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CLIENT ALERT

HHS's Regulatory Sprint to Coordinated Care

Part 3: CMS Proposes Expansive Set of Changes to Stark Regulations

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This Client Alert serves as the third in a three-part series in which we describe and analyze the rules proposed by the Department of Health and Human Services ("HHS") Centers for Medicare & Medicaid Services ("CMS") as part of its "Regulatory Sprint to Coordinated Care."

On October 17, 2019, the HHS Office of Inspector General ("OIG") and CMS published in the *Federal Register* companion proposed rules that present significant changes to the regulatory framework of the federal health care program's Anti-Kickback Statute ("AKS"), the civil monetary penalties ("CMP") law, and the federal physician self-referral law (commonly referred to as the "Stark Law"). Unless an extension is granted, public comments must be delivered to the agencies by 5 p.m. (EST) on December 31, 2019.

Part 1 of this three-part series provided background on the different proposed rules.[1] Part 2 focused on OIG's proposed new and modified safe harbors to the AKS and exceptions to the CMP law.[2] In Part 2, we not only provided summaries of the important aspects of OIG's proposed regulations, but also identified areas and topics on which we believe the public should consider submitting comments.

[1] The full text of Part 1 of this series is available at https://www.ebglaw.com/news/hhss-regulatory-sprint-to-coordinated-care-part-1-cms-and-oig-issue-long-awaited-proposed-rules/.
[2] The full text of Part 2 of this series is available at https://www.ebglaw.com/news/hhss-regulatory-sprint-to-coordinated-care-part-2-oig-issues-long-awaited-proposed-rules/.

This Part 3 focuses on CMS's proposed changes to the Stark regulations.[3] In contrast to OIG's regulatory issuance, which focused primarily on ways in which OIG believed changes to the regulations were needed in the context of coordinated care and alternative payment models, CMS takes a more expansive view of the categories of issues that need to be addressed and modified as part of the government's interpretation of the physician self-referral law.

About one-third of CMS's proposed changes overlap with the same categories of issues addressed by OIG in connection with the need for these regulations to facilitate the transition to value-based care and foster care coordination. As such, CMS proposes three new regulatory exceptions that would apply to value-based arrangements in which (1) participants assume "full financial risk," (2) physicians assume "meaningful downside financial risk," and (3) participants do not assume financial risk but foster the delivery of coordinated patient care and promote the goals of transitioning to a value-based payment model. While the nomenclature of the exceptions is the same in both OIG's and CMS's proposed regulations, the definitions of "financial risk" vary greatly in the two proposed regulations. In addition, similar to OIG, CMS proposes a new exception to the Stark Law concerning the provision of non-monetary remuneration to physicians in the form of cybersecurity technology and related services, and CMS proposes a number of modifications to the existing exception for electronic health records ("EHRs").

The remaining two-thirds of CMS's proposed changes address a variety of issues impacting the overall application and interpretation of the Stark Law even though they are not specifically related to the issue of value-based care. In CMS's June 2018 Request for Information ("RFI") on modifications to the Stark Law, CMS requested public comment on a number of issues that CMS addressed in this proposed rule. Most significantly, CMS proposes changes to the definitions of some key and important terms that apply in many (if not most) of the Stark Law exceptions, such as the definitions of "fair market value" and "commercial reasonableness." CMS also provides interpretations of the standards associated with "volume or value of referrals" and "other business generated" between the parties. Moreover, CMS proposes changes and clarifications to the requirements of satisfying the definition of a "group practice," which is a significant factor in qualifying for many Stark Law exceptions—most specifically, the requirements in the in-office ancillary services exception.

For the most part, the proposed modifications are welcome to health care organizations wanting to participate meaningfully in value-based care, as well as those that strive to comply with the physician self-referral rules in a health care environment requiring organizations to remain nimble in the face of rules demanding substantial advance preparation and documentation. However, the proposed regulations inexplicably narrow protections in a few fundamental ways, especially as they relate to integrated delivery systems and academic medical centers ("AMCs") that, by virtue of their clinical integration, may be in the best position to deliver value-based care. Under the proposed rules, however, they may essentially need to overhaul their established, long-standing

[3] *See* CMS, "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations," 84 FR 55766 (October 17, 2019), *available at* https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations.

processes in order to take full advantage of the new value-based safe harbor protection or simply to continue operations. For instance, CMS proposes to add to the AMC exception a requirement that AMCs comply with the revised special rule on compensation at 42 CFR § 411.354(d)(4), which imposes signed writings and fair market value standards in a particularized manner not contemplated by the existing AMC exception in which physicians are employed by a component of the AMC and fair market value is assessed in the aggregate from all AMC components. CMS requests comment on whether the proposal is necessary in light of "the nature of academic medical centers," but the proposed language nonetheless includes such limitations.

An overarching issue addressed in both OIG's proposed rule and CMS's proposed rule is the interrelationship between the AKS safe harbors and Stark Law exceptions. Both HHS agencies have developed their own respective rules, and both agencies acknowledge that, where appropriate, they try to propose consistent definitions and requirements. At the same time, CMS proposes "decoupling" the requirements in numerous Stark Law exceptions so that the financial relationships remain in compliance with the AKS and other federal and state laws or regulations governing billing or claims submission. Meanwhile, CMS does not propose modifications to any of the existing exceptions (i.e., the exception for referral services and obstetrical malpractice subsidies) that cross-reference the satisfaction of certain requirements in the analogous safe harbor regulations to the AKS. Moreover, while CMS eliminates some of the AKS cross-references in the name of clarity, the agency adds a cross-reference to the information-blocking prohibition of the interoperability rule, which itself is not well defined and a moving target since it is subject to ongoing rulemaking.

CMS states that its proposals "in no way affect parties' liability under the anti-kickback statute" and that "the fact that a financial relationship complies with an exception to the physician self-referral law does *not* entail that the financial relationship does not violate the anti-kickback statute." Nevertheless, we believe that CMS should consider the ways in which it might provide Stark Law protection for arrangements recognized under the AKS safe harbors, such as the development of an exception to the Stark Law for physicians' ownership interest in entities that satisfy the small investment interest safe harbor. In addition, CMS and OIG should take a fresh look at making the rules, especially those affecting value-based arrangements, consistent between AKS and physician self-referral. It does no good for a value-based arrangement to be structured to accept downside risk at 25 percent of the physician's remuneration to comply with the physician self-referral law, when a much more stringent downside risk standard of assumption of losses (at 40 percent for shared savings or 20 percent for episodes of care) is required for safe harbor protection from AKS liability.

