King & Spalding
Client Alert

OCTOBER 14, 2019

For more information, contact:

Kyle Gotchy
+1 916 321 4809
kgotchy@kslaw.com

Robert M. Keenan
+1 404 572 3591
rkeenan@kslaw.com

Adam Robison
+1 713 276 7306
arobison@kslaw.com

Kim H. Roeder
+1 404 572 4675
kroeder@kslaw.com

Catherine (Kate) Stern
+1 404 572 4661
kstern@kslaw.com

King & Spalding

Atlanta
1180 Peachtree Street, NE
Atlanta, Georgia 30309
Tel: +1 404 572 4600

Houston
1100 Louisiana Suite 4000
Houston, Texas 77002
Tel: +1 713 751 3200

Sacramento
621 Capitol Mall, Suite 1500
Sacramento, CA 95814
Tel: +1 916 321 4800

Major Changes Proposed to Stark Rules, Anti-Kickback Statute Safe Harbors and the Beneficiary Inducements CMP

More Value than Value-Based Arrangements

CMS and OIG released highly anticipated proposed changes to the rules implementing the Stark Law, the safe harbors issued under the Anti-Kickback Statute (AKS) and the beneficiary inducements provision in the civil monetary penalties law (the Beneficiary Inducement CMP) on October 9, 2019 (the Proposed Rules). The Proposed Rules address value-based arrangements, propose major changes to other key Stark Law concepts and definitions, address the donation of cybersecurity technology and services, and create flexibility to provide patient incentives in value-based arrangements and with respect to telehealth. The Proposed Rules would:

- Create AKS safe harbors for value-based arrangements;
- Create a Stark exception for value-based arrangements;
- Modify the personal services AKS safe harbor;
- Revise Stark exceptions to address value-based arrangements;
- Modify key Stark regulatory definitions (such as FMV);
- Create Stark special rules for the volume and value of referrals;
- Ease compliance with the Stark writing requirement;
- Create a Stark exception for limited remuneration to physicians;
- Modify other Stark exceptions to address industry comments;
- Create an AKS safe harbor for cybersecurity technology;
- Create a Stark exception for cybersecurity technology;
- Revise the EHR donation AKS safe harbor and Stark exception;
- Create AKS safe harbors for patient incentives;
- Create a telehealth exception to the Beneficiary Inducement CMP;
- Revise the local transportation AKS safe harbor; and
- Revise the AKS safe harbor for warranties.

Comments are due by December 31, 2019. This Client Alert describes the key proposals. King & Spalding will be hosting a webinar in the coming weeks to discuss these Proposed Rules in greater detail.

NEW STARK LAW EXCEPTION AND AKS SAFE HARBORS FOR VALUE-BASED ARRANGEMENTS

CMS proposed one new Stark Law exception that essentially corresponds to three new proposed AKS safe harbors. At the core of each is the protection of "value-based arrangements," which are arrangements to provide at least one value-based activity for a target patient population between or among, what is termed by the agencies as the "value-based enterprise" or "VBE" and one or more of its VBE participants or VBE participants within the same VBE. A "value-based activity" is either the provision of an item or service or the taking or refraining from taking an action that is reasonably designed to achieve at least one value-based purpose of the VBE and does not include making a referral. The agencies propose that a "value-based purpose" consist of coordinating and managing the care of a target patient population, improving the quality of care for a target patient population, appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population, or transitioning from healthcare delivery and payment mechanisms based on the volume of items and services provided to those based on quality and controlling costs for a target population.

"Value-based enterprise" or "VBE" is used by the agencies to mean two or more VBE participants, which are individuals or entities that engage in at least one value-based activity as part of a VBE, (i) collaborating to achieve at least one value-based purpose; (ii) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the VBE; (iii) that have an accountable body or person responsible for financial and operational oversight of the VBE; and (iv) that have a governing document that describes the VBE and how the VBE participants intend to achieve its value-based purpose(s). OIG proposes that a lab, DME supplier, pharmaceutical manufacturer or distributor may not be a VBE participant.

Notably, the proposed Stark Law exception does not require that the compensation paid pursuant to a value-based arrangement be set in advance, fair market value or that it not be determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated between the parties (unless the remuneration is conditioned on the physician's referrals). CMS shares commenters' concerns that these requirements conflict with collaborative models. CMS states that it has instead proposed a "carefully woven fabric of safeguards, including requirements incorporated through the applicable value-based definitions."

Both the proposed Stark Law exception and three AKS safe harbors impose fewer requirements as the VBE generally assumes more financial risk. The applicable requirements to protect a value-based arrangement depend on whether: (i) the VBE has assumed full financial risk; (ii) the VBE participant, and the VBE in the case of the safe harbor, have assumed meaningful or substantial financial risk; or (iii) less than meaningful substantial financial risk is assumed by the VBE.

Regardless of risk level, all three of the proposed OIG safe harbors require that: (1) remuneration exchanged between the VBE and VBE participant not induce the VBE or VBE participants to reduce or limit medically necessary items or services furnished to any patient and not be funded by or result from the contributions of, any individual or entity outside of the VBE; (2) the value-based arrangement not include marketing to patients or engaging in patient recruitment activities; and (3) the VBE or VBE participants not take into account the volume or value of or condition remuneration on referrals of patients who are not part of the target population or business covered under the value-based arrangement. OIG recognizes that VBE participants may encourage referrals of the target population for value-based activities.

Similarly, all categories of the proposed Stark Law exception require: (1) remuneration be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target population; (2) remuneration not be an inducement to reduce or limit medically necessary items or services to any patient; (3) remuneration not be conditioned

on referrals of patients who are not part of the target population or business not covered under the value-based arrangement; and (4) 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 satisfy the applicable requirements for special rules on compensation.

We discuss below key additional requirements that vary according to the level of risk assumed and what it means for the VBE or VBE participant to assume risk.

Value-Based Arrangements with Full Financial Risk

The least onerous requirements would apply to remuneration under a value-based arrangement when the VBE is at full financial risk. "Full financial risk" would mean that the VBE is financially responsible for the cost of all patient care items and services covered by the payor prospectively for each patient in the target patient population for a specified period of time. The Stark exception would require full financial risk for the duration of the value-based arrangement, with the AKS safe harbor requiring a signed writing with the payor evidencing full financial risk for at least one year.

