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HHS Issues Landmark Proposed Regulations for Stark, AKS and the Beneficiary Inducements Provision of the CMP Statute

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On October 9, 2019, the Department of Health and Human Services (HHS) revealed its long-awaited proposals to update the Physician Self-Referral Law (Stark), the federal Anti-Kickback Statute (AKS), and the Beneficiary Inducements provision of the Civil Money Penalty (CMP) Statute as part of its Regulatory Sprint to Coordinated Care.[1] The proposed regulations promote and remove barriers to value-based arrangements and care coordination, in addition to easing compliance burdens associated with existing regulatory provisions.[2]

The proposed regulations for Stark, and for the AKS and the CMP Statute were issued by the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG), respectively, and both agencies emphasize the need for these regulations to evolve to keep pace with the transition from volume-based healthcare to a value-based system that reimburses based on the quality of patient care provided.[3] The proposals take into account industry comments received in response to the agencies' 2018 Requests for Information (RFI) as well as the agencies' experience in administering or enforcing the regulations, including CMS' experience in administering the self-referral disclosure protocol (SRDP). Notably, the proposed regulations aim to achieve alignment with each other, where appropriate, in an effort to reduce the compliance burden pertaining to arrangements that implicate both Stark and the AKS.[4] However, differences may continue in light of the differing scopes, statutory structures, and penalties associated with each law.

This article provides an overview of the proposed regulations as well as some insight into some notable proposed changes and the types of comments that CMS and OIG are soliciting from the public in an effort to further refine the regulations for publication of final regulations. However, given the breadth of these proposed regulations, this article does not purport to address all

relevant proposed provisions. Commenters have until December 31, 2019 to submit their comments to CMS and OIG, as appropriate, yet each agency may consider comments received by the other if the comments are determined to be relevant to both agencies' proposals.[5]

1. Stark Proposed Regulations Overview

The proposed regulations for Stark create new exceptions for certain value-based compensation arrangements, donations of cybersecurity technology and related services, and a physician's receipt of limited remuneration for his or her provision of items or services. In addition, the proposed regulations revise existing exceptions and definitions in an effort to provide guidance, address non-abusive relationships that CMS identified through the RFI comments and SRDP administration, and reduce the burdens of compliance with Stark while balancing CMS' legitimate program integrity concerns.[6]

A. New Value-Based Exceptions (proposed 42 C.F.R. § 411.357(aa))

CMS proposes three new Stark exceptions for compensation arrangements that would satisfy certain value-based requirements depending on the level of financial risk undertaken by the parties participating in the arrangement: (1) full financial risk, (2) value-based arrangements with meaningful downside financial risk, and (3) value-based arrangements. Notably, these exceptions would apply regardless of whether care is rendered to Medicare beneficiaries, non-Medicare patients, or both.[7] CMS intends that these exceptions would protect CMS-sponsored models and that they would eliminate the need for any new waivers of Section 1877 of the Social Security Act that otherwise might be issued in conjunction with such models.[8]

To provide context to these new exceptions, new definitions are proposed to be included within 42 C.F.R. § 411.351 for: value-based activity, value-based arrangement, value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population. Understanding these definitions is critical to determining compliance with one of the three exceptions, as they apply only to remuneration paid under value-based arrangements between the VBE and one or more of its VBE participants, or between or among VBE participants within the same VBE, for the provision of at least one value-based activity that is reasonably designed to achieve at least one value-based purpose of the VBE for a target patient population.[9]

CMS proposes flexibility in determining the legal structure of a VBE, which would need not be a separate legal entity, and which would not require that a value-based arrangement be reduced to

writing.[10] Also, the proposed exceptions would not require that the compensation amount be set in advance, fair market value, and not take into account the volume or value of a physician's referrals or other business generated between the parties.[11]

However, the exceptions would have limitations. Specifically, the making of a referral for designated health services (DHS) would not be a value-based activity.[12] In addition, CMS is considering whether to exclude compensation arrangements between physicians and laboratories; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS); pharmaceutical manufacturers; pharmacy benefit managers; wholesalers; distributors; or health technology companies from the protection of the exceptions because these entities and individuals may not serve to benefit the coordination of care for patients.[13]

CMS acknowledges that further clarification regarding these defined terms may be needed to achieve the intended goals of the proposed regulations and, accordingly CMS solicits comments regarding aspects of these terms. For example, with regard to the definition of "value-based purpose," the terms "coordinating and managing" care and the concept of transitioning from a volume-based delivery system to a value-based system lack some clarity that may result in difficulties in determining whether a value-based purpose exists.[14] Given that a value-based purpose is a necessary component of these new exceptions, industry feedback is encouraged.