While we laud CMS's willingness to address many of the issues that have resulted over the last two decades in what we believe are unintended consequences due to unnecessarily conservative interpretations of the Stark Law, we do not believe that CMS has gone far enough in its proposed modifications and clarifications to the Stark Law in this rulemaking initiative. Specifically, we are disappointed that CMS did not use this regulatory issuance as an opportunity to (1) adopt a new general exception for financial relationships that are unrelated to any federal health care program business or provide a broader meaning than proposed for the "unrelated to designated health services" ("DHS")

statutory exception; (2) create a new standard, overarching exception to the application of the Stark Law for financial arrangements involving a clinically integrated network; (3) expand the application of the prepaid plan and risk-sharing exceptions to a wider range of plans and arrangements involving a pre-defined patient population; and (4) finalize in regulations CMS's prior statements and position that the Stark Law itself is not an enforcement tool or prohibition on the referral of Medicaid patients when a physician has a prohibited financial relationship, but rather a prohibition on the ability of a state to receive the applicable funds through the federal financial participation program.

Proposed Value-Based Exceptions

In proposing its tiered value-based exception construct, CMS incorporates additional flexibilities for participants in mature, value-based payment models based on their assumption of downside financial risk in those models. In so doing, CMS rejects the "one-size fits all" approach recommended by many commenters. CMS cites its continuing concerns that value-based payment models may pose risks, such as stinting on care, "cherry-picking," "lemon-dropping," and manipulating or falsifying data used to verify outcomes.

CMS also acknowledges that the traditional requirements of the Stark Law exceptions—grounded in notions of fair market value and compensation set in advance that do not take into account the volume or value of referrals—may not be suited to collaborative models that reward value and outcomes. These traditional requirements may also inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures. Accordingly, CMS states that while it proposes two value-based exceptions that permit fee-for-service payment by a payor, neither of these proposed exceptions requires that remuneration be consistent with fair market value nor determined in any manner that takes into account the volume or value of a physician's referrals or other business generated by the physician by the entity. CMS requests comment on whether such requirements should be included in the final regulation, as well as whether a commercial reasonableness requirement is necessary.

Despite its elimination of the "volume or value" standard, CMS includes a constraint on the usage of the special rules that permit entities to require employed or contracted physicians to direct physician referrals to a particular provider, practitioner, or supplier. The preamble language states broadly that the special rule is not applicable to value-based arrangements; however, the actual proposed regulatory language states more narrowly that, if remuneration is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement must satisfy 42 CFR § 411.354(d)(4)(iv), which, even as proposed to be revised, requires the referral condition to be set out in writing and signed by the parties and that patient, provider, and insurer choice be honored. This is an important distinction because integrated delivery systems rely on the special rules to protect their "closed" systems and, due to their close and consistent working relationship among system providers, are perhaps best suited to implement meaningful value-based reform. Removing integrated delivery systems from the protections of the special rules may result in their inability to meaningfully participate in the value-based care arrangements protected by the rule.

Value-Based Definitions

Central to all of CMS's proposed value-based exceptions are several key definitions. The definitions are not exceptions themselves but, in many ways, constitute key core elements of the three proposed value-based exceptions, similar to the function of the definition of "group" in the in-office ancillary services exception.

CMS proposes the following value-based definitions for these new exceptions:

- **"Value-based activity"** would mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) the provision of an item or service, (2) the taking of an action, or (3) the refraining from taking an action. The making of a referral is not a value-based activity. CMS's definition seems to suggest not limiting the specific manner in which value-based objectives are achieved. The proposed rule suggests flexibility and acknowledges that value-based remuneration may not always involve a one-to-one payment for an item or service and can include payments to more generally influence physician behavior and practice in furtherance of a value-based purpose. CMS notes that the act of referring for DHS is not itself a value-based activity, although later discusses the concept that referrals can play a role in effectuating a value-based activity.

- **"Value-based arrangement"** would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among (1) the value-based enterprise and one or more of its VBE participants, or (2) VBE participants in the same value-based enterprise. For a value-based exception to apply, CMS proposes that parties enter into a "value-based arrangement," although whether a formal writing is required will vary based on the particular exception as more fully described *infra.* Notably, CMS intends for these exceptions to only protect value-based compensation arrangements. Accordingly, physicians with an ownership interest in a DHS entity who seek to enter into a valued-based arrangement, or who wish to have an ownership interest in a value-based enterprise, may have to qualify for another exception (if one is available) to the extent the Stark Law is implicated. CMS expects that most value-based arrangements would involve coordination and managing the care of a patient cohort / target patient population but requests comment on whether to include other activities.

- "**Value-based enterprise**" would mean two or more VBE participants: (1) collaborating to achieve at least one value-based purpose, (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise, (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise, and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). CMS's proposed definition of an "enterprise" is somewhat amorphous. It could include, on the one hand, both a single formal legal entity (to the extent

otherwise permitted) and, on the other hand, more informal enterprises that can consist only of two or more parties to a value-based arrangement with documentation recording the arrangement and its purpose. CMS did not intend to limit or dictate the legal structures necessary to qualify, which should offer flexibility and creativity in setting up an "enterprise." Accordingly, whether something is an enterprise is a question of function rather than form, meaning that, so long as participants have agreed to collaborate for a value-based purpose, the structure of the enterprise itself may be mutable as situationally appropriate. However, CMS requires value-based enterprises to have an "accountable body or person" who is responsible for the finances and operational oversight of the enterprise. CMS also requires a "governing document" that describes the enterprise and how it intends to achieve its purpose. Importantly, some of the proposed value-based exceptions do not require a specific writing to effectuate the arrangement (see below).