When the VBE assumes full financial risk, only the requirements for the Stark Law exception listed in the preceding section would apply. In addition to the requirements in the preceding section, OIG proposes the following additional requirements: (1) the value-based arrangement must be in a signed writing specifying material terms, the value-based activities and be for a period of at least one year; (2) the VBE participant may not claim payment from a payor for items or services covered under the value-based arrangement; (3) the remuneration between the VBE and the VBE participant must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be coordination and management of the care for the target population and may not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and (4) the VBE must provide for or arrange an operational utilization review program and a quality assurance program that protects against underutilization and specifies patient goals.

Value-Based Arrangements with Meaningful or Substantial Downside Risk

Additional requirements would apply to value-based arrangements when "meaningful" (CMS's term) or "substantial" (OIG's term) downside financial risk is assumed. OIG's proposed safe harbor requires that the VBE assume substantial downside financial risk from a payor for providing or arranging for the provision of items and services for a target population. CMS's proposal does not include this requirement. OIG proposes substantial downside financial risk to mean risk for the entire term of the value-based arrangement in one of four forms: (1) shared savings with a 40% repayment obligation of shared losses; (2) a repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20% of any total loss; (3) a prospectively paid population-based payment for a defined subset of the total cost of care for a target population; or (4) a partial capitated payment from the payor for a set of items and services for the target population that reflects at least a 60% discount of the total expected FFS payments.

CMS proposes that a physician must be at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE for the duration of the value-based arrangement. CMS proposes to define "meaningful downside financial risk" as meaning the physician either is responsible for paying the entity at least 25% of the value of the remuneration the physician receives under the value-based arrangement or is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target population for a period of time.

OIG likewise proposes to require that a VBE participant meaningfully share in the VBE's substantial downside financial risk under the value-based arrangement under one of three methodologies. One methodology is satisfaction of the Stark Law exception for value-based arrangements with meaningful downside financial risk if the VBE participant is a

physician. The other two methodologies are: (1) a risk-sharing payment pursuant to which the VBE participant is at risk for eight percent of the amount for which the VBE is at risk under its agreement with the applicable payor; or (2) a partial or full capitation payment or similar payment methodology, excluding the Medicare IPPS or like payment methodology.

For value-based arrangements with meaningful downside financial risk, the Stark Law exception imposes all of the same requirements as it does when the VBE is at full financial risk, with the addition of two requirements. These two additional requirements include that (1) a description of the nature and extent of the physician's downside financial risk must be in writing, and (2) the methodology used to determine the amount of the remuneration must be set in advance of the value-based activities for which remuneration is to be paid.

The proposed AKS safe harbor requires that: (1) the value-based arrangement be in a signed writing specifying material terms, which includes more information than is required when the VBE assumes full financial risk; (2) the remuneration between the VBE and the VBE participant: (i) 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 and that are set forth the writing requirement; (ii) must be directly connected to one or more of the VBE's value-based purposes, at least one of which must be coordination and management of the care for the target population; and (iii) may not include the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership or investment interest; and (3) the value-based arrangement not place any limit on the VBE participant's ability to make decisions in the best interest of their patients or direct or restrict referrals to a particular practitioner, provider or supplier if a patient or payor selects a different provider, practitioner or supplier.

Value-Based Arrangements with No Financial Downside Risk

If neither full financial risk nor meaningful or substantial downside financial risk are assumed, then the value-based arrangement must satisfy more onerous requirements.

Some general requirements exist in the proposals by both agencies. The terms of the value-based arrangement, or any material change to the value-based arrangement, must be in a signed writing, with OIG specifically requiring that the writing be made prior to or contemporaneous with the start of the value-based arrangement. Although the writing requirements differ, they generally both require: (i) a description of the value-based activities to be undertaken by the parties; (ii) a description of the target population; (iii) a description of the remuneration for the AKS safe harbor, and a description of the type or nature of the remuneration for the Stark Law exception; and (iv) the performance or quality standards against which the recipient will be measured. The remuneration must be related to the value-based activities for the target population and may not be not conditioned upon referrals of patients who are not part of the target population or business not covered under the value-based arrangement.

The proposed AKS safe harbor would require the VBE participants to establish one or more specific evidence-based, value outcome measures that the parties reasonably anticipate will advance the coordination and management of care of the target population and against which the recipient of remuneration in a value-based arrangement would be measured. On the other hand, the proposed Stark Law exception, would not require the recipient be measured against any standards, but if the recipient is subject to outcome measures, the measures must be objective, measurable, made prospectively and set forth in writing.

Notably, OIG proposes that remuneration be in-kind, that the recipient pay at least 15% of offeror's cost of the remuneration in advance, and that such cost and percentage contribution must be in the signed writing. The Stark Law exception would require that the methodology used to determine the amount of remuneration be in the writing and set in advance of the value-based activities for which the remuneration is paid, but it does not require a minimum recipient contribution.

OIG also proposes the following additional requirements, among others. OIG would require the value-based arrangement be commercially reasonable. Further, a VBE participant or the VBE's accountable body or responsible person must monitor, assess and report on the coordination and management of care for the for the target population in the value-based arrangement, any deficiencies in the quality of care and progress towards achieving the evidence-based, valid outcome measure in the arrangement. The parties must terminate the arrangement within 60 days in certain scenarios.

New Safe Harbor for CMS-Sponsored Models and Model Patient Incentives

OIG proposes a new safe harbor to protect arrangements entered into and patient incentives offered as part of a CMS-sponsored model, which include the Medicare Shared Savings Program (MSSP) and other models tested by the CMS Innovation Center. Under the proposed safe harbor, several requirements must be met to protect a CMS-sponsored model arrangement or a CMS-sponsored model patient incentive. OIG states that parties within CMS-sponsored models for which OIG has issued fraud and abuse waivers may continue to use applicable CMS-sponsored waivers or may choose to comply with this new safe harbor or any other AKS safe harbor or CMP exception. Notably, CMS does not propose a corresponding Stark Law exception for CMS-sponsored models. CMS takes the position that CMS-sponsored model arrangements must either satisfy one of the value-based arrangements exceptions or one of the applicable waivers, but the agency notes that it believes that the value-based arrangements exceptions would eliminate the need for any new waivers. CMS, however, solicits feedback on this issue.