In addition, CMS seeks industry comments regarding how to address CMS' price transparency objectives in the context of Stark and whether, to what extent and how such information should be provided to patients, particularly considering potential burdens associated with such a requirement.[15] CMS also inquires as to whether including a price transparency requirement in a value-based exception would provide additional protections against program or patient abuse.

i. Full Financial Risk Exception (proposed 42 C.F.R. § 411.357(aa)(1))

The proposed full financial risk exception would apply to remuneration paid under value-based arrangements between VBE participants in a VBE that has prospectively 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.[16] CMS does not limit the type of remuneration that may be provided or the manner in which a VBE may assume full financial risk, but provides examples of risk assumption including capitation payments and global budget payments. The financial risk must be prospectively determined and, although the VBE and

payor would be able to agree to losses that the payor will offset, such offsetting agreements would be required to be prospectively administered.[17] CMS would also recognize and protect a ramp-up period beginning with the commencement of a value-based arrangement in which the VBE intends to assume full-financial risk, provided that assumes full-financial risk within six months of commencement.[18]

As written, the proposed exception would be available for remuneration for, or resulting from, value-based activities, but CMS is considering whether it should also, or alternatively, relate to the value-based purposes of the VBE or value-based arrangement. Whereas this could expand the scope of the exception, the remuneration still would be required to relate to the target patient population and the exception would, therefore, not protect general marketing or sales arrangements.[19] Also noteworthy is the fact that the exception would not protect arrangements that condition the remuneration on referrals of patients who are not part of the target patient population or referrals of business that are not covered under the value-based arrangement.[20]

ii. Value-Based Arrangements with Meaningful Downside Financial Risk Exception (proposed 42 C.F.R. § 411.357(aa)(2))

The proposed meaningful downside financial risk exception would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for the entire term of the arrangement for failure to achieve the value-based purpose(s) of the VBE.[21] For purposes of the exception, a "meaningful downside financial risk" would mean that the physician is: (1) responsible to pay the entity at least 25 percent of the value of the remuneration that the physician receives under the value-based arrangement or (2) financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items or services covered by the applicable payor for each patient in the target patient population for a specified period of time. CMS would also distinguish this exception from the full financial risk exception by not including a six-month ramp-up period, by requiring that the physician be at meaningful downside financial risk for the entire term of the value-based arrangement, and by requiring that the nature and extent of the physician's financial risk be set forth in writing.[22]

CMS notes some areas of concern with regard to this exception. For example, the remuneration can be paid by or to the physician under this exception, and CMS seeks comments as to whether the physician has the same incentive to modify practice and referral patterns to achieve the goals of the exception if the entity furnishing DHS assumes the downside risk and pays remuneration under the value-based arrangement.[23]

iii. Value-Based Arrangements Exception (proposed 42 C.F.R. § 411.357(aa)(3))

In consideration of the fact that allowing physicians to assume only upside risk or no risk at all may encourage more physicians to participate in care coordination activities, CMS proposes the value-based arrangements exception to protect both monetary and nonmonetary remuneration paid under a value-based arrangement for value-based activities that are expected to further the value-based purpose(s) of a VBE for a target patient population. Because the exception would not require any party to take downside risk, CMS imposes requirements beyond those imposed under the full financial risk and meaningful downside financial risk exceptions to safeguard against program and patient abuse. For example, the arrangement must be set forth in writing that is signed by the parties and includes a description of the value-based activities undertaken, how those activities are expected to further the value-based purpose(s) of the VBE, the target patient population, the type or nature of remuneration and methodology used to determine the remuneration, and performance or quality standards against which the recipient of the remuneration will be measured, if any.[24] While the amount of remuneration need not be set in advance, the methodology used to determine the amount of remuneration must be set in advance to comply with the exception. Also, the standards against which the recipient will be measured, if any, must be prospective, objective, measurable, and not simply reflect the status quo.[25]

Considering the flexibility of the proposed exception, CMS is considering requiring that the VBE or VBE participant providing the remuneration monitor the value-based activities to determine whether they are furthering the value-based purpose(s) and, if they are not, then the physician must cease referring DHS to the entity within 60 days of the determination.[26] Further, CMS is considering requiring a recipient contribution of 15 percent or some other percentage of the donor's cost of any nonmonetary remuneration paid under a value-based arrangement, although CMS raises concerns that such contribution may inhibit the adoption of such arrangements.[27] CMS solicits industry comments regarding these and other elements of the proposed exception.

iv. Indirect Compensation Arrangements to which New Value-Based Exceptions are Applicable (proposed 42 C.F.R. § 411.354(c)(4))

Because it believes that an indirect compensation arrangement that includes a value-based arrangement may not satisfy all of the requirements of the indirect compensation exception at 42 C.F.R. § 411.357(p), CMS proposes adding language to Section 42 C.F.R. § 354(c) to specify that when

the value-based arrangement is the link in the chain closest to the physician (i.e., the physician or physician organization in whose shoes the physician stands is a direct party to the value-based arrangement), the indirect compensation arrangement qualifies as a "value-based arrangement" for purposes of applying one of the three proposed value-based exceptions.[28] Notably, the link must be a compensation arrangement that meets the definition of a value-based arrangement under Stark, and must not be an ownership interest.

B. Fundamental Terminology and Requirements

CMS proposes various clarifications and revisions to existing regulatory requirements and definitions within Stark to provide clear, bright-line rules in order to reduce the burden of compliance and achieve the goals of the Regulatory Sprint to Coordinated Care. These proposed changes involve key terms that affect how industry stakeholders will approach Stark exceptions going forward and may affect recent and ongoing court cases.

i. Commercially Reasonable (42 C.F.R. § 411.351)

CMS proposes to include a definition for the term "commercially reasonable" under Stark and offers two alternative definitions. Under the first, "commercially reasonable" would mean the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, even if it does not result in profit for one or more of the parties involved.[29] Under the second, "commercially reasonable" would be defined as an arrangement that makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if it does not result in profit for one or more of the parties involved.[30]

ii. Volume or Value Standard and Other Business Generated Standard (42 C.F.R. § 411.354(d)(5) and (6))