- **"Value-based purpose"** would mean (1) coordinating and managing the care of a target patient population; (2) improving the quality of care for a target patient population; (3) appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (4) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided, to mechanisms based on the quality of care and control of costs of care for a target patient population. One or more of these enumerated value-based purposes must "anchor" each value-based compensation arrangement. CMS indicates that each of the goals is potentially itself a separate "purpose" and that a given arrangement need not meet all four purposes. CMS states its belief that stakeholders are familiar with the plain language and meaning of these goals, but it solicits comments for further clarification. The four "purpose" qualifiers are concepts that simply have no universally accepted definition and are continuing to evolve. For example, one entity's interpretation of "improving the quality of care" or "coordinating and managing care" may be vastly different from another's. Despite the apparent latitude granted in this definition, we would expect a number of comments seeking clarification regarding the meaning of this definition.

- **"VBE participant"** would mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. Importantly, similar to the treatment by OIG in its proposed AKS rule, CMS signals that it is considering excluding or treating differently labs; manufacturers and distributors of durable medical equipment, prosthetics, orthotics, and supplies (or "DMEPOS"); pharmacy benefit managers; wholesalers; pharmaceutical manufacturers; and distributors. While not a surprising move given CMS's and OIG's long-standing concerns and separate treatment of these entities, the activities of these entities certainly affect quality, cost, and outcomes. Accordingly, their pushback and request to be included as players in the value-based framework are both expected and warranted.

- **"Target patient population**" would mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the

value-based arrangement and further the value-based enterprise's value-based purpose(s).The proposed definition also includes a writing prior to the value-based activity that contains the description and criteria of the patient cohort. CMS's definition qualifies by stating that the criteria must be (1) legitimate, which focuses on whether the selection process is *bona fide,* and (2) verifiable, which focuses on the integrity, objectiveness, and quality of evidence to corroborate the criteria for selection. Under this broad description, a number of potential patient cohorts may exist under a value-based arrangement. Therefore, CMS cautions against illegitimate selection criteria, such as "cherry-picking" and "lemon-dropping," which could skew as a measure of success and drive profits rather than a *bona fide* value-based purpose. CMS seeks comment with respect to what may satisfy "legitimate" and "verifiable" criteria. This is another area that is ripe for the industry to comment on, given the innumerable strategies managed care plans, vendors, and downstream entities have deployed for decades to manage the care of targeted patient populations (e.g., those with specific chronic disease burdens).

Full Financial Risk Exception

The first proposed exception is for value-based enterprises accepting "full financial risk" from a payor. The exception sets forth a definition of "full financial risk" to mean that the value-based enterprise is financially responsible on a prospective basis for the cost of ***all patient care items and services covered by the applicable payor*** for each patient in the target patient population for a specified period of time. "Prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the payor ***prior to*** providing patient care items and services to patients in the target patient population. CMS states that for payment to be prospective, there can be no additional payment to cover costs for specific patient care items or services furnished, nor can payment be claimed from the payor for such items or services. However, payment can be made to offset losses incurred above those prospectively agreed to by the parties, and also for shared savings or other incentive payments for achieving quality, performance, or other benchmarks.

According to CMS, full financial risk may take the form of capitation payments or global budget payments from a payor and would not prohibit other approaches to full financial risk. CMS states that for Medicare patients, full financial risk is the financial responsibility for all items and services covered under Medicare Parts A and B. CMS seeks comment on other types of full financial risk payment models that exist or are anticipated in the transition to value-based care, as well as whether full financial risk should apply to only a defined set of patient care services for a target population.

CMS states that this exception was meant to parallel the existing risk-sharing exception in the physician self-referral law applicable to managed care organizations in light of the similarities to value-based enterprises at full financial risk, with maximum flexibility and no documentation requirements. Nevertheless, CMS notes its belief that reducing to writing any arrangement between referral sources is a good business practice (and, we note, is helpful to demonstrate compliance with the requirements of the exception).

CMS requests comment on whether there should be an additional requirement for the parties to engage in value-based activities that include, at a minimum, the coordination and management of care of the target patient population, or that the value-based arrangement be reasonably designed to coordinate and manage the care of the target patient population. While CMS believes that this is the most direct way to further the goals of the Regulatory Sprint, it acknowledges that value-based arrangements, by their nature, would have care coordination and management at their heart, and so an explicit requirement may not be necessary—and may eliminate from protection certain beneficial value-based arrangements.

Exception for Meaningful Downside Financial Risk to the Physician

In recognition that not all providers are prepared to accept full financial risk, CMS proposes an exception for value-based arrangements with meaningful downside financial risk, which requires the physician to pay the entity no less than 25 percent of the value of the remuneration he or she receives under the value-based arrangement. "Meaningful downside financial risk to the physician" may also require the physician to be 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 payor for each patient in the target patient population for a specified period of time. CMS says that it chose this risk threshold because it is consistent with the physician incentive plan ("PIP") definition of "substantial financial risk" adopted elsewhere in the proposed regulation (although the PIP rule does not limit the definition of "substantial financial risk" to downside risk).

Although CMS believes that downside financial risk curbs the influence of traditional fee-for-service payment, contains inherent protections against program and patient abuse, and has great potential to shape behavior to improve outcomes, eliminate waste, and reduce cost, CMS nonetheless includes additional guardrails beyond those set forth in the full financial risk exception—specifically, the traditional requirements of a writing and that the methodology be set in advance.

Exception for Value-Based Arrangements without Financial Risk

In response to comments from the industry that centered around the belief that physicians and DHS entities are central to health care transformation and the very real concern that many physician practices are simply too small to absorb downside risk, in a surprising—albeit welcome—move, CMS proposes to create a value-based exception that would apply without regard to financial risk.

The proposed exception imports the same safeguard requirements from the value-based financial risk exception, namely (1) the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, (2) the remuneration is not provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population, (3) the remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement, (4) the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided, and (5) records

of the methodology for determining the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least six years and made available to the Secretary of HHS upon request.

Significantly, this proposed exception does not include certain traditional requirements of physician self-referral compensation exceptions—i.e., that the compensation be fair market value and not determined in a manner based on the volume or value of referrals. In doing so, CMS acknowledges that these traditional requirements are impeding the development of value-based care, and the agency seeks to propose a regulatory framework that contains other guardrails it views as less constraining to value-based care arrangements. Nevertheless, CMS has included additional safeguards, citing program abuse concerns when the parties to the arrangement do not share risk—most significantly, physician downside risk—but has also requested public comment on whether these safeguards are, in fact, required.

