without modification. These changes provide important new flexibility to industry stakeholders and allow for potential safe harbor protection for many common, non-abusive arrangements in the healthcare industry. OIG is finalizing additional proposed additions at 42 C.F.R. § 1001.952(d)(2) and (3), respectively, with modification, with respect to certain outcomes-based payments. OIG revised the definition of "outcomes-based payment" under 42 C.F.R. § 1001.952(d)(3)(ii) to clarify that the payment may be a reward for successfully achieving an outcome measure or recoupment or reduction in payment for failure to achieve an outcome measure.

In 42 C.F.R. § 1001.952(d)(2)(i), the OIG consolidates and streamlines proposed paragraphs 42 C.F.R. § 1001.952(d)(2)(1) and (ii) related to acceptable outcomes measures. To receive a protected outcomes-based payment, the agent must achieve one or more legitimate outcome measures selected based on clinical evidence or credible medical support with specific benchmarks on care quality, reduction in costs, or both.

OIG revised its proposal related to "rebasing" of outcomes measures to clarify in 42 C.F.R.

§ 1001.952(d)(2)(vii)(B) that the parties must periodically both assess and revise benchmarks and remuneration under the agreement as necessary to ensure any remuneration is consistent with fair market value in an arm's length transaction as required by 42 C.F.R. § 1001.952(d)(2)(ii).

In 42 C.F.R. § 1001.952(d)(3)(iii), OIG finalized the scope of entities ineligible for safe harbor based on outcomes-based payments to include: (1) pharmaceutical companies: (2) PBMs; (3) laboratory companies; (4) pharmacies that primarily compound drugs or primarily dispense compounded drugs; (5) manufacturers of a device or medical supply; (6) medical device distributors or wholesalers that are not manufacturers; or (7) DMEPOS companies.

OIG also clarified in § 1001.952(d)(d)(2)(ii) and § 1001.952(d)(d)(3)(ii) that remuneration may be "between or among" the parties, rather than being limited to remuneration from the principal to the agent.

*Warranties (42 CFR 1001.952(g))*

OIG substantively adopted the Proposed Rule's modification to the existing safe harbor for warranties. In addition, OIG clarified in the preamble to the Final Rule that the safe harbor is designed to accommodate the various reimbursement systems under which buyers may report price reductions. OIG-F-816.

In the Final Rule, the Warranties Safe Harbor: (i) protects certain warranties for one or more items and related services upon certain conditions, such as all federally reimbursable items and services subject to bundled warranty arrangements, must be reimbursed by the same Federal health care program and in the same payment ("same program/same payment requirement"); (ii) excludes beneficiaries from the reporting requirements applicable to buyers; and (iii) defines "warranty" directly and not by reference to 15 U.S.C. 2301(6).

*Local Transportation (42 CFR 1001.952(bb))*

The Final Rule (1) expands the mileage limitation for patients in rural areas to 75 miles; and (2) eliminates distance limitations on transportation of discharged patients to their residence, which includes travel to custodial care facilities, homeless shelters, or residences of a friend or relative caring for the patient post-discharge. In addition, the finalized Local Transportation Safe Harbor protects remuneration related to the patient's transportation home following inpatient discharge or for patients who have been under observation status for at least 24 hours. The Final Rule did not expand the Safe Harbor to protect transportation costs the patient receives for nonmedical purposes.

## V. Value-Based Framework, Value-Based Terminology, and Value-Based Safe Harbors

The AKS Final Rule finalized the value-based framework of three safe harbors that support the transformation of industry payment systems in recognition that arrangements involving higher levels of downside financial risks for those in a position to make referrals or order products or services could curb, to some degree, fee for service incentives to order medically unnecessary or overly costly items and services. OIG-F-35. These three safe harbors (Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency; Value-Based Agreements with Substantial Risk; Value-Based Arrangements with Full Financial Risk), discussed below, do not include elements of fair market value or prohibit taking into account the volume or value of any referrals – instead they focus on elements of risk sharing and contributions by the recipient to safeguard against fraud and abuse. The Final Rules specifically declined to use or define the term "value" in these safe harbors because OIG believed that industry stakeholders and its participants were best positioned to make that determination. OIG-F-46.