CMS proposes to define and interpret the volume or value standard and the other business generated standard in the proposed regulations with two separate special rules for each standard to address whether compensation is paid from the entity to the physician or from the physician to the entity. For both standards, compensation takes into account the volume or value of referrals or other business generated only if the formula used to calculate the compensation includes the physician's referrals to, or other business generated for, the entity as a variable, resulting in an increase or decrease in compensation that: (1) for compensation paid by an entity to a physician,

positively correlates with the volume or value of the physician's referrals to the entity or the physician's generation of other business for the entity, and (2) for compensation paid by a physician to an entity, *negatively correlates* with the volume or value of the physician's referrals to the entity or the physician's generation of other business for the entity.[31] In addition, compensation will be deemed to take into account the volume or value of referrals to, or other business generated for, the entity if there is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement. CMS also reaffirms its prior position that productivity bonuses paid for services personally performed by an employed physician and compensation that is unit-based (and meets the conditions of the special rule at 42 C.F.R. § 411.354(d)(2)) are not based on the volume or value of referrals or other business generated.

iii. Patient Choice and Directed Referrals (42 C.F.R. § 411.354(d)(4))

CMS proposes revisions to the special rule on compensation that permits conditioning physician compensation upon referrals to a particular provider, practitioner or supplier by clarifying that the rule is applicable to bona fide employment relationships, personal service arrangements and managed care contracts and by specifying that: (1) the compensation must be consistent with fair market value, (2) the compensation or formula for determining the compensation must be set in advance for the duration of the arrangement, and (3) any changes to compensation or the formula for determining compensation must be made prospectively.[32] In addition, CMS proposes to include a requirement that the arrangement must comply with this revised special rule in the Stark exceptions for academic medical centers, bona fide employment relationships, personal service arrangements, physician incentive plans, group practice arrangements with a hospital, fair market value compensation, and indirect compensation arrangements.[33]

iv. Fair Market Value (42 C.F.R. § 411.351)

CMS proposes revising the definition of "fair market value" to remove any connection to the volume or value standard, as it reiterates that the two requirements are independent. The proposed modification to "fair market value" would include a general definition and definitions specifically applicable to the rental of equipment and the rental of office space in a manner that would reorganize, but not significantly differ from the statutory language used for the phrase.[34]

However, CMS is proposing changes to the definition of "general market value," which is included within the definition of "fair market value." The definition for "general market value" would be the

price that results from bona fide bargaining between the parties in the subject transaction on the date of the acquisition or when the arrangement was entered into, while "fair market value" relates to hypothetical parties in a hypothetical transaction.[35] This proposed change is intended to ease the burden on compliance with the fair market value requirement of many Stark exceptions.

C. Group Practice Modifications (42 C.F.R. § 411.352)

CMS proposes restructuring the group practice rules for profit shares and productivity bonuses to clarify and express affirmatively which profit shares and productivity bonuses are permissible. As it relates to profit sharing, CMS proposes that profit shares must be derived from "all" of the DHS of the practice, which must be aggregated and distributed in accordance with the special rule, and that a practice cannot distribute profits from different DHS using different methodologies.[36] With respect to productivity bonuses, CMS proposes to allow a group practice to pay a physician in the group profits from DHS that are directly attributable to the physician's participation in a VBE, and such remuneration would not be deemed to directly take into account the volume or value of the physician's referrals.[37]

D. Recalibrating the Scope and Application of the Regulations

CMS proposes revisions to, and deletions of, certain regulatory requirements that it finds unnecessary at this time. For example, CMS proposes to remove the requirement in various Stark exceptions that the arrangement comply with the AKS and other state and federal laws governing billing or claims submission, although this does not affect the parties' obligations under those laws or regulations.[38] CMS also proposes deleting the rules on the period of disallowance at 42 C.F.R. § 411.353(c)(1) in their entirety because they appear to be impractical and too narrow.[39] Instead, in an effort to encourage active, ongoing review of arrangements for Stark compliance, CMS provides general guidance as to how to remedy compensation problems and, when a remedy is not available, how to determine on a case-by-case basis when the period of disallowance ends.[40]

In addition, CMS proposes various revisions to definitions within Stark. For example, CMS proposes to revise the definition of "DHS" to clarify that for inpatient hospital services only (i.e., not outpatient or other services), a service is not a DHS payable, in whole or in part, by Medicare if furnishing the service does not affect the amount of the payment to the hospital under the inpatient prospective payment system (IPPS).[41] CMS also proposes revising the definition of "referral" to clarify that a referral is not an item or service for purposes of Stark.[42] Based on observations that parties are misusing the Stark exception for isolated transactions to

retroactively cure noncompliance, CMS proposes to independently define "isolated transaction" apart from the definition of a transaction and clarify its policy that a single payment for multiple or repeated services (e.g., services previously provided that were not compensated) does not constitute an isolated transaction.[43] CMS also proposes clarifying revisions to the definitions for physician and remuneration.