OTHER PROPOSED STARK LAW AND AKS CHANGES RELATED TO VBE PARTICIPATION

Proposed Change to Group Practice Definition

CMS states that it shares commenters' concerns that current regulatory language in the special rules for profit sharing could be interpreted to discourage physician participation in value-based payment models. Therefore, CMS proposes to revise the special rules for profit shares and productivity bonuses in the group practice definition by permitting profits from DHS that are directly attributable to a physician's participation in a VBE to be distributed to the participating physician.

Proposed Special Rule for Indirect Compensation Arrangements with Value-Based Arrangements

CMS proposes that indirect compensation arrangements including a value-based arrangement directly with a physician, or a physician organization in whose shoes the physician stands, can only qualify for the indirect compensation exception, the new value-based arrangements exception, or one of the exceptions that protect both ownership and compensation arrangements (such as physician services, in-office ancillary services, services of certain managed care organizations to enrollees, and academic medical centers). Given that CMS is also proposing to codify a position that it has previously only espoused in preamble commentary that an indirect compensation arrangement may be protected only by the indirect compensation exception or one of the exceptions covering both ownership and compensation arrangements, CMS believes that it is actually providing more flexibility to indirect compensation arrangements that include a value-based arrangement by explicitly permitting the use of the value-based arrangements exception. CMS's rationale is that some indirect compensation arrangements with value-based arrangements would not qualify for the indirect compensation exception if the compensation to the physician is not fair market value or varies with or otherwise takes into account the volume or value of referrals or other business generated by the physician for the entity.

OIG Personal Services and Management Contracts Safe Harbor

OIG also proposes to protect "outcomes-based payments" under the personal services and management contracts safe harbor if several criteria are met. Among others, the criteria include that the methodology for determining the aggregate compensation be set in advance, commercially reasonable, consistent with fair market value and not determined in a

manner that *directly* takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made by a Federal healthcare program. OIG proposes to define "outcomes-based payments" as "payments from a principal to an agent that: (i) reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients." The agency also seeks input on whether it should include in the definition the specific types of payment arrangements that would qualify, and whether they should be defined, including shared savings payments, shared losses payments and gainsharing payments, among others.

OTHER PROPOSED MODIFICATIONS TO THE STARK LAW RULES

In addition to proposing new exceptions for value-based arrangements, the proposed amendments to the Stark rules address a number of other points, including the addition of definitions of key terms, the addition of a new compensation exception, a loosening of restrictions in rules addressing certain statutory exceptions, and clarification of certain points of confusion in the industry. Key modifications in the Stark rules as proposed by CMS are summarized below. A few general points stand out in the discussion of these proposals by CMS in its preamble commentary:

- A stated purpose of the Proposed Rules is to reexamine whether the agency has held true to the intention stated in the Phase I rulemaking to interpret the referral and billing prohibition narrowly and the exceptions broadly. Several proposed modifications would, if applied in keeping with the agency's commentary, recalibrate the scope and application of the Stark regulations.
- In addition, in light of concerns raised by providers in response to the RFI and the interpretation of the Stark rules adopted in certain court decisions, CMS takes the opportunity to clarify its policy with respect to the application of the "volume or value of referrals" standard and the meaning of "commercially reasonable."
- The Proposed Rules are responsive to comments received in response to the RFI. These proposals also reflect the agency's experience in the Self-Referral Disclosure Protocol, including reports submitted by providers disclosing arrangements that CMS either did not think actually violated the law or that presented no risk of harm to the program.
- The Proposed Rules would carve out a broader interpretation for certain compensation exceptions that, through prior rulemakings, had been so narrowly construed as to be of little utility to the industry. These include the exceptions for payments made by physicians, as well as compensation unrelated to designated health services.
- Certain proposals would provide some breathing room for situations in which documentation of an arrangement lags payment for services and would establish a new exception for certain arrangements involving a "de minimis" level of compensation ($3,500 per year).

Proposed Modifications to Definitions

Fair Market Value

Based on a "fresh look" at the definition of "fair market value" and the structure of exceptions for various compensation arrangements, CMS discusses two key determinations in its preamble commentary. First, the fair market value requirement is separate and distinct from the "volume and value of referrals" and "other business generated" standards. Second, CMS found no indication in the legislative history or statutory language that the term "general market value" in the Stark law should deviate from general concepts and principles in the valuation community. Therefore, the proposed definition of fair market value eliminates the language in the existing rule that refers to *bona fide* bargaining between parties who are not otherwise in a position to generate business for each other, and to *bona fide* service agreements where the compensation has not been determined in any manner that takes into account the volume or value of

anticipated or actual referrals. In addition, modifications in the definition of "fair market value" are intended to address discrepancies between the existing definition and general valuation principles.

As proposed, "fair market value" means "the value in arm's-length transactions with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction." "General market value," in turn, is defined as "the price that assets or services would bring as the result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the asset or at the time the parties enter into the service arrangement." This definition flows into the rules addressing fair market value in the context of rental of office space and equipment. Fair market value for rental of equipment still refers to the value of rental property for general commercial purposes not taking into account its intended use; and fair market value for rental of office space still includes the condition that the value is not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

Volume or Value of Referrals

The industry has long complained that CMS has offered little guidance regarding the interpretation and application of key concepts in several exceptions that compensation cannot take into account the "volume or value of referrals" or "other business generated" between the parties. For the first time, the agency proposes to codify definitions of these terms that, if and when finalized, would supersede any previous guidance that may appear to be inconsistent. Further, in response to comments received through the RFI process, the agency proposes an "objective test" to serve as a "bright line" that "defines exactly when compensation will be considered to take into account the volume or value of referrals or other business generated between the parties." Although codified as special rules on compensation, the proposed provisions would be interpreted as definitions: "*If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation would not take into account the volume or value of the physician's referrals or the other business generated by the physician, as appropriate, for purposes of applying the exceptions to the physician self-referral law." (emphasis added)* These special rules would not apply to the exceptions for value-based arrangements.