The Final Rule added several new value-based defined terms in connection with additions to the three value-based Safe Harbors. 42 CFR 1001.952(ee), which are substantively aligned with the Stark Law definitions in the CMS Final Rule. While there are minor deviations in the definitions between the two Rules, we have determined that they are not material enough to restate here, with the exception of:

Coordination and Management of Care: The Final Rule modified the proposed definition to clarify that

(i) the organization of patient care activities and sharing of information must occur between two or more VBE participants, VBE participants and the VBE, or VBE participants and patients and (ii) that the parties efforts must be designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient language. Coordination and management of care now means the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population.

*NEW Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency Safe Harbor (42 CFR 1001.952(ee))*

OIG finalized, with modifications, its new safe harbor at § 1001.952(ee) to protect *in-kind* remuneration exchanged between qualifying parties to a value-based arrangement (not to patients) to facilitate improved care coordination for patients by providers assuming no less than substantial downside financial risk. OIG-F-198. The Care Coordination safe harbor finalizes conditions related to commercial reasonableness, outcomes measures, monitoring and periodically assessing (no less than annually) an outcome or process measure against its benchmark, written and signed documentation establishing a value-based purpose, record retention of at least 6 years, medical necessity, termination (or prompt remediation through a corrective action plan), marketing and patient recruitment, and further requires that protected remuneration be used predominately to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. OIG-F-200. OIG clarified that parties need not successfully achieve the outcome or process measure selected for qualification; however, parties must monitor and periodically assess their arrangements and potentially revise measures and benchmarks. OIG-F-226. OIG declined to adopt its proposal to require rebasing of benchmarks and instead uses the broader term "revise." OIG-F-233. OIG is further codifying its proposal that all recipients must pay 15 percent of the offeror's cost or 15 percent of the fair market value of the remuneration, but stopped short of adopting its proposed condition related to outside funding of the remuneration. OIG-F-275. OIG added a condition in the safe harbor that the remuneration exchanged result in no more than incidental benefit to persons outside of the target patient population and the remuneration not be used more than incidentally by the recipient for billing or financial management services. OIG-F-260. Notably, the safe harbor prohibits the offeror of the remuneration from considering the volume or value of, or conditioning an offer of remuneration on, referrals or business generated *outside of* the target population only. OIG-F-273. OIG finalized the marketing limitation to prohibit the "exchange of remuneration for the purpose of engaging in patient recruitment activities or marketing." OIG-F-308. OIG declined to define "marketing" and instead provided numerous examples in the Final Rule commentary. OIG-F-308. OIG also declined to adopt a "phase-in" period in advance of the commencement of a value-based arrangement, citing concerns about heightened risks of fraud and lack of assumption of risk. OIG-F-207. OIG rejected commenters' suggestions to require patient notice of the entity's participation in a VBE under the care coordination safe harbor. OIG-F-298. OIG is also not finalizing its proposals regarding: bona fide determinations, cost-shifting prohibition, fair market value requirement, additional conditions on dialysis providers, data submission to HHS, or the alternative regulatory structure for coordination without full risk. OIG-F-339-345.

*NEW Value-Based Arrangements with Substantial Downside Financial Risk (42 CFR 1001.952(ff))*

OIG finalized, with modifications, its new safe harbor at § 1001.952(ff) to protect both *monetary and in-kind remuneration* exchanged pursuant to value-based arrangements between VBE and VBE Participants. For a value-based arrangement to be protected under this safe harbor, a VBE must assume substantial downside financial risk from a payor under one of three methodologies, and a VBE Participant must assume a meaningful share of the VBE's total risk, which share has been reduced to at least 5% in the final rule (from 8% in the Proposed Rule). OIG-F-353. OIG understands that this safe harbor may be used by participants in CMS-

sponsored models, but the safe harbor is primarily for other kinds of value-based arrangements, including arrangements in the commercial market.