Further, CMS proposes to exclude from the meaning of "ownership and investment interests": (1) titular ownership or investment interests that exclude the ability or right to receive financial benefits of ownership or investment and (2) interests in an entity that arise from an employee stock ownership plan (ESOP) that is qualified under § 401(a) of the Internal Revenue Code.[44] CMS also proposes deleting the special rule for temporary noncompliance with signature requirements at 42 C.F.R. § 411.353(g) and deeming the writing requirement to be satisfied if the compensation arrangement satisfies all requirements of a Stark exception except for the writing or signature requirement and the required writing or signature(s) is obtained within 90 consecutive calendar days of the inception of the arrangement as set forth in newly proposed 42 C.F.R. § 411.354(e)(3).[45]

CMS would additionally distinguish the "set in advance" requirement from the "writing" requirement and would retract any previous suggestions that the rate of compensation must be in writing before furnishing the items or services in order to be "set in advance" by clarifying that while such a writing may deem the compensation to be set in advance, informal communications via email or text, internal notes to file, generally applicable fee schedules, similar payments between the parties from prior arrangements, and records of a consistent rate of payment over the entire course of the arrangement may also support that the compensation was set in advance, depending on the facts and circumstances.[46]

CMS also proposes to narrow the restrictions on exclusive use in the Stark exceptions for rental of office space and rental of equipment to define exclusivity as only excluding use by the lessor and any persons or entities related to the lessor (i.e., the lessees may share space and equipment with other persons and entities that are unrelated to the lessor and still meet the exclusivity requirement).[47] CMS proposes to remove the requirement that the physician practice sign a physician recruitment agreement if the practice does not receive a financial benefit from the recruitment arrangement (i.e., the practice receives remuneration and passes all, not part, of it through to the physician).[48] CMS proposes to revise the exception for certain arrangements with hospitals (remuneration unrelated to DHS) to make it less restrictive and applicable to protect remuneration that: (1) is not determined in a manner that takes into account the volume or value

of the physician's referrals for DHS, (2) is unrelated to the provision of patient care services (e.g., items, supplies, devices, equipment and space used in the diagnosis and treatment of patients and technology used to communicate with patients), and (3) involves services that could be provided by persons who are not licensed medical professionals.[49]

To better align the Stark regulatory and statutory exceptions for payments by a physician, CMS proposes revising the regulatory exception to: (1) limit its availability to protect compensation arrangements specifically addressed in a statutory exception (codified in the regulations at 42 C.F.R. §§ 411.357(a)-(h)), including arrangements for the rental of office space and equipment, and (2) no longer restrict its availability to protect compensation arrangements that are not for cash or cash equivalents and that may be addressed in other regulatory compensation exceptions including for space that is not office space, such as storage space or residential real estate.[50] Also, to provide further flexibility, CMS proposes expanding the fair market value compensation exception to make it available for the rental or lease of office space, including short-term rentals of less than one year in duration, under the same compensation restrictions applicable to the rental of equipment under the existing regulatory exception.[51]

With respect to the Stark exception for electronic health record (EHR) items and services, CMS proposes to expand the exception to incorporate donations of certain cybersecurity software and services to protect the EHR, remove the sunset provision, modify the definitions of "EHR" and "interoperable" to promote consistency with the 21st Century Cures Act, and restrict the donor from engaging in information blocking in connection with donated items.[52] Further, CMS solicits comments regarding the exception's 15 percent contribution requirement with regard to whether it should be reduced or eliminated for certain providers.[53]

With regard to the exception for assistance to compensate nonphysician practitioners, CMS proposes to clarify that services provided by the individual before he or she became an NPP do not constitute "NPP patient care services" for purposes of the exception's limitation on previous services performed.[54] In addition, the exception would be amended to require that the compensation arrangement between the hospital, federally qualified health center (FQHC) or rural health clinic (RHC) commences before the physician (or physician organization in whose shoes the physician stands) enters into the compensation arrangement with the NPP.[55]

In sum, the above-described proposed revisions and deletions to existing regulatory provisions is intended to remove compliance burdens while balancing the need to retain Stark's protections against program and patient abuse.

E. Providing Flexibility for Non-Abusive Business Practices

In addition to the newly proposed value-based exceptions, CMS also proposes two additional new exceptions relating to limited remuneration to a physician and cybersecurity technology and related services.

i. Limited Remuneration to a Physician (proposed 42 C.F.R. § 411.357(z))

Based on administering Stark and reviewing arrangements in the SRDP, CMS proposes a new exception to Stark based on a limited amount of remuneration being provided to a physician, even in the absence of documentation and where there the compensation is not set in advance, if: (1) the arrangement is commercially reasonable and for items or service actually provided by the physician (i.e., not a physician's immediate family member); (2) the amount of the remuneration to the physician is limited to $3,500 per calendar year (which would be adjusted for inflation similarly to the limit in the nonmonetary compensation exception); (3) the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, regardless of whether it results in profit; (4) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; (5) the remuneration does not exceed the fair market value for the items or services; and (6) compensation paid for the lease of office space or equipment or the use of the premises, equipment, personnel, items, supplies or services is restricted with respect to percentage-based and per-unit of service compensation in a similar manner to the Stark exceptions for indirect compensation arrangements and timeshare arrangements.[56] CMS notes that this exception can be used for multiple undocumented, unsigned arrangements and that this exception can be used in certain circumstances in conjunction with other exceptions to protect an arrangement during the course of a calendar year.[57]

ii. Cybersecurity Technology and Related Services (proposed 42 C.F.R. § 411.357(bb))