The proposed special rule on compensation states that compensation from an entity furnishing designated health services to a physician takes into account the volume or value of referrals (or other business generated) only if one of the following applies:

- The formula used to calculate the physician's compensation includes the physician's referrals to (or other business generated for) the entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlates with the number or value of the physician's referrals to (or generation of other business for) the entity. An example of such a formula is the following: a physician is paid a percentage of collections that includes amounts collected for designated health services that the physician ordered but did not personally perform.
- There is a predetermined direct correlation between the physician's prior referrals to (or other business previously generated for) the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined. This would apply to fixed rate compensation (such as a fixed annual salary or an unvarying per-unit rate of compensation) where there is a "predetermined, direct and meaningful 'if X, then Y' correlation between the volume or value of the physician's prior referrals (or other business previously generated) and the prospective rate of compensation to be paid over the relevant period." In this connection, the agency notes that *"[m]erely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or other business generated by the physician for the entity."* (emphasis added)

For purposes of this section, a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

With respect to arrangements where the physician is compensating the entity furnishing designated health services, the converse applies: compensation from the physician takes into account the volume or value of referrals only if:

- The formula used to calculate the physician's compensation includes the physician's referrals to (or other business generated for) the entity as a variable, resulting in an increase or decrease in the physician's compensation that negatively correlates with the number or value of the physician's referrals to (or generation of other business for) the entity; or
- There is a predetermined direct correlation between the physician's prior referrals to (or other business previously generated for) the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

A negative correlation between two variables exists when one variable increases as the other variable decreases, or one variable decreases as the other variable increases. The example given in the commentary is that under a rental formula for office space leased by a physician from a hospital, the rental rate decreases as the number of the physician's referrals for hospital outpatient services increases.

In response to concerns raised in responses to the RFI (arising from cases such *United State ex rel. Drakeford v. Tuomey Healthcare System, Inc.*), CMS also takes the opportunity to clarify in its commentary that *a physician's compensation does not take into account the volume or value of referrals or other business generated solely because corresponding hospital services are billed each time the physician personally performs a service.*

Commercially Reasonable

Although the "commercially reasonable" standard appears in several exceptions, the only guidance provided to date appeared years ago in agency preamble commentary to published rules. The Proposed Rules add a definition of this term: commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In response to RFI comments and certain court rulings, the rule as proposed would codify that *"an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."* (emphasis added) Notably, this definition does not include the concept from the prior guidance that focused on a business purpose unrelated to the volume or value of referrals. However, where the terms of certain exceptions - such as for employment arrangements – specifically state that the arrangement must be commercially reasonable even in the absence of referrals, the agency is not proposing to modify those exceptions to remove the reference to referrals.

Designated Health Services

A proposed addition to the definition of designated health services addresses an issue that has been raised by providers calculating Medicare payments tainted by noncompliant physician referrals in the context of a disclosure under the Self-Referral Disclosure Protocol or the settlement of a False Claims Act case. The Proposed Rule would exclude from "designated health services" hospital inpatient services "if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS)." As noted in the preamble commentary, if a physician involved in a noncompliant financial arrangement with a hospital serves as a consultant for a hospital inpatient and orders diagnostic tests, but that service does not impact the DRG that will determine the payment to the hospital, then Medicare payments for that hospital inpatient stay would not be subject to the billing prohibition under the Stark law.

Isolated Financial Transactions

Responding to what the agency considers an erroneous interpretation of arrangements intended to be protected under the exception for isolated financial transactions, the definition of this term would be modified to exclude "a single payment for multiple or repeated services (such as a payment for service previously provided but not yet compensated."

Modification of Ownership or Investment Interests

The Proposed Rules carve out from all ownership or investment interests both (a) "titular" interests that exclude the right to financial benefits of ownership, such as profits, dividends, proceeds of sale and other returns on investment, as well as (b) interests arising from employee stock ownership plans.

Exceptions for Indirect Compensation

As described above, as proposed, the definition of "indirect compensation arrangement" is modified to include an express provision stating that the only exceptions available to protect these arrangements are the indirect compensation exception, and those general exceptions available for both ownership and compensation arrangements (among which are the exceptions for physician services, in-office ancillary services, services of certain managed care organizations to enrollees, and academic medical centers). In addition to these exceptions, the arrangement may be protected by the new exception for value-based arrangements if the unbroken chain of financial relationships includes a "value-based arrangement" to which the physician (or physician organization in whose shoes the physician stands) is a direct party.

Modification of Writing and Signature Requirements

The Proposed Rules would provide greater flexibility to meet the writing requirements that exist in several exceptions. CMS proposes a special rule that would set out in one section a provision that the writing requirement or the signature requirement are deemed to be satisfied if the arrangement satisfies all other elements of an applicable exception, and the parties obtain the required writing or signature within 90 consecutive calendar days. As established in previous legislation and rules, the writing requirement can be satisfied through a collection of documents.

The allowance of additional time to comply with the writing requirement would not eliminate the need for compensation to be set in advance, if required under the applicable exception. Contrary to prior guidance, CMS notes that compensation does not have to be set in writing before the furnishing of items or services in order to meet the "set in advance" requirement. The agency offers an example of compensation set in advance where the parties agree on a rate of compensation before items or services are furnished without reducing the compensation to writing and compile sufficient documentation in the 90-day period thereafter to meet the writing requirement and demonstrate a consistent rate of compensation from the beginning of the arrangement.

Period of Noncompliance

The Proposed Rule would eliminate the section of the Stark rules that addresses the duration of a period of noncompliance for arrangements not meeting the terms of an applicable exception. CMS comments reinforce that there are no definite rules for establishing in each and every case when a financial relationship has ended; rather, that analysis must usually be done on a case-by-case basis. Although the existing rules regarding the presumed end of a noncompliant financial relationship (for example, the repayment of excess compensation) were intended to provide bright lines, the agency acknowledges that they in fact appear to be "overly prescriptive and impractical." While proposing to delete these period of noncompliance rules, CMS does offer some guidance in its commentary about how to remedy compensation problems that may arise in the course of an arrangement. Intending to encourage compliance reviews of physician arrangements, CMS states that if the parties detect and correct administrative or operational errors during the course of an active financial arrangement, then the arrangement may comply with the law for its duration. However, if an arrangement has already ended, and the period of noncompliance has ended with the end of the financial relationship, the parties cannot retroactively cure previous noncompliance by repaying or recovering problematic compensation.