OIG provided more clarity about the way parties must calculate savings and losses pursuant to methodologies in the definition of "substantial downside financial risk." The definition of "substantial downside financial risk" was finalized with modifications – for example, under the first payment methodology (Shared Savings and Losses Methodology), the risk threshold that parties must assume in order to meet the definition was lowered to 30% from 40% in the Proposed Rule. OIG-F-362.

Under the second methodology (Episodic Payment Methodology), the Final Rule replaced the Proposed Rule term "episodic or bundled payment methodology" with "clinical episode of care." OIG-F-364. OIG stated that parties must design the clinical episode of care to cover items and services furnished collectively in more than one care setting. OIG is also retaining the 20% risk threshold for Episodic Payment Methodology.

OIG also finalized, with modifications, a VBE partial Capitation Methodology pursuant to which the VBE is at a substantial downside financial risk if the VBE receives from the payor a prospective, per-patient payment that is (1) designed to produce material savings and (2) paid on a monthly/quarterly/annual basis for a predefines set of items and services furnished to the target patient population designed to approximate the expected total cost of expenditures of the predefined set of items and services. OIG removed the discount percentage requirement in recognition that the partial capitation payment constitutes the assumption of substantial downside financial risk. While this methodology is designed to result in material savings, material savings is purposefully left undefined to provide more flexibility when defining capitation payments. OIG also is not requiring that parties rely on historical expenditure or evidence-based comparable expenditures to determine a benchmark in calculating any losses or savings realized.

Under the Shared Savings and Losses Methodology and Episodic Payment Methodology, OIG clarified that the savings and losses must be calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a *bona fide* benchmark designed to approximate the expected total cost of such care or defined clinical episode of care. OIG-F-357. The bona fide benchmark may be adjusted through a prospective/retrospective risk-adjustment if it is designed to approximate the expected total cost of care. Benchmarks that are validated or designed consistent with general actuarial principles will likely be bona fide. OIG-F-374.

OIG also finalized the definition of "meaningful share" with modifications. OIG revised the Shared Savings and Losses Methodology definition of "meaningful share" to clarify that any risk assumed by a VBE participant pursuant to this methodology must be a 2-sided risk and revised the Episodic Payment Methodology to apply to prospective per patient payments for a predefined set of items and services furnished.

OIG further identified entities who are ineligible for the protections of this safe harbor: pharmaceutical manufacturers, wholesalers, and distributors; PBMs; laboratory companies; pharmacies that primarily compound drugs or primarily dispense compounded drugs; manufacturer of devices or medical supplies; entities or individuals that manufacturer sell or rent DMEPOS (other than a pharmacy or a physician, provider, or other entity that primarily furnishes services); and medical device distributors or wholesalers that are not otherwise manufacturers or devices or medical suppliers. OIG-F-392.

OIG also finalized the requirement that the VBE assume substantial downside financial risk from the payor through (1) an arrangement that meets the definition of a value-based arrangement or (2) a contract that places the VBE at substantial downside financial risk. The VBE may assume risk directly from the payor or through a single VBE Participant acting on its behalf.

OIG finalized the six-month phase in period from the Proposed Rule and the requirement that remuneration exchanged pursuant to this safe harbor must be used primarily to engage in value-

based activities that are directly connected to the items and services for which the VBE is at substantial downside financial risk, noting that monetary remuneration exchanged pursuant to a risk methodology that meets the definition for substantial downside financial risk or meaningful share does not need to be used predominantly to engage in value-based activities. OIG-F-401.

Additionally, the OIG finalized that protected remuneration must be directly connected to at least one of the three value-based purposes in § 1001.952(ee)(13)(x)(A)-(C). OIG-F-416. OIG clarified that value-based arrangements, not merely remuneration exchanged, may not induce the VBE or VBE Participants to reduce or limit medically necessary items or services to be furnished to any patient. OIG-F-421.

OIG finalized, with modifications, the writing requirement, stating that it may be satisfied by a collection of documents and does not require documentation of the offeror's costs. The writing must be established in advance of or contemporaneous with the commencement of the value-based arrangement *and* any material change to the value-based arrangement. OIG-F-418-419.