The first requirement that CMS seeks comments on is safeguard (3) above, which exempts from the general prohibition on referrals those patients who are in the value-based arrangement. CMS instead may require, broadly, that remuneration specifically not be conditioned on referral of *any patients* to the entity or the volume or value of other business generated by the physician. CMS seeks further comment on this proposal, pointing out the confusing possible interplay with other exceptions where referrals can be a condition of an arrangement. Therefore, if CMS imposes this potential requirement, integrated delivery systems and AMCs, which are currently highly integrated and likely most well positioned to collaborate effectively on value-based initiatives, may not be able to take advantage of the new, non-risk value-based exception to the extent they choose to remain closed systems.

The second additional safeguard in the proposed exception requires a fully executed writing, in contrast with the two risk-sharing proposed exceptions. Mentioned earlier, the proposed definition requires some formal documentation, e.g., to memorialize an "enterprise," but this exception tracks more closely with historic self-referral exceptions, like personal services that require that the arrangement be set forth in a writing and signed by the parties. In addition, CMS wants the writing to include a description of the following: (1) the value-based activities to be undertaken under the arrangement; (2) how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; (3) the target patient population for the arrangement; (4) the type or nature of the remuneration; (5) the methodology used to determine the amount of the remuneration; and (6) the performance or quality standards against which the recipient of the remuneration will be measured, if any. Of course, all of this must occur in advance of the commencement of the arrangement.

We believe that the public should consider submitting comments on these requirements as they appear unreasonable. Nevertheless, CMS is already requiring substantially all of these characteristics to be present under its proposed definitions in this section to qualify for a value-based exception in the first place. In light of the substantial difficulties health care organizations have had with the "signed written agreement" requirements of the physician self-referral law, resulting in voluminous self-disclosures under the CMS protocol, many of which are now years-old without settlement, one wonders why CMS

would import a "signed written agreement" requirement into this new exception. This is especially so since health care organizations may wish to make the value-based arrangement part of an already-existing compensation methodology, such as for a group practice, or for certain employed physicians, which would not otherwise require a signed writing. Although a writing can be proven through a collection of documents under CMS's existing approach, the signature requirement often is more difficult to substantiate even where it is apparent through available documentation and the parties' course of performance that the arrangement was "set in advance" in a meaningful way.

Another perhaps more cumbersome proposed safeguard requires that the performance or quality standards that trigger remuneration be objectively measured and tracked using a prospective methodology. Not protected would be payment tied to quality standards set today for yesterday. As with the writing requirement generally, standards often are articulated prospectively, but it takes some time for the parties to reduce the metrics to writing or determine the measurement methodology with particularity. CMS is also considering whether to require that performance or quality standards be designed to "drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery." It is entirely unclear how CMS expects that to be measured or what would be reasonable and not reasonable. This also seems potentially redundant since presumably a qualifying value-based activity (for any of the proposed exceptions) would have one or more of these criteria already.

In this proposed exception, CMS also specifically states that it expects parties to monitor their arrangement to determine whether "they are operating ***as intended*** and serving ***their intended purposes***, regardless of whether the arrangements are value-based, and have in place mechanisms to address identified deficiencies, as appropriate" (emphasis added). While not wholly unreasonable on its face, this safeguard may present a complexing morass of subjectivity for which no real standards exist. Although the physician self-referral law is a strict liability law for which intent is mostly irrelevant, CMS is injecting concepts that examine not only the reasonableness and defensibility of acts, but also, literally, the intent of the parties.

CMS also sets out that it is considering whether to require that:

> (1) The value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, the physician must cease referring designated health services to the entity, either immediately upon the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination.

We believe that there are interesting parallels between this proposal and the 60-day overpayment rule. Although CMS seems to have been very careful so as not to propose the creation of an intent or reasonableness-of-action standard, this proposal certainly mirrors a number of common *facts and circumstances* themes more commonly found in False Claims Act and AKS litigation. For example, if adopted, these requirements would

lead to the following questions: Were the entity's monitoring and oversight activities reasonable? Did the entity know, or should it have known, that the value-based activity was not achieving its intended purpose? When did the physician become aware? If one party conceals the failure of the program from the other, will both be held accountable? As proposed, this "moving target" standard will present challenges to an industry looking for bright-line protection.

Finally, CMS is also seeking comments on whether additional safeguard requirements, such as temporal limitation (achieving value-based activities in a defined timeframe, e.g., three years), and whether requiring physicians to contribute some percentage (e.g., 15 percent) towards non-monetary remuneration would be consistent with the stated goals of the exemption. This contribution requirement is worthy of comment since it has posed an impediment to the adoption of electronic medical records, and may similarly impede the adoption of value-based activities.

Indirect Compensation Arrangements to Which the Value-Based Exceptions Are Applicable

The physician self-referral law can attach to direct and indirect ownership and compensation arrangements. There is a long-standing compensation exception for indirect arrangements that protects unbroken chains of compensation arrangements. This exception does not, however, allow the compensation to vary based on the volume and value of referrals. CMS acknowledged that it expects indirect compensation arrangements stemming from unbroken chains of financial relationships between the value-based enterprise and its VBE participants and that such arrangements might fail the indirect exception because they are based on volume and value of referrals. Accordingly, CMS outlined the circumstances under which the value-based exceptions would apply to an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain.

Rather than proposing a wholesale new exception that would purport to protect indirect value-based compensation arrangements under the applicable proposed exceptions, CMS proposes two alternative methodologies to achieve this goal.

In its first iteration, CMS proposes to protect indirect arrangements when the value-based arrangement *is the link in the chain closest to the physician*, meaning that a physician would need to be the direct party to the value-based arrangement for the indirect compensation arrangement to qualify as a "value-based arrangement" for purposes of applying the proposed value-based exceptions. Under this proposal, CMS states that parties would need to determine first if an indirect compensation arrangement exists and, if so, confirm that the remuneration paid to the physician qualifies under a value-based arrangement. If it does qualify, the value-based exceptions would be available to protect the arrangement. CMS provides an example of an arrangement that would qualify. Assume that a physician's own practice pays the employed physician a bonus on a basis that varies with the volume and value of referrals to a hospital, *provided that the physician adheres to certain new value-based care protocols.* In this example, CMS also stated that a common parent organization owns both the hospital and the physician practice. Here, CMS clarified that the bonus compensation payments linked to referrals to the hospital

could be protected under one of the proposed value-based exceptions if the arrangement *closest to the physician* (the physician practice and the physician) qualifies as a value-based arrangement. This presumably means that not only would the hospital need to have a qualifying value-based arrangement with the practice, the relationship between the practice and the employed physician would need to be analyzed and qualify as well.