In an effort to improve cybersecurity within the healthcare industry by removing any perceived barriers to donations, CMS proposes a new Stark exception to protect arrangements set forth in writing involving nonmonetary remuneration consisting of certain types of cybersecurity technology and services. Specifically, the technology and services under the proposed exception must be necessary and used predominantly to implement, maintain, or reestablish cybersecurity. Also, the amount or nature of the technology or services and the physician's eligibility for them

cannot be determined in a manner that takes into account the volume or value of referrals or business generated between the parties, and the physician and physician's practice (including the practice's employees and staff) cannot make the receipt, amount, or nature of the technology or services a condition of doing business with the donor.[58]

CMS proposes a broad range of cybersecurity services including services associated with developing, installing, and updating cybersecurity software; cybersecurity training services; cybersecurity services for business continuity and data recovery; "cybersecurity as a service" models; cybersecurity risk assessments and analyses; and services associated with sharing information about known cyber threats and assisting in responding to such threats.[59]

Notably, "technology" is not defined to include hardware because CMS believes that hardware is usually multifunctional and would not likely be necessary and used predominantly for these purposes.[60] That said, CMS is considering two alternative proposals to allow for the donation of certain hardware: (1) that is necessary for cybersecurity, provided that it is stand-alone and serves only cybersecurity purposes; or (2) that the donor has determined is reasonably necessary based on cybersecurity risk assessments of its own organization and the proposed recipient.[61] CMS is also considering whether a 15 percent financial contribution from the recipient, similar to that in the current EHR exception, would be appropriate and, if so, whether there should be any reductions or exceptions to that contribution.[62]

2. AKS and CMP Law Proposed Regulations Overview

OIG's proposed regulations for the AKS prospectively create new safe harbors for certain value-based arrangements and donations of cybersecurity technology and related services. In addition, the proposed regulations revise existing AKS safe harbors for personal services and management contracts, warranties, EHR arrangements, and local transportation. The proposed regulations would also add a new safe harbor under the CMP law for certain telehealth technologies offered to patients who receive in-home dialysis. OIG states that the purpose of the proposed regulations is to remove potential barriers to coordination of care and delivery of value-based care in a manner that allows for beneficial innovations in healthcare delivery that are useful for a range of individuals and entities in the coordination and management of patient care while balancing OIG's concerns about misuse or perpetuation of fraud.[63] If finalized, the proposed regulations' new safe harbors and revisions to existing safe harbors would apply prospectively.

OIG notes that while its proposed new safe harbors for cybersecurity technology and services and

modifications to the existing AKS safe harbor for EHR items and services are closely aligned with CMS' proposed regulations, OIG's proposed regulations for value-based arrangements differ from and are more restrictive than CMS' comparable proposals due to the differences in statutory structures and penalties and the recognition that the AKS, as a criminal, intent-based statute, should serve as a backstop protection for certain arrangements that may be permitted under Stark.[64]

A. New Value-Based Enterprise Safe Harbors (proposed 42 C.F.R. § 1001.952(ee), (ff), (gg), (hh), and (ii))

OIG proposes three new value-based safe harbors: (1) care coordination arrangements; (2) value-based arrangements with substantial downside risk; and (3) value-based arrangements with full financial risk. In general, these value-based safe harbors operate similarly to their Stark counterparts in that they protect remuneration paid under value-based arrangements (which may involve public, commercial and private insurer agreements) between or among the VBE and one or more of its VBE participants, or between or among VBE participants within the same VBE, for the provision of at least one value-based activity that is reasonably designed to achieve at least one value-based purpose of the VBE for a target patient population. In addition to these three proposed safe harbors, OIG is proposing a safe harbor to protect arrangements for patient engagement and support to improve quality, health outcomes, and efficiency, and a safe harbor to protect CMS-sponsored model arrangements and patient incentives.

Similar to Stark's value-based exceptions, newly defined terminology is essential to determining compliance with the AKS value-based safe harbors. The relevant terminology is similar to that under CMS' proposed regulations and includes VBE, value-based activity, value-based arrangement, VBE participant, value-based purpose, and target patient population. Whereas most of these terms are defined similarly to their Stark counterparts, there are some key differences pertaining to the meaning of a "VBE participant." Specifically, while CMS contemplates excluding certain entities from the definition of a "VBE participant," OIG would, in fact, exclude pharmaceutical manufacturers; manufacturers, distributors, or suppliers of DMEPOS; and laboratories from the meaning of a "VBE participant."[65] Similar to CMS, OIG is also considering excluding pharmacy benefit managers, wholesalers, distributors, and certain medical device manufacturers from the definition of VBE participant, but does not propose doing so as part of the proposed regulations.

Also similar to CMS, OIG confirms that a "value-based activity" does not include making a referral

for purposes of the AKS value-based safe harbors.[66] In addition, the safe harbors do not apply to protect ownership or investment interests in the VBE. However, unlike CMS, to further protect against fraudulent or abusive practices, OIG is considering and solicits comments on precluding some or all of the protection under the proposed value-based safe harbors for value-based arrangements between commonly owned entities.[67]

i. Care Coordination Arrangements Safe Harbor (proposed 42 C.F.R. § 1001.952(ee))

The care coordination arrangements safe harbor is proposed to protect in-kind remuneration exchanged between VBE participants as part of a value-based arrangement and does not require any party to assume downside financial risk. Each offer of remuneration between VBE participants would need to be separately analyzed for purposes of this safe harbor, and the safe harbor would not protect any remuneration from individuals or entities outside of the VBE.[68] The proposed safe harbor is similar to the value-based arrangements exception proposed by CMS, with some notable differences. Specifically, the safe harbor would require the VBE participants to establish a specific evidence-based value outcome measure(s) against which the recipient would be measured and which the parties reasonably anticipate will advance the coordination and management of care of the target population, while the proposed Stark exception would permit, but would not require, such standards.[69] In addition, the safe harbor would require that the recipient pay at least 15 percent of the offeror's cost of the in-kind remuneration in advance if it involves a one-time cost, and on an ongoing basis if it involves an ongoing cost.[70]

