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The Robinson+Cole Health Law Group is committed to examining and reporting on issues important to the health care and life sciences industries. Below are excerpts from our *Health Law Diagnosis* blog, where we post on fraud and abuse, government enforcement, Medicare and Medicaid, reimbursement, hospitals and health systems, pharmaceuticals, medical devices, and other areas of interest.

CMS Publishes Monumental Changes and Updates to the Physician Self-Referral (Stark) Law Regulations

On November 20, 2020, the Centers for Medicare and Medicaid Services (CMS) published its long-awaited and highly anticipated final rule updating regulations promulgated under the Physician Self-Referral or "Stark" law (the OIG simultaneously published updates to the Anti-Kickback Statute regulations). Among other things, CMS introduced new Stark exceptions for certain "value-based arrangements," the donation of cybersecurity technology and services and limited remuneration to physicians; introduced new definitions and updated key terms, including "commercial reasonableness," the "volume and value" standard and "fair market value"; and updated several existing exceptions, including the exception for the donation of electronic health record items and services. The changes to the Stark law regulations become effective January 19, 2021, except for the changes concerning profit shares and productivity bonuses for group practices, which go into effect January 1, 2022.

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A. Value-Based Arrangements (42 C.F.R. §411.357(aa)).

In response to industry comments that the Stark law is inhibiting providers from entering into beneficial, value-based arrangements that reduce costs and improve care quality, CMS introduces three new value-based arrangement exceptions, with requirements varying based on the amount of risk borne by the "value-based enterprise." Remuneration paid under arrangements meeting the requirements of one of the new value-based arrangements exceptions will not be considered a compensation relationship subject to Stark's referral prohibition. CMS intended these exceptions to encourage physicians to enter into new, innovative value-based care arrangements that focus on quality improvement and reduction of costs. It is important to note that these exceptions are not limited by payor (i.e., they do not apply to Medicare patients only).

1. **Definitions**. Before delving into the details of each exception, it is important to understand CMS' newly defined terms relating to these exceptions (defined terms appear below in italics):

   "Value-based arrangement" means an arrangement for the provision of at least one *value-based activity* for a *target patient population* to which the only parties are: (1) a *value-based enterprise* and one or more of its *VBE participants*; or (2) *VBE participants* in the same *value-based enterprise*.

   Practically, the parties to a value-based arrangement must include at minimum, an entity (as defined under Stark) and a physician. In commentary, CMS states its expectation that most value-based arrangements would involve care coordination and management of the target patient population.

   "VBE participant" means a person or entity that engages in at least one *value-based activity* as part of a *value-based enterprise*.

   It is important to note that the term "entity" as used in this definition is not limited to the definition of "entity" under Stark (see 42 C.F.R. §411.351).

   "Value-based activity" means the provision of an item or service, the taking of an action, or the refraining from taking an action, provided that the activity is reasonably designed to achieve at least one *value-based purpose* of the *value-based enterprise* of which the parties to the arrangement are participants.

   In one example provided in the final rule, if a value-based purpose of an enterprise is to coordinate and manage the care of patients who undergo joint replacements, a value-based activity may be routine post-discharge meetings between a hospital and the responsible physician. In contrast, if the value-based purpose of the enterprise is to reduce the costs to payors while improving or maintaining care quality, providing patient care services without monitoring utilization would not appear to be reasonably designed to achieve that purpose and would not be a value-based activity. CMS also reminds stakeholders throughout the final rule that referrals of patients for designated health services (DHS) are not themselves a value-based activity.

   "Value-based enterprise" (VBE) means two or more *VBE participants*:

   i. collaborating to achieve at least one *value-based purpose*;

   ii. each of which is a party to a *value-based arrangement* with the other or at least one other *VBE participant* in the *value-based enterprise*;

   iii. that have an accountable body or person responsible for the financial and operational oversight of the *value-based enterprise*; and

   iv. that have a governing document that describes the *value-based enterprise* and how the *VBE participants* intend to achieve its *value-based purpose(s)*.

   CMS clarifies that a VBE does not itself need to be a separate legal entity (e.g., an accountable care organization) with the ability to contract on its own. CMS instead focuses on the function of the VBE so as not to limit appropriate legal structures.