Alternatively, CMS is also considering whether to define specifically "indirect value-based arrangement" and specify in the proposed regulation that the value-based exceptions would be available to protect the arrangement. CMS attempted to clarify by stating the following:

> [A]n indirect value-based arrangement would exist if: (1) [b]etween the physician and the entity there exists an unbroken chain of any number (but not fewer than one) of persons (including but not limited to natural persons, corporations, and municipal organizations) that have financial relationships (as defined at § 411.354(a)) between them (that is, each person in the unbroken chain is linked to the preceding person by either an ownership or investment interest or a compensation arrangement); (2) the financial relationship between the physician and the person with which he or she is directly linked is a value-based arrangement; and (3) the entity has actual knowledge of the value-based arrangement in subparagraph (2).

This approach merely requires an unbroken chain of financial relationships between a physician and an entity qualifying as an "indirect value-based arrangement," and the three value-based exceptions would be potentially applicable to protect the remuneration.

Both indirect compensation proposals are a welcome attempt to sync up overlapping physician self-referral authorities, and CMS is soliciting comments on which approach is preferable.

Price Transparency

Health care price and consumer price transparency are common themes of interest in the Trump presidency. CMS noted that health care consumers may lack meaningful access to pricing information that could potentially help them choose providers. Therefore, CMS said it is committed to "ensuring that physician self-referral law policies do not infringe on patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest."

In almost a non-sequitur, CMS solicits comments regarding (1) the availability of pricing information and out-of-pocket costs to patients (including information specific to a particular patient's insurance, such as the satisfaction of the patient's applicable deductible, copayment, and coinsurance obligations); (2) the appropriate timing for the dissemination of information (i.e., whether the information should be provided at the time of the referral, the time the service is scheduled, or some other time); and (3) the burden associated with compliance with a requirement in an exception to the physician self-referral law to provide information about the factors that may affect the cost of services for which a patient is referred. Although it is unclear how, or more importantly why, price

transparency would be tackled in the dogmatic strict-liability maze of the physician self-referral law, CMS is nonetheless seeking comments to pursue price transparency in this forum.

CMS has one specific proposal under consideration with regard to price transparency—that it attaches as a requirement to all of the value-based exceptions. Although CMS does not have a specific proposal as to the content, form, or definition of "price transparency," it suggested examples, such as the provision of a public notice that alerts patients that out-of-pocket costs for DHS referred by the physician may vary based on the provider and the patient's insurance. CMS stated that a notice on the physician's website, a poster on the wall in the physician's office, or a notice in a patient portal used by the physician's patients might be acceptable. Requiring something more than a public notice, which has questionable utility, would likely operate like a lead balloon to the value-based exceptions and render them unusable. Price transparency has wide-reaching legal implications related to antitrust, consumer protection, and contracts, not to mention significant logistical and operational challenges inherent in the dynamic nature of patient costs because of unmet deductibles, in- or out-of-network provider status, and other complications, all of which are relevant irrespective of whether the physician making a referral has a financial relationship with the DHS entity. If CMS finalizes more specific and less generic transparency requirements applicable only to entities engaging in value-based arrangements, entities that seek to enter into beneficial value-based cost-reduction activities may be subject to a major disincentive to do so.

Modifications to Certain Definitions

Commercially Reasonable

Although a large number of physician self-referral law exceptions include the requirement that the arrangement be "commercially reasonable," to date, CMS has not codified a definition of the term. Although, in the preamble, CMS states that it proposes two alternative definitions, the actual proposed rule only contains one definition. Primarily, CMS proposes to define "commercially reasonable" to mean that the "particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements" and specifically states that a financial arrangement can be commercially reasonable "even if it does not result in profit for one or more of the parties." This issue of whether an arrangement must be profitable is extremely significant as a number of government regulators and enforcers outside of CMS, as well as government expert witnesses, have attempted to argue that an arrangement is de facto commercially unreasonable if the specific arrangement results in losses to a DHS entity, and even that it needs to be profitable as a stand-alone arrangement in order to be commercially reasonable. In the preamble (but not in the actual proposed regulation), CMS states that "commercially reasonable" could also be an "arrangement [that] makes commercial sense and is entered into by a reasonable entity of similar type of size and a reasonable physician of similar scope and specialty." Nevertheless, CMS seeks input on other possible definitions, in addition to commenting on these proposals.

Fair Market Value

In the preamble to the proposed regulation, CMS provides a history of the various regulatory issuances over the last 25+ years in which the agency has made modifications to the term "fair market value."

As part of the definition of "fair market value," CMS has also relied upon the term "general market value." In 1998, in the development of the proposed rules, CMS relied upon a definition elsewhere in HHS's regulations related to circumstances in which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. As such, in the preamble, CMS states that the current definition of "general market value" is "unconnected to the recognized valuation principle of 'market value' and itself may be the driver of valuation industry policy and procedure," and, therefore, CMS proposes to revamp the definition in order to be "consistent with the recognized principle of 'market' valuation to address this discrepancy and ease the burden on parties attempting to ensure compliance with the fair market value requirement…."

CMS proposes to define "general market value" as meaning "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 assets or at the time the parties enter into the service arrangement …." CMS also recognizes that the hypothetical value of a transaction may not always be "identical to the market value of the actual transaction being considered" as extenuating circumstances may require the parties to veer from identified surveys and theoretical valuation data.

To illustrate this point, CMS provides an example whereby a hospital is negotiating an employment arrangement with an orthopedic surgeon. The salary surveys indicate that compensation of $450,000 per year is appropriate. However, due to this particular surgeon's reputation as being highly sought after by professional athletes, the surgeon commands a significantly higher salary. CMS confirms that in this example, compensation substantially above $450,000 per year may be fair market value. This is a welcome development following the recent trend of health care valuation firms taking increasingly conservative positions within the framework of available market data, which is having the inevitable effect of driving down physician compensation.