Proposed Changes to the Definition of Group Practice

CMS proposes clarifying revisions in the rules relating to group practices and acceptable compensation in the context of a group practice. The proposals include:

- Stating in the affirmative that profit shares and productivity bonuses may indirectly take into account the volume or value of referrals.
- Revising the definition of "overall profits" that may be distributed to the group to mean the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all of the physicians in the group. Further, if there are fewer than five physicians in the group, "overall profits" means the profits derived from all of the designated health services of the group.
- Clarifying that the profits from all of the designated health service of the practice (or a component of at least five physicians in the practice) must be aggregated and distributed, with profit shares not determined in any manner that directly takes into account the volume or value of a physician's referrals. As proposed, a group practice could not distribute profits from designated health services on a service-by-service basis.
- Clarifying the language in the provision deeming certain methods for distributing profit shares to be permissible. The amended section would remove references to revenues derived from Medicaid. As proposed, revenues derived from designated health services could be distributed based on the distribution of the group's revenue attributed to services that are not designated health services payable by Medicare, and that would not be considered designated health services if they were payable by Medicare.
- Revising the provisions relating to payment of productivity bonuses to be consistent with the provisions addressing the distribution of overall profits. The deeming provision relating to acceptable productivity bonuses will incorporate a correction to the current regulation text and will state that a productivity bonus will be deemed not to take into account the volume or value of a physician's referrals if it is based on the physician's total patient encounters or the relative value units personally performed by the physician. CMS seeks comments as to whether this should be limited to physician work RVUs.

Proposed Changes to Compensation Exceptions

New Exception for Limited Remuneration to a Physician

For arrangements that are not documented and signed as required under several compensation arrangements, a new exception provides protection if the remuneration does not exceed $3,500 in the aggregate per calendar year (to be adjusted for inflation) for the provision of items and services, if certain conditions are met. The compensation in the limited remuneration arrangement must not exceed fair market value or be determined in a manner that takes into account the volume or value of referrals or other business generated by the physician; and the arrangement must be commercially reasonable. In addition, the compensation for the lease or use of office space, equipment, personnel, items or services must not be determined using a formula based on a percentage of revenue or collections attributable to services performed using the space, equipment, personnel, items, supplies or services, or using per-unit of service fees reflecting services provided to patients referred by the lessor to the lessee, or patients referred by the owner of the premises, equipment, personnel, items, supplies or services.

Elimination of References to the Anti-Kickback Statute

Acknowledging that the Stark and Anti-Kickback laws are distinct, the Proposed Rules eliminate from Stark exceptions the requirements that the financial relationship not violate the Anti-Kickback Statute, and that the claim or bill otherwise complies with applicable law. This change impacts numerous exceptions, including commonly used exceptions for

temporary noncompliance, academic medical centers, fair market value compensation, indirect compensation, risk-sharing arrangements, nonmonetary compensation, medical staff incidental benefits, physician recruitment, timeshare arrangements, and electronic health records.

Directed Referrals

An existing special rule on compensation allows the inclusion of a directed referrals provision in a physician employment agreement, personal services agreement or managed care contract based on compliance with several conditions. In the Proposed Rules, this provision is specifically included as an element in the academic medical center exception as well as exceptions for employment, personal services, physician incentive plans, fair market value compensation and indirect compensation.

Office Space and Equipment Leases

The "exclusive use" requirement in the exceptions for office space and equipment leases would be amended so that it is significantly less restrictive. The Proposed Rule is targeted to protect against sham leases by restricting the lessor from using the leased premises or equipment. Although there may be multiple lessees, all lessees must use the space or equipment to the exclusion of the lessor, or any person or entity related to the lessor. In addition, neither the lessor nor any person related to the lessor may use the space as an invitee of the lessee.

Fair Market Value Compensation

The exception for fair market value compensation would be modified to extend to arrangements for the rental of office space or equipment for a term of less than one year. Only one such arrangement could be entered into by the parties over the course of a year. As usual under this exception, the duration of the short-term arrangement could be extended on the same terms.

Compensation Unrelated to Designated Health Services

The industry has long complained that in formulating Stark rules over the years, CMS has been overly restrictive in imposing limitations on the statutory exception for remuneration provided by a hospital that is unrelated to designated health services. CMS now proposes to ease those restrictions. Under the Proposed Rule, remuneration would not relate to the provision of designated health services if it is not determined in any manner that takes into account the volume or value of the physician's referrals, and it is for an item or service that is "not related to the provision of patient care services." Services would be *deemed* to be *not related* to the provision of patient care services "if the service could be provided by a person who is not a licensed health care professional." The proposed rule further stipulates that *items related* to the provision of patient care services include, but are not limited to, "any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services."

In attempting to clarify its approach in the Proposed Rule, CMS offers examples of hospital payments to physicians for items and services that would be considered related to designated health services (and therefore outside the scope of the exception as proposed): payments for emergency department call coverage, medical director or utilization review services; and payments for rental of medical equipment, purchase of medical devices, and rental of office space where patient care services are provided (even if not designated health services). However, CMS seeks comments on other ways to distinguish between remuneration that is related and unrelated to the provision of designated health services. CMS specifically seeks comments on an approach that would expand the scope of the exception, namely, whether CMS should limit remuneration "related to the provision of designated health services" to "remuneration paid explicitly for a physician's provision of designated health services to a hospital's patients."

Payments by a Physician

Under the Proposed Rule, this exception may apply generally to fair market payments for items or services made by a physician to an entity furnishing designated health services, but still would ***not*** be available to protect compensation arrangements addressed in one of the *statutory* compensation exceptions. Notably, this means the less restrictive exception for payments by a physician would still not apply to leases of office space or equipment, but may protect an arrangement even if the arrangement is covered by one of the non-statutory exceptions adopted by CMS.

Physician Recruitment

CMS commentary acknowledges that through the voluntary disclosure process, the agency has reviewed several arrangements in which the terms of the recruitment exception were not met because the physician practice did not sign the recruitment agreement, even though the practice did not receive a financial benefit through the arrangement. This may occur, for example, if the hospital pays remuneration directly to the recruited physician, or if the practice passes through to the physician all payments received from the hospital. The Proposed Rule would clarify that the practice is required to sign the writing documenting the recruitment arrangement if payment is made to the practice and the practice does not pass directly through to the recruited physician all of the remuneration received from the hospital.

Assistance to Compensate a Non-Physician Practitioner (NPP)

An existing compensation exception protects remuneration provided by a hospital, Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) to a physician to compensate an NPP to provide patient care services. The industry has raised certain questions with CMS about this exception, which are addressed in the Proposed Rule.

CMS notes it has received many questions about the meaning of the term “patient care services,” including whether services provided by the individual before becoming an NPP would be “patient care services.” To avoid confusion with the already defined term “patient care services” (which refers to physician services), CMS proposes to define a new term, “NPP patient care services”, to mean direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement. Under this definition, the exception would be available for an individual who has worked in the hospital’s service area for some period before entering into the arrangement with the physician or physician practice but has not worked as an NPP in that area.