OIG moved the language that VBE or VBE Participant offering remuneration could not take into account the volume or value of, or condition the remuneration on, referrals of patients outside of the target patient population or business not covered under the value-based arrangement to § 1001.952(ff)(6). OIG-F-420.

OIG finalized, with modifications, the requirement to not limit the VBE participant's ability to make decisions in the best interest its patients, and the record maintenance requirement of keeping records and materials for at least 6 years. OIG-F-423.

In terms of marketing, OIG modified, from its proposal of prohibiting all marketing and patient recruitment activities under this safe harbor, to prohibiting only the exchange of remuneration of the purpose of marketing items or services furnished by the VBE or VBE Participants to patients for patient recruitment activities. OIG-F-424.

OIG finalized without modification: (1) the condition that the safe harbor would not protect an ownership or investment interest in the VBE or any distributions related to an ownership or investment interest and relocated it to § 1001.952(ff)(4)(iii) (OIG-F-415); (2) safe harbor only protects remuneration exchanged between a VBE and a VBE Participant. OIG-F-425.

OIG did not finalize: the proposed limit on outside funding of protected remuneration (OIG-F-354); the proposed population-based payment methodology (OIG-F-358); proposed methodology (CMS Exception Methodology) applicable to physician payments that meet the requirements of the physician self-referral law's regular exception for value-based arrangements at 411.357(aa)(2) (OIG-F-380).

*NEW Value-Based Arrangements with Full Financial Risk (42 CFR 1001.952(gg))*

The OIG adopts the full financial risk safe harbor that would protect remuneration exchanged between a VBE and VBE participant pursuant to either a value-based arrangement or contract where the VBE assumes full financial risk. OIG modifies the definition of "full financial risk" in the Final Rule to require the VBE to be at risk on a prospective basis for the cost of all items and services covered by the payor for each patient in the target population for at least one year.

OIG finalized the requirement that parties to a value-based arrangement must have a signed writing that specifies all materials terms. The Final Rule added that this requirement may be satisfied by a collection of documents.

OIG also finalized the proposed requirement that remuneration be directly connected to one or more of the VBE's value-based purposes. OIG no longer requires that all remuneration be connected to the purpose of coordinating and managing care for the target population.

This safe harbor also requires that the value-based arrangement, not merely the remuneration exchanged, does not induce the VBE or VBE participants to reduce or limit medically necessary items or services for any patient.

The OIG finalized the requirement that the VBE must provide or arrange for a quality assurance program

that protects against underutilization and assesses the quality of care furnished to the target patient population. The proposed requirement for an operational utilization review program was not adopted by the Final Rule.

The OIG finalized the following Proposed Rule conditions without modification: VBE or VBE participant cannot include referrals of patients outside the target patient population or business not covered under the value-based arrangement; the condition that the full financial risk safe harbor does not protect ownership or investment interest in the VBE.

Consistent with the care coordination arrangements safe harbor, the exchange or use of remuneration for purposes of marketing items or services furnished by VBE or VBE participants or patient recruitment activities is prohibited.

Additionally, a list of entities ineligible to use the safe harbor has been added. For the full financial risk safe harbor, remuneration may not be exchanged by: pharmaceutical manufacturers, wholesalers, and distributors; PBMs; laboratory companies; pharmacies that primarily compound drugs or dispense compounded drugs; medical device or supply manufacturers; entities or individuals manufacturing, selling, or renting DMEPOS (other than pharmacy, physician, provider or entity primarily furnishing services); and medical device distributors or wholesalers.

The following proposed elements were not finalized: (1) one-year minimum term; (2) proposed requirement that the remuneration exchanged be used primarily to engage in the value-based activities detailed in the parties' signed writing; (3) condition that the full financial risk safe harbor would not protect any remuneration funded or contributed by any individual or entity outside the applicable VBE; (4) safe harbor protection extension to remuneration that passes from one VBE participant to another, or to a downstream contractor; and (5) additional proposed safeguards (cost-shifting prohibition and requirement that parties submit information to HHS).