Volume or Value of Referrals or Other Business Generated Between the Parties

In response to RFI comments expressing a lack of clear understanding as to when compensation is considered to take into account the volume or value of referrals or other business generated, CMS proposes codifying regulations defining and interpreting the "volume or value" and "other business generated" standards outside of the context of value-based arrangements. CMS makes clear that, if finalized, these special rules would supersede all other regulatory guidance and provide objective bright-line benchmarks for determining when compensation is considered to take into account the volume or value of referrals or other business generated. In the proposed rule, instead of focusing on defining when compensation has not been determined in a manner that takes into account the volume or value of referrals or other business generated, CMS looks to define exactly

when compensation will be considered to take into account the volume or value of referrals or other business generated between the parties.

Under the proposed rule, compensation takes into account the volume or value of referrals only if the formula used to calculate the physician's (or immediate family member's) compensation includes referrals as a variable. Alternatively, compensation may take into account 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 for which the compensation is determined. More explicitly, compensation will take into account the volume or value of referrals only if:

- the formula used to calculate the compensation will result in an increase or decrease of the compensation that positively correlates with the number or value of referrals. CMS proposes to define a positive correlation as existing between two variables when one variable increases as the other variable increases, or when one variable decreases as the other variable decreases. By way of example, compensation positively correlates with the number or value of referrals if the physician receives more compensation as the number or value of referrals increases. Likewise, compensation negatively correlates with the number or value of referrals if the physician receives less compensation as the number or value of referrals decreases; or

- there is a predetermined, direct, and meaningful "if X, then Y" correlation between the volume or value of referrals and the prospective rate of compensation to be paid over the duration of the arrangement. By way of example, a hospital-employed physician is entering into a renewal employment agreement in which the physician is paid based on personally performed services via a predetermined tiered compensation system according to the number of outpatient tests that were ordered during the previous year. Under this example, the compensation varies based on the volume or value of referrals, even if the physician is paid an unvarying rate per work relative value unit.

Remuneration

The statutory definition of "remuneration" contains a carve-out for the following: items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Historically, and based on CMS's decision in a 2013 Advisory Opinion, CMS took the position that surgical items, devices, or supplies could never fit within the carve-out. In this proposed rule, CMS proposes to amend the definition of "remuneration" to make clear that just because an item, supply, or device is classified as a "surgical device" does not mean that it falls outside of the carve-out. In addition, CMS clarifies the "used solely" provision by explaining that "the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes does not automatically mean that the furnishing of the item, device, or supply at no cost constitutes remuneration."

Transaction

In the proposed rules, CMS discusses the term "transaction" and the use of the exception for isolated transactions. Through its administration of the self-referral disclosure protocol ("SRDP"), CMS is aware of some parties "stretching" the exception for isolated transactions to protect arrangements where a single party makes a single payment for multiple services provided over an extended period of time.

CMS proposes revising the definition of "isolated financial transaction" to read as follows:

> (1) [A] transaction involving a single payment between two or more persons or a transaction that involves integrally related installment payments, provided that—
>
> (i) [t]he total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and
> (ii) [t]he payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.
>
> (2) An isolated financial transaction includes a one-time sale of property or a practice, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).

CMS states that "[t]he exception for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law," opining that Congress would not have imposed the requirements of the personal services exception and permit them to be evaded through use of the isolated transactions exception, and adding that the exception must be met for payments "at that time." While it is understandable that CMS would restrict arrangements involving multiple services over a lengthy time period as not sufficiently "isolated," nevertheless, the exception has been widely used to protect circumstances such as a single payment to a physician for fulfilling a hospital's unanticipated call coverage needs on a weekend or holiday where no other services are performed for the previous or subsequent six-month period, making a personal services contract unwarranted. Such circumstances happen, and health care organizations need to remain nimble to address such occurrences without running afoul of the physician self-referral law. CMS clearly believes such protection is appropriate under the physician self-referral law, since it is now proposing to protect these types of financial transactions as "limited remuneration" under a newly proposed exception. In so doing, and in proposing to restrict the application of the statutory isolated transaction exception, CMS should ensure that its preamble language in the final rule does not unnecessarily call into question previous instances of truly isolated occurrences and payments protected under this exception. Nor should CMS fashion a rule that relies on eliciting the parties' intent as to which exception might apply at the inception of the transaction, as CMS suggests here.

Group Practice Requirements

Although CMS acknowledges comments received during the RFI process requesting clarifications related to qualifying as a "group practice," CMS only proposes making some conforming revisions consistent with the proposed definitions and special rules for "commercially reasonable" compensation arrangements, "fair market value" compensation, and the volume or value standard. In addition, in order to address the transition from a volume-based to value-based health care system, CMS proposes clarifications to the special rules for profit shares and productivity bonuses. Specifically, CMS proposes allowing downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. In particular, CMS proposes a deeming provision related to the distribution of profits from DHS that is directly attributable to a physician's participation in a value-based enterprise. When profits are distributed to the participating physician, they would be deemed to not take into account the volume or value of the physician's referrals.

CMS's proposal would protect only the distribution of profits, as opposed to revenue, from DHS that are directly attributable to a physician's participation in a value-based enterprise, and CMS requests comment as to whether distribution of revenues should be protected as well. Because physicians who participate in value-based arrangements through group practices may not be partners or otherwise share in the group's profits, only group practice owners would be able to benefit from participation in value-based arrangements under CMS's proposal. Since CMS acknowledges that value-based enterprises want to reward the particular physicians who have brought value to the enterprise under the arrangement, this omission of group practice employees and independent contractors is inexplicable.

CMS also proposes clarifying the interpretation of the overall profits that can be distributed to physicians in a group to make clear that "overall profits" means either "the profits derived from all the DHS of any component of the group that consists of at least five physicians, which may include all physicians in the group" or "if there are fewer than five physicians in the group, the profits derived from all the DHS of the group." CMS also proposes a restriction on its "pooling" position from previous pronouncements that group practices cannot distribute profits from DHS on a service-by-service basis—i.e., to one subset of physicians using a particular methodology and a different subset or the same subset using a different methodology—even if the subset of physicians qualifies as a "pool."

Physician practices should consider submitting comments on CMS's proposed modifications to the requirements for qualifying as a group practice given the importance this definition has on satisfying the requirements for the in-office ancillary services exception.