The industry also raised questions about the timing of the arrangements that are permissible under this exception. CMS notes that the underlying policy goal of increasing access to care is not served if the physician is reimbursed by a hospital, FQHC or RHC for overhead costs of current employees or contractors. Therefore, the existing rule would be amended to expressly require that the compensation arrangement between the hospital/FQHC/RHC and the physician must start before the physician or physician organization enters into the compensation arrangement with the NPP.

PROPOSALS RELATED TO PATIENT INCENTIVES

OIG proposes greater flexibility for the provision of patient incentives under both the AKS and the Beneficiary Inducements CMP. The agency proposes a new AKS safe harbor to protect patient incentives in value-based arrangements and another to protect certain patient incentives in ACOs. OIG also proposes revisions to the local transportation safe harbor. Because any practice that is permissible under the AKS is also excepted from the Beneficiary Inducements CMP, patient incentives that satisfy the new AKS safe harbors are also permissible under the Beneficiary Inducements CMP. Finally, OIG proposes a new exception to the Beneficiary Inducements CMP for the provision of telehealth services for in-home dialysis.

Proposed New Safe Harbor for Patient Engagement and Support

OIG proposes a new safe harbor that would protect certain arrangements for in-kind patient engagement (PE) tools and supports to improve quality, health outcomes, and efficiency, that are furnished directly by a VBE participant to a patient in a target patient population, and that are directly connected to the coordination and management of care. This safe harbor "is intended to remove barriers presented by the [AKS] and the [Beneficiary Inducement] CMP to providers offering patients beneficial tools and supports to improve quality, health outcomes, and efficiency, by promoting patient engagement with their care adherence to care protocols." As proposed, the aggregate retail value of protected tools and supports would ordinarily be subject to an annual cap of $500.

OIG acknowledges that some PE tools and supports may be protected under existing safe harbors and exceptions to the definition of "remuneration" under the Beneficiary Inducement CMP, such as: the local transportation safe harbor; the exception for remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs; and the exception for incentives given to individuals to promote the delivery of preventive care. However, the agency also recognized that many types of beneficial tools and supports may fall outside the scope of existing safe harbors and exceptions.

The conditions that a protected PE tool or support would need to satisfy include the following:

- *Offeror*. Only PE tools and supports furnished by a VBE participant would be eligible for protection. Pharmaceutical manufacturers, distributors, and suppliers of DMEPOS, and labs, which OIG has proposed excluding from the definition, could not provide PE tools and supports under this safe harbor. A VBE participant's eligibility would not depend on whether the participant is at any degree of financial risk, but OIG is considering whether to limit the safe harbor to parties that assume at least some risk.
- *Recipients*. Patients who could receive protected PE tools and supports would need to be members of a target patient population. The safe harbor's scope is not limited to beneficiaries of Federal health care programs, as the VBE or VBE participants may define the patient population without regard to payor type. OIG is seeking comments regarding the challenges that this limitation could create where a VBE's beneficiaries are identified retrospectively or on a preliminary prospective basis (e.g., under some ACO arrangements).
- *Remuneration Protected*. PE tools and supports would be limited to "in-kind, preventive items, goods, or services, or items, goods or services such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient's social determinants of health, that have a direct connection to the coordination and management of care of the target patient population." Gift cards, cash, and cash equivalents would be excluded from safe harbor protection. However, OIG is considering whether to protect incentives and supports in the form of cash and cash equivalents in some circumstances. If the agency does so, it may impose some limits. OIG advised that "health-related technology" and "patient health-related monitoring tools and services" might include, for example, "wearable monitoring devices, such as a smart watch or tracker designed to collect information and transmit data to a patient's physician for treatment and disease monitoring."

  In discussing the safe harbor's application to supports and services designed to address social determinants of health, OIG explained, "[t]here is substantial evidence that unmet social needs related to these determinants of health, such as transportation, nutrition, and safe housing, play a critical role in health outcomes and expenditures," and that such "needs must be considered when thinking about maximizing health outcomes and lowering healthcare costs." The agency noted that it is considering "whether explicitly to include protection for tools and supports that address some social determinants of health that meet all other safe harbor conditions," and whether to make

distinctions among categories of social determinants of health by, for example, "protecting some types of tools and supports but not others."

- *Cost-Sharing Obligations.* The safe harbor would not protect the routine waiver or reduction of cost-sharing obligations. OIG explained that cost-sharing in the Medicare and Medicaid programs is required pursuant to statutes and regulations set forth by CMS and state programs, and that in the agency's view, AKS safe harbors "are [not] the right tool to obviate these programmatic requirements." The agency also observed that several safe harbors and exceptions to the Beneficiary Inducements CMP already protect certain non-routine reductions, waivers, and differentials in cost-sharing amounts.
- *Provider Recommended.* The PE tool or support would need to be recommended by the patient's licensed healthcare provider. OIG is considering whether to require the provider to certify in writing that the item or service is recommended solely to treat the patient's documented chronic condition.
- *Advancement of Specified Goals.* The PE tool or support would need to advance one or more of the following goals: adherence to a treatment, drug regimen, or follow-up plan of care as determined or established by the patient's licensed healthcare provider; management of a disease or condition as directed by the patient's licensed healthcare provider; improvement in evidence-based measurable health outcomes for the patient or the target patient population; or ensuring patient safety.
- *No Diversion or Resell.* The safe harbor would not protect the provision of a tool or support if the offeror knows or should know that the tool or support is likely to be diverted, sold, or utilized by the patient other than for the express purpose for which the tool or support is provided.
- *Monetary Cap.* The aggregate retail value of PE tools and supports furnished under this safe harbor would be subject to an annual limit of $500, unless such items or services are furnished "based on a good faith, individualized determination of the patient's financial need." Such determinations would need to be based on "a reasonable set of income and resource guidelines uniformly applied in all cases" and "objective criteria and appropriate for the applicable locality."
- *Monitoring for Effectiveness.* OIG is considering whether offerors should be required "to use 'reasonable efforts' to monitor the effectiveness of the tool or support in achieving the intended coordination and management of care for the patient," including the use of policies and procedures "to address any identified material deficiencies."
- *Retrieval of Items and Goods.* OIG is also considering whether to require offerors to engage in "reasonable efforts" to retrieve an item or good furnished as a PE tool or support in certain circumstances (e.g., where the patient is no longer part of the target patient population; the VBE ceases to exist; or the offeror ceases to be a VBE participant). If OIG imposes this requirement, the agency may set a minimum value for items and services that are subject to retrieval.