Further, the proposed safe harbor would require that the VBE, VBE participant or the VBE's accountable body monitor the value-based activities, and if the accountable body determines that the arrangement is unlikely to further coordination of care or achieve the outcome measures, or if the arrangement has resulted in material deficiencies in the quality of care, then the arrangement would be required to terminate within 60 days of the determination. In addition, the safe harbor would not permit marketing items or services to patients or engaging in patient recruitment activities.[71] OIG is also considering the following with regard to the safe harbor: (1) requiring that the VBE's accountable body or responsible person make certain bona fide determinations, (2) requiring that the remuneration be fair market value and not take into account the volume or value of referrals, (3) precluding cost-shifting, and (4) making certain exceptions for dialysis providers.[72] OIG solicits comments regarding these considerations and other elements of the proposed safe harbor.

ii. Value-Based Arrangements with Substantial Downside Financial Risk Safe Harbor (proposed 42 C.F.R. § 1001.952(ff))

The value-based arrangements with substantial downside financial risk safe harbor is proposed to protect both monetary and in-kind remuneration exchanged between a VBE and VBE participant pursuant to a value-based arrangement in which the VBE (or VBE participant acting on behalf of the VBE) has assumed, or is contractually required to assume within six months, substantial downside risk from a payor for providing or arranging for the provision of items and services to a target patient population. In general, "substantial downside financial risk" would mean that, for the entire term of the value-based arrangement, the VBE must take on risk in the form of: (1) shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, (2) a repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, (3) a prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, or (4) a partial capitated payment from a payor for a set of items or services for the target population that reflects a discount of at least 60 percent of the total expected fee-for-service payments based on historical expenditures.[73]

For purposes of the safe harbor, VBE participants receiving remuneration would be required to "meaningfully share" in the VBE's substantial downside financial risk, which means that a VBE participant would: (1) be at risk for at least eight percent of the amount that the VBE is at risk for under the VBE's agreement with the payor, (2) be subject to risk under a partial or full capitation payment or similar methodology (excluding the Medicare IPPS and the like), or (3) if the VBE participant is a physician, be subject to the condition that the payment meets the proposed Stark exception for value-based arrangements with meaningful downside financial risk (proposed 42 C.F.R. § 411.357(aa)(2)).[74] The safe harbor would also require that various terms of the value-based arrangement be set forth in a signed writing in advance of, or contemporaneous with, the commencement of the arrangement. Further, the safe harbor incorporates many of the requirements of the proposed care coordination arrangements safe harbor.

iii. Value-Based Arrangements with Full Financial Risk Safe Harbor (proposed 42 C.F.R. § 1001.952(gg))

The value-based arrangements with full financial risk safe harbor is proposed to protect both monetary and in-kind remuneration exchanged between the VBE and a VBE participant pursuant to a value-based arrangement that is set out in a writing signed by the parties in which the VBE (or VBE participant acting on behalf of the VBE) assumes, or is contractually obligated to assume

within six months, full financial risk from a payor for a target patient population for at least one year pursuant to a signed writing with the payor.[75] For purposes of the safe harbor, "full financial risk" would mean that the VBE is financially responsible for the cost of all items and services covered by the payor for each patient in the target patient population and is prospectively paid by the payor.[76] While this safe harbor incorporates some requirements of the proposed value-based arrangements with substantial downside financial risk safe harbor, OIG intends for this safe harbor to provide the greatest flexibility because the VBE assumes full financial risk.

iv. Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes and Efficiency Safe Harbor (proposed 42 C.F.R. § 1001.952(hh))

The arrangements for patient engagement and support to improve quality, health outcomes, and efficiency safe harbor is proposed to protect nonmonetary patient engagement tools and support furnished by a VBE participant directly to a patient in a target patient population. The patient engagement tool or support must not be contributed or funded by any individual or entity outside of the VBE and it must have a direct connection to the coordination and management of care of the target patient population.[77] The patient engagement tool and support must meet other requirements as well, including that it be recommended by the patient's licensed healthcare provider and advance certain goals related to the patient's treatment. Further, the aggregate value of such patient engagement tools and supports furnished to a patient by a VBE participant cannot exceed $500 per year, except as determined in good faith, based on the individual patient's financial need.[78] OIG notes that some VBEs may not be able to prospectively identify individual patients in the target patient population (e.g., in an accountable care organization (ACO) under CMS-sponsored models) and requests industry feedback regarding any challenges presented by the proposed safe harbor.[79]

v. CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Initiatives Safe Harbor (proposed 42 C.F.R. § 1001.952(ii))

The CMS-sponsored model arrangements and CMS-sponsored model patient initiatives safe harbor is proposed to protect monetary and in-kind remuneration between or among CMS-sponsored model parties during their participation in a CMS-sponsored model arrangement or a CMS-sponsored model patient initiative in a model for which CMS has determined that the safe harbor is available if certain requirements are met. The goal of this safe harbor is to standardize AKS compliance for CMS-sponsored models by applying uniform requirements and, accordingly, OIG intends that this safe harbor may be used as an alternative to fraud and abuse waivers.[80]