Limited Remuneration to a Physician

CMS proposes an exception for limited remuneration to a physician where the amount of, or formula for, calculating the remuneration is not set in advance, provided that, among

other things, (1) the arrangement is for items or services actually provided by the physicians, (2) the remuneration does not exceed an aggregate amount of $3,500 in a calendar year, (3) the remuneration does not vary with the volume or value of referrals or other business generated, and (4) the remuneration does not exceed fair market value.

Similar to the non-monetary compensation exception, the monetary limitation will be adjusted for inflation. However, unlike the non-monetary compensation exception, this proposed exception must be for actual items and services provided. CMS seeks comments related to the $3,500 limit and whether it is necessary to limit the applicability of the exception to services that are personally performed by the physicians and items provided by the physician.

In proposing this exception, which, if adopted, will be very helpful to eliminate inadvertent, procedural physician self-referral law violations, CMS acknowledges that this exception can be used in conjunction with other exceptions. As such, the proposed exception may provide relief for entities that may begin an arrangement for items or services before squarely fitting into another exception.

Denial of Payment/Disallowance

The current physician self-referral regulations address the period of time during which a physician may not make referrals of DHS to an entity, and an entity cannot bill for the referred DHS, because the financial relationship between the referring physician and the entity fails to satisfy the requirements of an applicable exception. CMS has referred to this timeframe as the “period of disallowance.” In the proposed rule, CMS notes that its administration of the SRDP revealed that application of the “period of disallowance” rules were “overly prescriptive and impractical.” As a result, CMS proposes to delete the “period of disallowance” provisions in their entirety, removing the specific steps and process required to end a period of noncompliance. Instead, the proposed rule provides general guidance on how to remedy compensation problems that arise during the course of an arrangement and determine when the period of noncompliance ends.

In particular, CMS makes a key distinction related to when corrective actions are taken with respect to potential noncompliance. CMS notes that parties who identify and remedy errors during the course of the arrangement in a timely manner are not necessarily “turning back the clock” to address noncompliance. In contrast, once a financial relationship has ended, the parties cannot “unring the bell” and cure past noncompliance by recovering/repaying compensation. Through this distinction, CMS emphasizes the importance of implementing an effective compliance program that identifies and remedies issues with financial relationships in a timely manner, when a financial relationship is still active. We note that the position taken here with respect to addressing noncompliance during the course of a financial relationship is somewhat inconsistent with the stricter position CMS takes with respect to remedying noncompliance after the fact (but during the course of a relationship) through use of the isolated financial transactions exception.

Ownership and Investment Interests

CMS proposes two new exclusions to the types of relationships that constitute an "ownership or investment interest"—one for titular ownership arrangements and one for employee stock ownership plans:

First, CMS proposes to extend the concept of titular ownership that was introduced in the application of the "stand in the shoes" doctrine by confirming that ownership and investment interests do not include titular interests. An ownership or investment interest would be considered "titular" if the physician does not have the ability or right to receive the financial benefits of ownership. This proposed change will be of significant interest to hospitals and other DHS entities that operate in states with corporate practice of medicine restrictions.

Second, CMS proposes that an ownership or investment interest that arises through participation in an employee stock ownership plan that is qualified under Internal Revenue Code Section 401(a) ("ESOP") would not constitute an ownership or investment interest for purposes of the Stark Law. Unlike the carve-out that currently applies to interests in an entity that arise from a retirement plan, the proposed ESOP exclusion is not restricted to an interest in an entity that both employs the physician and sponsors the plan.

Special Rules – Temporary Noncompliance

Beginning with the calendar year ("CY") 2008 proposed rule, CMS has been slowly evolving in its approach to arrangements that satisfy all but the "procedural" requirements of an exception. In the proposed rule, CMS notes its experience through administration of the SRDP with respect to reviewing compensation arrangements that involve short periods of noncompliance at the outset of the arrangement resulting from the parties' failure to reduce the terms of the arrangement to writing. As a result, CMS proposes to create a new special rule for compensation arrangements related to temporary noncompliance with the writing ***or*** signature requirements. Under the proposed rule, the writing requirement or signature requirement would be deemed satisfied if the parties obtain the required writing and/or signatures within 90 consecutive calendar days immediately following the date on which the arrangement became noncompliant, and the arrangement otherwise fully complies with an applicable exception.

In proposing the new special rule, CMS highlights a number of related issues that parties should keep in mind when assessing compliance with an applicable exception that may not satisfy certain "technical" requirements:

- A single, formal written agreement is not necessary to satisfy an applicable writing requirement.
- The proposed special rule does not negate the requirement under various exceptions that compensation be "set in advance."
- The "set in advance" requirement does not necessarily require that the compensation for a particular arrangement be reduced to writing before the furnishing of items or services—documentation of a consistent rate of

compensation over the course of an arrangement can provide evidence that compensation was "set in advance."
- There are many ways in which compensation can be documented before the furnishing of items or services, including, for example, documentation recording similar payments to or from similarly situated physicians for similar items or services.

In addition, CMS clarifies its well-established policy that the signature requirements under various exceptions can be satisfied by an electronic signature that is valid under federal or state law.

Office Space and Equipment Exception

The statutory and regulatory exceptions related to compensation arrangements for the rental of office space and the rental of equipment both require that the office space/equipment be used exclusively by the lessee, and not shared with or used by the lessor or any other entity related to the lessor. As noted by CMS, the purpose of the exclusive use rule was to prevent sham leases, and not to prohibit multiple lessees from using the rented space or equipment at the same time. Therefore, CMS proposes to clarify the regulatory exceptions for space and equipment rentals to reflect its long-standing policy that the lessor (or any other person or entity related to the lessor) is the only party that must be excluded from using the space or equipment while it is being used by the lessee.

Recruitment Exception

CMS proposes modifying the physician recruitment exception so that a physician practice is only required to sign underlying documentation of the recruitment arrangement if the practice is a conduit for the remuneration and does not pass all of the remuneration directly through to the physician. This modification would eliminate the need for a physician practice to sign the underlying documentation if the practice does not receive any financial benefit under the recruitment arrangement. Examples of recruitment arrangements that would not require a physician practice signature include:

- when the recruited physician joins a practice, but the recruitment payments are made directly from the hospital to the recruited physician;
- when recruitment remuneration is paid by a hospital to a physician practice, but the practice passes 100 percent of the remuneration through to the recruited physician; and
- when a recruited physician joins a physician practice after all income guarantee payments have been made but before the physician's community services obligations to the hospital are completed.