Proposed Revisions to the Local Transportation Safe Harbor

OIG proposes modifying the existing safe harbor for local transportation to: (i) expand the distance which residents of rural areas may be transported from 50 to 75 miles; and (ii) remove any mileage limit on transportation of a patient from a healthcare facility from which the patient has been discharged to the patient's residence. OIG is also considering whether to protect post-discharge transportation to any location of the patient's choice, including to another healthcare facility.

Currently, the safe harbor does not protect transportation for purposes other than to obtain medically necessary items and services. OIG is now considering expanding the safe harbor to non-medical purposes to "foster innovative

arrangements that are likely to improve health outcomes and address non-medical needs that significantly influence those outcomes." In inviting commentary on this issue, the agency acknowledged that such transportation might help address not only patients' health outcomes, but also social determinants of health.

Proposed New Safe Harbor for ACO Beneficiary Incentive Programs

Under the MSSP, ACOs in certain two-sided models may operate CMS-approved ACO Beneficiary Incentive Programs to provide incentive payments to assigned beneficiaries who receive qualifying primary care services. The Bipartisan Budget Act of 2018 (the Budget Act) amended the Social Security Act by adding an exception to the definition of "remuneration" under the AKS for such incentive payments that meet certain requirements and conditions. OIG now proposes to codify this statutory exception, with minor adjustments, including language clarifying the incentives may be furnished only to the ACO's assigned beneficiaries.

Proposed Telehealth Exception to Beneficiary Inducements CMP for In-Home Dialysis

The Proposed Rule would codify changes enacted by the Budget Act by adding an exception to the definition of "remuneration" under the Beneficiary Inducements CMP for the provision of certain telehealth technologies related to in-home dialysis services. The Budget Act permits an individual with ESRD receiving home dialysis to elect to receive their monthly ESRD-related clinical assessments via telehealth, if certain conditions are met.

The Proposed Rule would apply to the provision of such telehealth technologies by providers of services or renal dialysis facilities to ESRD patients who are receiving home dialysis for which payment is being made under Medicare Part B. The provider or facility would need to be currently providing the patient in-home dialysis, telehealth visits, or other ESRD care, and the technologies may not be offered as part of any advertisement or solicitation. Protected technologies would need "contribute substantially" to the provision of ESRD-related telehealth services and could not be excessive in value nor duplicative of technology already owned by the beneficiary if that technology is adequate for the telehealth purposes. Finally, providers and facilities would be prohibited from shifting the cost of the telehealth technologies onto Federal healthcare programs, payors, or individuals.

For purposes of the exception, "telehealth technologies" would be defined as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B—between a patient and the remote healthcare provider." Telephones, facsimile machines, and electronic mail systems would be excluded from the definition. However, smart phones that meet the definition's specifications would not be considered a "telephone."

CYBERSECURITY TECHNOLOGY AND ELECTRONIC HEALTH RECORDS

New Stark Law Exception and AKS Safe Harbor for Donations of Cybersecurity Technology and Related Services

The agencies have proposed a new Stark Law exception and AKS safe harbor designed broadly to permit non-monetary donations of cybersecurity technology and related services. The proposed regulations are refreshingly short and simple and appear to be designed for straightforward implementation. The regulation drafts contain a few interesting differences, discussed below, that would benefit from reconciliation prior to promulgation of final rules.

The agencies recognize that the digitization of the healthcare delivery system and regulation designed to increase interoperability have created an interconnected "ecosystem" where the weakest cybersecurity link can jeopardize the entire system. According to the agencies, providing protection for the donation of cybersecurity technology will allow the

healthcare industry to promote increased security for interconnected healthcare information systems by mobilizing economic assistance for entities with fewer resources to invest in cybersecurity measures.

Importantly, because the agencies view donations of cybersecurity technology and services to involve less fraud and abuse risk than donations of EHR technology, the regulations as proposed will not require recipients to contribute a portion of the donor's cost, in contrast to the EHR donation exception and safe harbor, which require the recipient to contribute at least 15% of the donor's costs. Like the EHR donation exception and safe harbor, the agencies continue to be wary of permitting donations of hardware, because of their belief that donations of valuable, multifunctional hardware pose a higher risk of constituting a disguised payment for referrals. Despite this wariness, however, the agencies are soliciting comments regarding the possibility of extending the protection of the regulations to donations of hardware in certain circumstances.

The Stark Law exception and AKS safe harbor will protect donations of cybersecurity technology and related services that are necessary and used predominantly to implement and maintain (and, in the case of the Stark exception safe harbor, to reestablish) effective cybersecurity. "Cybersecurity" is defined to mean the process of protecting information by preventing, detecting and responding to cyberattacks. "Technology" means any software or other types of information technology, other than hardware.

Protected technology could include malware prevention software; software security measures to protect endpoints that allow for network access control; business continuity software that mitigates the effect of cyberattacks; encryption software; and email traffic filtering software. Software can be cloud-based or locally installed. Services could include any services associated with developing, installing and updating cybersecurity software; any kind of cybersecurity training; cybersecurity services for business continuity during and after a cyberattack; "cybersecurity as a service" models that rely on a third-party service provider to manage, monitor or operate cybersecurity of a recipient; cybersecurity risk assessments, vulnerability analysis or penetration testing; and services associated with the sharing of information about known cyber threats. Covered donations can include technology that is neither software nor a service, such as an Application Programming Interface or API.

Again, donations cannot include hardware. In addition, cybersecurity technology and related services would not include donations of installation, improvement or repair of infrastructure related to physical safeguards, such as upgraded wiring or the installation of high security doors.

To ensure that donated technology or services are necessary and used predominantly for cybersecurity purposes, the agencies believe that the "core function" of the donated technology or service must be to protect information by preventing, detecting and responding to cyberattacks. More general purpose technology or services that are otherwise used in the recipient's business, such as general IT help desk services, would not be protected. The agencies are seeking comment on whether to add a "deeming" provision that would allow donors and recipients to establish that technology or services are necessary and used predominantly for cybersecurity if the donation furthers a recipient's ability to comply with a written cybersecurity program that reasonably conforms to a widely recognized cybersecurity framework or set of standards.