## VI. Other New AKS Safe Harbors

*NEW Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency (42 CFR 1001.952(hh))*

A new safe harbor was proposed at § 1001.952(hh) to protect remuneration in the form of patient engagement tools and supports furnished directly to VBE participants in a target patient population.

The Final Rule expanded the list of entities that are ineligible to use the safe harbor to furnish protected remuneration to patients: Manufacturers, distributors, and wholesalers of pharmaceuticals; Pharmacy Benefit Managers; Laboratory Companies; Pharmacies that primarily compound drugs or primarily dispense compounded drugs; Manufacturers of devices and medical supplies (unless the tool or support is digital health technology); Entities or Individuals that sell or rent DMEPOS (other than a pharmacy, a manufacturer of a device or medical supply, or a physician, provider, or other entity that primarily furnishes services); Medical Device Distributors and Wholesalers; Physician-owned Medical Device Companies. (§ 1001.952(hh)(1)). This change reflected the concerns that certain types of entities present a higher risk of misusing this safe harbor primarily or significantly to offer remuneration to beneficiaries as a means to market their products and services rather than to improve the coordination and management of patient care.

The Final Rule provides that a tool or support furnished or funded by a manufacturer of a device or medical supply (as defined in paragraph § 1001.952(ee)(14)) is eligible for safe harbor protection only if the tool or support is digital health technology as defined at § 1001.952(ee)(14).

The final rule clarified that to qualify for safe harbor protection, a tool or support must be furnished by a VBE participant to a patient in the target patient population of a value-based arrangement to which the VBE participant is a party.

While the proposed rule reflected that the tool or support must be furnished directly to the patient by a VBE participant, the final rule modifies the proposed rule by extending the safe harbor

protection to a VBE participant that provides patient engagement tools or supports through a third party that qualifies as an "eligible agent". § 1001.952(hh)(9).

To minimize the possibility of the prohibition of a third party entity or individual outside of the VBE from financing or contributing to the provision of patient engagement tools or supports being circumvented, the final modified rule provides that the patient engagement tool or support must not be funded or contributed by a VBE participant that is not a party to the applicable value-based arrangement or by an ineligible entity. § 1001.952(hh)(4).

In response to specific types of remuneration, the Final Rule reflects the following modifications: (i) protection is offered only for in-kind items, goods or services that meet all applicable safe harbor conditions with the Final Rule not specifying the categories of items, goods or services; (ii) the proposal to exclude protection for remuneration in the form of cash, cash equivalents and gift cards was modified with the justification that some gift cards (such as limited-use gift cards) are considered in-kind remuneration; (iii) the proposed waiver or reduction of cost-sharing obligations was not finalized; (iv) the Final Rule removed health-related technology and patient health-related monitoring tools and services as examples of permissible tools and support; instead stating that the Final Rule reflects an in-kind item, good or service without qualifiers or examples; (vi) the Final Rule did not finalize the requirement that the VBE participant confirm that the tool or support is not duplicative of, or substantially the same as, tools and services the patient already has.

The Final Rule clarifies that neither the VBE participant nor an eligible agent of the VBE participant may use patient engagement tools or supports to market other reimbursable items or services of for patient recruitment purposes. § 1001.952(hh)(6). The Final Rule does not preclude providers from educating their patients or otherwise providing information about available tools and supports to established patients.

The Final Rule reflects a condition that the availability of patient engagement tools and supports cannot be determined in a manner that takes into account the type of insurance coverage of the patient. § 1001.952(hh)(8).

The Final Rule is not requiring the monitoring of the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient.

A monetary cap on the tools and supports protected under this safe harbor is being finalized at an annual $500 monetary cap. While the Final Rule does not include an exception to the cap requirement for patients with demonstrated financial need, an inflation adjuster is included. § 1001.952(hh)(5).

OIG finalized the following requirements without modification: the tool or support furnished to the patient must have a "direct connection" to the coordination and management of care of the target patient population, § 1001.952(hh)(3)(ii); the tool or support must not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program is being finalized without modification, § 1001.952(hh)(3)(iv);

The following requirements were not finalized: requirement to patients receiving the tools or support; proposed diversion or resale condition; retrieval of items and goods requirement; prohibitions on cost-shifting.