Notably, unlike the above four proposed value-based safe harbors that exclude pharmaceutical manufacturers; manufacturers, distributors, and suppliers of DMEPOS; and laboratories from their protection, this safe harbor would not exclude these entity types from protection under the safe harbor if they participate in the CMS-sponsored model, meet all safe harbor requirements, and CMS determines that the safe harbor applies.[81]

B. New Proposed Cybersecurity Technology and Related Services Safe Harbor (proposed 42 C.F.R. § 1001.952(jj))

The proposed cybersecurity technology and related services safe harbor would protect nonmonetary donations of certain types of cybersecurity technology and services, excluding hardware, provided that they are used predominantly to implement and maintain effective cybersecurity and meet certain requirements.[82] The terms of this proposed AKS safe harbor are similar to the corresponding proposed Stark exception. However, unlike CMS, OIG is not considering a financial contribution from the recipient. Also, OIG does not propose to restrict the scope of recipients protected under the safe harbor, which means that the safe harbor may be available to patient recipients.[83] Accordingly, among other comments OIG requests pertaining to this safe harbor, OIG requests comments regarding situations in which cybersecurity technology and related services may appropriately be provided to a patient.

C. Proposed Modifications to Existing AKS Safe Harbors

OIG proposes various modifications to safe harbors within the proposed regulations. For example, OIG proposes to revise the EHR safe harbor, at 42 C.F.R. § 1001.952(y), in a similar manner to the changes that CMS proposes making to the EHR items and services exception to Stark discussed above.[84]

In addition, OIG proposes modifying the personal services and management contracts safe harbor at 42 C.F.R. § 1001.952(d) to reduce the burden of non-compliance by removing the requirements pertaining to services provided on a part-time, periodic, or sporadic basis, and most notably, by removing the requirement that the "aggregate" compensation to be paid over the term of the agreement be set in advance.[85] Instead, OIG proposes requiring only that the *methodology* of determining the compensation over the term of the agreement be set in advance. This proposal would allow formulaic compensation, such as percentage-based, or per relative value unit (RVU), consistent with how CMS implements the set in advance requirement in the Stark

exceptions. OIG also proposes expanding that safe harbor by including a second provision within the safe harbor that protects outcomes-based payments that meet certain safe harbor requirements and that reward: (1) the improvement in patient or population health by achieving outcome measures or (2) the achievement of outcome measures that appropriately reduce payor costs while improving or maintaining improved quality of care for patients.[86] However, payments that relate to the achievement of internal cost savings for the principal, and payments made (directly or indirectly) by a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of DMEPOS; or a laboratory would be excluded from protection under the safe harbor.[87]

OIG also proposes modifications to the warranties safe harbor at 42 C.F.R. § 1001.952(g) to: (1) protect warranties for one or more items and related services (i.e., bundled warranties) upon meeting certain requirements, (2) exclude beneficiaries from the reporting requirements applicable to buyers, and (3) include a definition of warranty to clarify that the safe harbor applies to Food and Drug Administration-regulated drugs and devices.[88] Notably, the safe harbor would not protect warranties covering only services, as the services must be tied to one or more related items.[89]

OIG proposes modifications to the local transportation safe harbor at 42 C.F.R. § 1001.952(bb) to: (1) expand the distance in which patients residing in rural areas may be transported from 50 to 75 miles and (2) remove the distance limit on transportation of a patient discharged from a healthcare facility to the patient's residence.[90] OIG also clarifies its position that ride-sharing services may be protected under the safe harbor to the same extent that protects other forms of transportation.[91]

D. New ACO Beneficiary Incentive Programs Safe Harbor (proposed 42 C.F.R. § 1001.952(kk))

The ACO beneficiary incentive programs safe harbor is proposed by OIG to codify the statutory exception by adopting language nearly identical to the statutory language. The safe harbor would protect incentive payments made by ACOs to assigned beneficiaries under a beneficiary incentive program established under, and in accordance with requirements set forth in Section 1899(m) of the Social Security Act.[92]

E. Proposed Amendment to CMP Statute for Telehealth for In-Home Dialysis

OIG proposes amending the Beneficiary Inducements provision to the CMP Statute to protect, as an exception to prohibited remuneration, certain telehealth technologies related to in-home

dialysis services. To be protected, in addition to meeting other regulatory requirements, such technologies: (1) would have to be furnished to the patient by the provider or renal dialysis facility that is currently providing end stage renal disease (ESRD) care to the patient, (2) could not be offered as part of any advertisement or solicitation, and (3) would be required to be provided for the purpose of furnishing telehealth services related to the patient's ESRD and not be of excessive value or duplicative of technology that the patient already owns.[93] For purposes of the exception, "telehealth technologies" generally includes certain multimedia communications equipment including audio and video equipment permitting two-way, real-time interactive communication between the patient and the practitioner, and excludes phones, fax machines and email systems.[94]

3. Conclusion

CMS and OIG have made extensive efforts to modernize Stark, the AKS and the Beneficiary Inducements provision of the CMP Statute to ease compliance burdens and promote value-based care. These proposed sweeping changes are extensive and detailed. CMS and OIG further evidence their intentions to provide appropriate flexibility while balancing the need for proper safeguards by soliciting numerous comments related to both the proposed regulatory revisions and the agencies' considerations for additional changes that are not included within the proposed regulatory revisions. Industry stakeholders should take full opportunity to consider the impacts of these proposed regulations and comment on issues relevant to their businesses by December 31, 2019.