Both proposed regulations require that (1) neither the eligibility of the recipient for the technology or services, nor the amount or nature of the technology or services, directly take into account the volume or value of the referrals or other business generated between the parties; and (2) neither the recipient nor the recipients' practice makes receiving technology or services, or the amount or nature of the technology or services, a condition of doing business.

The agencies state that they understand and expect that a donor would provide cybersecurity technology and related services only to recipients that connect to the donor's systems, but that the proposed requirements are not intended to require, for instance, that a health system donor donate cybersecurity technology or services to every physician who

connects to its systems. Donors would be able to select recipients and the nature and amount of donated technology and services in a variety of ways, such as by performing risk assessments, based on the nature and risk of the interface, or by virtue of a physician's membership on a hospital's medical staff – so long as decisions regarding eligibility or the amount and nature of services are not determined in a manner that directly takes into account the volume or value of referrals or other business generated. The proposed AKS safe harbor text explicitly states that the donor cannot condition the donation of technology or services or the amount or nature of such technology or services on future referrals. Although CMS refers to such a requirement in the preamble discussion, the actual Stark Law exception text lacks this explicit language.

There are some interesting differences between the proposed regulations. One key difference is the writing requirement. The Stark Law exception would require only that the arrangement be documented in writing, while the proposed safe harbor would require a written agreement, signed by the parties, that describes the technology and services being provided and the amount of the recipient's contribution, if any. CMS states that it would not propose to require a written contract because such a requirement could lead to an inadvertent violation of the Stark Law in situations where parties need to act quickly and decisively but could be constrained by needing to obtain "the signature of each physician who is considered a party to the arrangement."

A more bewildering and potentially substantive difference relates to the fundamental purpose of the donation. The proposed safe harbor would protect donations necessary and used predominantly to "implement and maintain" effective cybersecurity, but the proposed Stark Law exception would protect such donations "to implement, maintain, or reestablish" cybersecurity. The agencies do not mention or discuss this difference.

As noted above, although wary of permitting hardware donations, the agencies propose and solicit comments on an alternative approach that would permit hardware donations to the extent the hardware is determined to be necessary based on a risk assessment of the donor and the potential recipient. Any such approach still would require that donated hardware be dedicated to cybersecurity and not be multifunctional. The agencies are considering and soliciting comments on other possible safeguards, such as requiring that donors make a financial contribution toward the cost of donated hardware.

EHR Donation Regulations

The agencies propose to modify the EHR donation regulations to incorporate prohibitions on information blocking, to clarify the applicability of the regulations to the donation of certain cybersecurity technology and services, and to eliminate the sunset provision. The agencies also are soliciting comments on possible revisions to the requirement that recipients of donated EHR technology and services contribute at least 15% of the donor's cost. Finally, the agencies are proposing to eliminate the prohibition on furnishing EHR technology that is equivalent to items or services already possessed by the recipient.

The EHR donation regulations require that EHR software be "interoperable" and include a requirement that a donor not take any action to limit or restrict the use, compatibility or interoperability of the items or services with other electronic prescribing or EHR items or services. The latter requirement was designed to prevent misuse of the EHR exception and safe harbor to create data and referral lock-in and to promote the free exchange of data. The agencies noted that there has been significant evolution in the understanding of this concept based on the anti-"information blocking" provisions of the 21st Century Cures Act and proposed regulations issued thereunder. Accordingly, the agencies propose to modify the EHR donation regulations to contain specific prohibitions on information blocking.

The agencies are proposing a language change to clarify that the EHR donation regulations are available to protect cybersecurity software and services that "protect" electronic health records. The agencies also noted their view that the EHR donation regulations always protected such software and services.

The agencies discussed the rationale behind setting an expiration date for the EHR donation regulations. According to the agencies, they had believed and continued to believe that the need for the EHR donation regulations, originally promulgated in 2006, would diminish over time as the use of EHR technology became a standard and expected part of practice. The regulations originally were set to expire on December 31, 2013. The 2013 final rule extended the sunset date to December 31, 2021. Now, however, the agencies believe that the value of the EHR donation regulations will continue notwithstanding achievement of the goal of widespread adoption of EHR technology, by promoting certainty with respect to EHR-related financial arrangements and addressing ongoing financial concerns with maintaining and updating EHR technology. Accordingly, the agencies now propose to eliminate the sunset provisions entirely.

The agencies have not proposed changes to the 15% cost sharing requirements but invite comments on several possible changes. First, the agencies invite comment on whether to eliminate a cost sharing requirement for small or rural physician organizations. Second, the agencies invite comment on whether to eliminate the cost sharing requirement entirely for all recipients. Finally, the agencies invite comment on whether to modify or eliminate the contribution requirement for updates to previously donate EHR software or technology.

The agencies also have proposed to delete the prohibition on furnishing EHR technology that is equivalent to items or services already possessed by the recipient. Comments have noted that recipients of donated EHR technology get locked in to the donated technology because they cannot afford the cost of improved technology that may nevertheless be viewed as equivalent technology, because the EHR donation regulation will not apply to protect subsidies of such equivalent replacement technology. Accordingly, the agencies propose to eliminate the prohibition on the furnishing of equivalent technology and invite comment on the proposal.

PROPOSED MODIFICATIONS TO THE WARRANTIES SAFE HARBOR

OIG proposes updating the existing warranties safe harbor to promote higher value items covered by warranties. The safe harbor protects remuneration consisting of “any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer . . . of the item.” OIG has interpreted the safe harbor as applying to warranties for single items and not to bundled items. The proposed updates would (i) protect warranties for one or more items and related services upon certain conditions; (ii) exclude beneficiaries from the reporting requirements applicable to buyers; and (iii) define “warranty” directly and not by reference to the Federal Magnuson-Moss Act. As proposed, the safe harbor would allow manufacturers and suppliers to warrant a bundle of items or one or more items in combination with related services, but it would not protect warranties covering only services.

The following conditions would apply to protected bundled warranty arrangements: (i) all warrantied, federally reimbursable items and services must be reimbursed by the same Federal health care program and in the same payment; (ii) a manufacturer or supplier must not pay any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the items and services subject to the warranty; and (iii) manufacturers and suppliers cannot condition bundled warranties on the exclusive use of one or more items or services or impose minimum-purchase requirements of any items or services.

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