Exception for Services Unrelated to DHS

CMS proposes an overhaul of the exception for "remuneration unrelated to the provision of DHS" in recognition of its perception of Congressional intent that the exception applies

to a narrow, "but not empty," subset of compensation arrangements. The proposed changes clarify that remuneration from a hospital to a physician does not relate to the provision of DHS if it is for items or services not related to "patient care services," while retaining the requirement that the remuneration not be determined in any manner that takes into account the volume or value of the physician's referrals. After identifying "patient care services" as the touchstone for determining when the exception is applicable, CMS attempts to further illustrate when the exception is applicable through examples and rules. Specifically, CMS sets out when the exception does not apply:

- Payments for call coverage, medical director services, or utilization review services are related to patient care services and therefore not able to take advantage of this exception.
- Remuneration for rental of medical equipment or purchasing of medical devices from a physician cannot utilize the exception because the items rented or purchased are used in the provision of patient care services.

CMS also sets out when the exception may apply:

- Payment for a service is unrelated to DHS if (1) the service can be provided legally by a person who is not a licensed medical professional, and (2) the service is of a type that is typically provided by such persons.
- If a physician sells his or her practice to join another practice and sells the furniture from his or her medical office to the hospital, this remuneration likely would not be related to patient care services and could take advantage of the exception, provided the other elements of the exception are satisfied.
- Rental payments made by a teaching hospital to a physician to rent his or her house for purposes of housing a visiting faculty member could continue to utilize the exception, consistent with an established CMS policy regarding the scope of the exception.

Payments by Physicians

CMS proposes changes to the exception for "payments by a physician" in an effort to clarify what has been a somewhat confusing history of interpreting the exception. Under the proposal, the exception would not be available to protect any arrangement that is specifically addressed by one of the other ***statutory exceptions*** to the Stark Law (i.e., those exceptions set forth at Section 1877(e) of the Social Security Act, which are codified at 42 CFR § 411.357(a) through § 411.357(i)). In particular, CMS highlights that the exception is not available to protect remuneration for the rental of office space or equipment. However, as a result of this clarification, the exception for payment by a physician would still be applicable even if another ***regulatory exception*** is available to protect the arrangement (i.e., those exceptions that are codified at 42 CFR § 411.357(j) *et seq*.).

In connection with this proposal, CMS highlights several considerations to keep in mind when assessing the applicability of the exception, such as the exception could apply to payments for the use of space that is not office space (e.g., storage space or residential

properties). At the same time, CMS sets out that the exception does not apply to a physician who makes in-kind "payments" in exchange for cash or cash equivalents from the entity.

Finally, through its discussion of the changes to this exception, CMS reminds parties that a financial relationship for purposes of the physician self-referral law is not created when a physician or DHS entity acts purely as a pass-through, taking remuneration from one party and passing the exact same amount to another party.

Fair Market Value Compensation Exception

After reconsidering its long-standing policy related to the application of the fair market value compensation exception, CMS proposes to revise the exception so that it is available to protect arrangements for the rental of office space. However, because the rental of office space has been the subject of abusive arrangements, CMS also proposes to incorporate into the exception a prohibition on percentage-based compensation and per-unit of service compensation formulas with respect to calculating rental charges under the lease. If finalized, the fair market value compensation exception would be available to protect short-term (i.e., less than one year) arrangements for the rental of office space.

Electronic Health Records and Cybersecurity

Even though CMS did not specifically request comments in the RFI with respect to the exception for arrangements involving the donation of interoperable EHR software or information technology and training services (the "EHR exception"), CMS received a number of comments related to the EHR exception and, as a result, is proposing modifications and clarifications to this exception. The key changes include:

- updating the requirements within the EHR exception pertaining to interoperability and that software will be deemed to be "interoperable" for purposes of compliance with the EHR exception if it is certified under the Office of the National Coordinator for Health Information Technology's certification program on the date of donation;
- revising the requirements to address the issue of data lock-in or "information blocking" by prohibiting a donor from both engaging in information-blocking activities that affect the donated items and services ***and*** using the donated items and services as a means of information blocking;
- clarifying that donations of cybersecurity software and services may be permitted under the current EHR exception;
- removing the EHR exception's sunset provision (or, in the alternative, extending the current sunset date past December 31, 2021);
- modifying certain definitions utilized in the EHR exception to ensure consistency with the 21st Century Cures Act;
- proposing two alternatives to the EHR exception's 15 percent donation requirement to eliminate or reduce the percentage contribution required for either rural/small physicians organizations or for all physician recipients; and
- permitting certain donations of replacement technology under the EHR exception, while safeguarding against instances where donors inappropriately offer

unnecessary technology rather than upgrading their existing technology for appropriate reasons.

Provision of Non-Physician Practitioners

In the CY 2016 final rule, CMS finalized a new exception to permit hospitals, federally qualified health centers ("FQHCs"), and rural health clinics ("RHCs") to provide remuneration to a physician or physician practice to assist with employing a non-physician practitioner, such as an advanced practice nurse or a physician assistant (referred to in the rules as an "NPP"). A key requirement of the exception is that the NPP has not, within one year of the commencement of his or her compensation arrangement with the physician/practice, been employed or engaged to provide patient care services by a physician/practice that has a medical practice located in the geographic area served by the hospital.

In response to several inquiries regarding the interpretation of this requirement, CMS proposes a number of modifications. For example, the terms "patient care services," "referral," and "practiced" would be revised to refer to "NPP patient care services," "NPP referral," and "furnished NPP patient care services." As a result of these changes, if an individual previously worked in the hospital's geographic area in a different clinical capacity (e.g., as a registered nurse or medical assistant), it would not prevent the provision of assistance covered by the exception.

In an attempt to prevent potential abusive relationships, CMS proposes to require that the arrangement between the NPP and the physician/practice commence ***on or after*** the commencement of the assistance arrangement between the physician/practice and the hospital/FQHC/RHC.

* * *

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