1 The Regulatory Sprint to Coordinated Care was announced by HHS in 2018 as a focus on "identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care." 83 Fed. Reg. 29524 (June 25, 2018). The Regulatory Sprint to Coordinated Care focuses on Stark, the AKS, HIPAA and 42 C.F.R. Part 2. *Secretary Azar Highlights Recognition of HHS as Top Agency for Regulatory Reform*, U.S. Department of Health & Human Services Press Release, October 17, 2018, *available at:* https://www.hhs.gov/about/news/2018/10/17/secretary-azar-highlights-recognition-of-hhs-as-top-agency-for-regulatory-reform.html.

2 *HHS Proposes Stark Law and Anti-Kickback Statute Reforms to Support Value-Based and Coordinated Care*, U.S. Department of Health & Human Services Press Release, October 9,

2019, *available at:* https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html.

3 *See Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule (CMS-1720-P)*, Centers for Medicare & Medicaid Fact Sheet, October 9, 2019, *available at*: https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule; *see also*, *HHS Office of Inspector General Fact Sheet: Notice of Proposed Rulemaking OIG-0936-AA10-P*, October, 2019, *available at*: https://oig.hhs.gov/authorities/docs/2019/CoordinatedCare_FactSheet_October2019.pdf.

4 *See* 84 Fed. Reg. 55772 (Oct. 17, 2019).

5 *See id. at 55700, 55772.*

6 *See id.* at 55771-55772.

7 *Id.* at 55772-55773.

8 *Id.* at 55778-55789.

9 *Id.* at 55773, 55775, and 55776.

10 *Id.* at 55774.

11 *Id.* at 55777. However, note that the methodology used to determine the amount of remuneration is required to be set in advance in two of the proposed exceptions. *Id.*

12 *Id.* at 55773.

13 *Id.* at 55775-55776.

14 *See id.* at 55775.

15 *See id.* at 55788.

16 *Id.* at 55779.

17 *See id.* at 557790-55780.

18 *See id.* at 55780.

19 *See id.*

20 *Id.* at 55781.

21 *Id.* at 55781-55782.

22 *See id.* at 55782.

23 *See id.* at 55781.

24 *Id.* at 55783.

25 *Id.* at 55784.

26 *See id.* at 55785.

27 *See id.* at 55785-55786.

28 *Id.* at 55786.

29 *Id.* at 55790.

30 *See id.*

31 *See id.* at 55793.

32 *See id.* at 55796.

33 *Id.* at 55795.

34 *Id.* at 55797.

35 *See id.* at 55798-55799.

36 *See id.* at 55801.

37 *Id.* at 55800.

38 *Id.* at 55803-55804.

39 *See id.* at 55809-55810.

40 *See id.* at 55811.

41 *See id.* at 55805.

42 *Id.* at 55806.

43 *See id.* at 55808.

44 *See id.* at 55811 – 55812.

45 *See id.* at 55814.

46 *Id.* at 55814-55815.

47 *See id.* at 55815.

48 *Id.* at 55816.

49 *See id.* at 55818-55819.

50 *See id.* at 55820-55821.

51 *See id.* at 55821-55822.

52 *Id.* at 55822-55824. The 21st Century Cures Act is available at: https://www.govinfo.gov/content/pkg/PLAW-114publ255/html/PLAW-114publ255.htm.

53 *Id.* at 55825.

54 *See id.* at 55826.

55 *Id.* at 55827. In general, Federally Qualified Health Centers are community-based healthcare providers that receive funds from the Health Resources & Services Administration (HRSA) Health Center Program to provide primary care services in underserved areas. For more information *see*: https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html. Rural Health Clinics are certified as such by CMS and generally provide primary care and preventative health services in underserved rural areas. For more information *see*: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/RuralHlthClinfctsht.pdf.

56 *See id.* at 55828-55829.

57 *Id.* at 55829-55830.

58 *See id.* at 55833-55834.

59 *Id.* at 55832.

60 *See id.* at 55831.

61 *See id.* at 55831, 55834.

62 *See id.* at 55835.

63 *See id.* at 55694-55696.

64 *Id.* at 55696.

65 *Id.* at 55703-55704.

66 *Id.* at 55703.

67 *See id.* at 55707.

68 *See id.* at 55708, 55710-55711.

69 *See id.* at 55710.

70 *See id.* at 55711.

71 *Id.* at 55712.

72 *See id.* at 55714.

73 *Id.* at 55717.

74 *Id.* at 55718.

75 *See id.* at 55720.

76 *Id.* at 55719.

77 *See id.* at 55722, 55727.

78 *See id.* at 55726-55728.

79 *Id.* at 55723.

80 *See id.* at 55730-55731.

81 *Id.* at 55731.

82 *See id.* at 55733.

83 *See id.* at 55737-55738.

84 *Id.* at 55740.

85 *Id.* at 55744.

86 *Id.* at 55745.

87 *See id.* at 55746.

88 *Id.* at 55748, 55750.

89 *See id.* at 55749.

90 *See id.* at 55750-55751.

91 *Id.* at 55752.

92 *Id.* at 55753.

93 *See id.* at 55754.

94 *Id.* at 55755.

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