*NEW CMS-Sponsored Model Arrangements and CMS-Sponsored Model-Patient Incentives (42 CFR 1001.952(ii))*

A new safe harbor was proposed at § 1001.952(ii) to: (i) permit remuneration between and among parties to arrangements (e.g., distribution of capitated payments, shared savings or losses distributions) under a model or other initiative being tested or expanded by the Innovation Center under section 1115A of the Act or under the Medicare Shared Savings Program under section 1899 of the Act (collectively, "CMS-sponsored models"); and (ii) permit remuneration in the form of incentives provided by CMS-sponsored model participants and their agents under a CMS-sponsored model to patients covered by the CMS-sponsored model. The

safe harbor is being finalized with clarifications to certain defined terms.

Safeguards were proposed to ensure the arrangements protected by the safe harbor operated as intended by CMS, including: (i) that remuneration to induce furnishing medically unnecessary services or reduce or limit medically necessary care; (ii) that remuneration not induce referrals of patients outside the CMS-sponsored model; (iii) the parties make materials and records available to the Secretary upon request; the parties satisfy programmatic requirements imposed by CMS; and a patient incentive offered under the safe harbor have a direct connection to patient care. Such proposals are being finalized with modifications that include a clarification in item (ii) that CMS-sponsored model patient incentive must have a direct connection to the patient's health care (unless the participation documentation specifies a different standard).

The final rule reflects a new paragraph at § 1001.952(ii)(4) that specifies timeframes for when safe harbor protection begins and ends to align with the duration of the participation documentation under a CMS-sponsored model.

## VII. Civil Monetary Penalty Authorities

The Civil Monetary Penalty Authorities (CMP) was enacted to provide an administrative remedy to combat fraud and abuse in Medicare and Medicaid, but was extended to apply to all Federal health care programs. The Beneficiary Inducements CMP, SSA 1128A(a)(5), provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or Medicaid beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or services for which payment may be made, in whole or in party, by Medicare or Medicaid. "Remuneration" for the Beneficiary Inducement CMP, SSA 1128A(i)(6), means transfers of items or services for free or for other than fair market value.

*Exception for Telehealth Technologies for In-Home Dialysis (42 CFR 1003.110)*

OIG clarified that the safe harbor protects the provision of telehealth technologies by a provider or renal dialysis facility to individuals with end-stage renal disease receiving home dialysis.

OIG finalized a broader definition of "telehealth technologies" to mean technology used to support remote communication between providers and patients for diagnosis, intervention, or ongoing care management. The modified definition removes references to specific types of technology, limits on types of communication, and the requirement that telehealth services be paid for by Medicare Part B. The Final Rule also modifies the definition of "telehealth technologies" and allows physicians to donate telehealth technologies to a patient.

OIG finalized its proposal that telehealth technologies may not be offered as part of any advertisement or solicitation.

Other potential conditions that were not adopted include: (1) prohibiting providers and facilities from discriminating in offering telehealth technologies; (2) requiring providers or facilities to provide a written explanation of reason for the technology and any potential hidden costs; (3) requiring offerors of telehealth technologies to advise patients that they retain the freedom to choose any provider or supplier of dialysis services; (4) a materials and records retention requirement; (5) the condition that providers and facilities not separately bill Federal health care programs, other payors, or individuals for telehealth technologies; and (6) requiring providers and facilities to retain ownership of and retrieve hardware once no longer needed for telehealth purposes.

*Accountable Care Organization (ACO Beneficiary Incentive Program) (42 CFR 1001.952(kk))*

OIG finalized the Proposed Rule Safe Harbor without modification, codifying the statutory exception to the definition of "remuneration" at SSA 1128B(b)(3)(K) for ACOs operating a CMS-approved beneficiary incentive program under the Medicare Shared Savings Program.

We hope you have found this introduction to the new Stark Law, AKS and CMP rules useful. Please reach out to your DLA Piper LLP (US) relationship partner or any member of our Healthcare Industry Team and we will be happy to help you prepare for the implementation of these new rules.

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