   "Value-based purpose" means any of:

   i. coordinating and managing the care of a *target patient population*;

   ii. improving the quality of care for a *target patient population*;

   iii. appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a *target patient population*; or

   iv. transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a *target patient population*.

Importantly, CMS notes that the new regulations do not require that the value-based purpose(s) must be achieved for a value-based arrangement to be protected by a value-based arrangements exception. However, if the parties are aware that a specific activity will not further a value-based purpose, it will cease to qualify as a value-based activity, and the parties may need to amend or terminate their arrangement.

"Target patient population" means an identified patient population selected by a *value-based enterprise* or its *VBE participants* based on legitimate and verifiable criteria that:

i. are set out in writing in advance of the commencement of the *value-based arrangement*; and

ii. further the *value-based enterprise*'s *value-based purpose(s)*.

CMS does not define the criteria on which the identification may be based, however, it states in the final rule that criteria may include health characteristics, geographic characteristics, payor status or other defining characteristics. CMS also cautions stakeholders that selecting a target patient population consisting only of lucrative patients or avoiding expensive patients would not be legitimate criteria.

2. **The Value-Based Arrangements Exceptions.**

a. **Full Financial Risk Exception.** This exception applies where the VBE has accepted full, prospective financial risk from a payor for providing all patient care items and services to a target patient population. The requirements of this exceptions are as follows:

i. The VBE must take on this full financial responsibility within 12 months of the start of the value-based arrangement and must remain responsible for the duration of the value-based arrangement. CMS notes this is designed to allow the parties to a VBE to prepare for taking on full financial risk prior to the start date of the payor agreement;

ii. The remuneration is for or results from value-based activities provided to the target patient population;

iii. The remuneration is not for the reduction or limitation of medically necessary items or services;

iv. The remuneration is not conditioned on referrals of patients who are not part of the target patient population;

v. The remuneration may be conditioned on referral of patients to a particular provider if (a) the referral requirement is in writing and signed by the parties; and (b) the requirement does not apply if the patient prefers a different provider, if the patient's insurer determines the particular provider, or the referral is not in the patient's best interest; and

vi. Records of the methodology and amount of remuneration must be kept for 6 years and made available to the HHS Secretary upon request.

CMS provides additional commentary interpreting the above requirements. While we cannot replicate it all here, a few significant points are as follows:

- In-kind remuneration may be protected under this exception, as long as it is necessary and not duplicative of infrastructure the recipient has.
- While payments must be tied to a value-based activity, the exception does not require a one-to-one payment for a particular activity, and payments such as gainsharing, shared savings and similar payments may be protected.
- This exception does not prohibit a payor from making payments to a VBE to offset losses incurred by the VBE above those prospectively agreed to by the parties, nor does it prohibit application of stop-loss protections or risk corridors. However, CMS states that it is not permissible for the payor to fully offset the VBE's losses.

b. **Meaningful Downside Risk Exception.** This exception applies to value-based arrangements where a physician is responsible to repay or forgo at least 10% of the total value of the remuneration the physician receives under the value-based arrangement for failure to meet the value-based purpose(s) of the arrangement. In addition to the requirements of (ii) through (vi) of the full financial risk exception, the parties must satisfy the following:

i. A description of the nature and extent of the physician's downside risk must be set forth in writing; and

ii. The methodology used to determine the remuneration must be set in advance before performance of the value-based activities for which remuneration will be paid.

Unlike the full financial risk exception, this exception is not applicable to arrangements that occur in preparation of a value-based arrangement and prior to a physician assuming downside risk. Further, CMS explains that remuneration under this exception is from an entity (as defined under Stark) to a physician. This exception is focused on the risk assumed by an individual physician, as opposed to the VBE.

c. **Other Value-Based Arrangements Exception.** This exception applies to value-based arrangements that do not fit into the above exceptions, i.e., where no downside risk is assumed by an individual physician. In addition to the requirements of (ii) through (vi) of the full financial risk exception, the parties must satisfy the following:

   i. The arrangement must be set forth in a writing signed by the parties and must include at least the following:

      - the value-based activities to be undertaken under the arrangement;
      - how the value-based activities are expected to further the value-based purpose(s) of the VBE;
      - the target patient population;
      - the type or nature of the remuneration;
      - the methodology used to determine the amount of the remuneration; and
      - the standards against which the recipient of the remuneration will be measured, if any.

   ii. The outcome measures must be objective, measurable and based on clinical evidence or credible medical support;

   iii. Any changes to the outcome measure must apply prospectively only and must be set forth in writing;

   iv. The arrangement is commercially reasonable;

   v. The methodology used to determine the remuneration must be set in advance before performance of the value-based activities for which remuneration will be paid;

   vi. At least once annually, or once during the term if the term is less than one year, the parties or the VBE must monitor:

      - Whether the parties provided the required value-based activities;
      - Whether and how the value-based activities will further the value-based purpose; and
      - Progress toward reaching the outcome measures.

   vii. If the monitoring reveals that a value-based activity will not further a value-based purpose, the parties must either terminate the arrangement within 30 days or modify the value-based activity within 90 days. If the monitoring reveals that an outcome measure is unattainable, the parties must replace or terminate the outcome measure within 90 days.

For purposes of this exception, an "outcome measure" is a benchmark that quantifies improvements in or maintenance of the quality of patient care, or reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care. CMS emphasizes that although outcome measures may be central to many value-based arrangements, they will not apply to all. For example, the exception may protect a hospital's donation of infrastructure to a physician in the same VBE without necessitating that the physician meet particular outcome measures.

B. Group Practices & Profit-Sharing (42 C.F.R. §411.352).

The group practice rule under the Stark regulations allows a physician group (or a subset of at least five physicians within the group) to pool "overall profits" from DHS and distribute them, provided the distribution method does not take into account the volume or value of referrals. Compliance with this rule is required for a group practice to take advantage of the in-office ancillary services exception. The final rule provides updates and clarifications to the rules surrounding group practices. The below changes are effective January 1, 2022.

1. **"Overall Profits."** Currently, "overall profits" means a group practice's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. CMS has noted that this definition has caused

confusion when applied to groups that provide multiple DHS, and in particular whether profits may be distributed on a service-by-service basis. In response to this confusion, CMS is revising the term "overall profits." Under this new definition, profits from *all* DHS of any component of the group that consists of at least five physicians (which may include all physicians in the group) must be aggregated before distribution. Importantly, this definition prohibits service-by-service distribution of DHS profits. CMS also clarifies that for physician groups with less than five physicians, overall profits means the profits from all DHS provided by the group.

2. **Profits in a Value-Based Enterprise.** Given CMS's clarification to the definition of "overall profits" described above and the introduction of the new VBE exceptions, the final rule includes a regulatory provision to permit distribution of profits relating to participation in a VBE. CMS anticipates that this new policy will encourage physicians to participate in VBEs. Under this new policy, CMS is permitting a group practice to distribute to a physician the group's DHS profits that are attributable to such physician's participation in a VBE, including profits resulting from referrals by the physician. These profit shares will be deemed to not take into account the volume or value of referrals.

3. **Personally Performed Services.** In the final rule, CMS is revising the provision related to a physician's total patient encounters or relative value units (RVUs) to state that a productivity bonus will be deemed *not* to relate directly to the volume or value of the physician's referrals if it is based on the physician's total patient encounters or RVUs of services personally performed by the physician. CMS confirms that compensation to a physician in a group practice, including profit shares and productivity bonuses, may not take into account the volume or value of referrals or other business generated by the physician, unless the referrals are incident-to services personally performed by the physician.

C. Donation of Electronic Health Record Items and Services (42 C.F.R. §411.357(w)).

Currently, a Stark exception is available to permit an entity to donate electronic health record (EHR) items and services to physicians, subject to compliance with the requirements of the exception. The final rule updates and revises several significant aspects of the EHR donation exception.

1. CMS makes permanent the EHR donation exception and removes the exception's December 31, 2021 sunset date.

2. CMS clarifies that its existing position is and has been that the EHR items and services may include cybersecurity software and services, as long as the software and services have a predominant purpose of protecting electronic health records. (See subsection D below regarding the new cybersecurity technology donation exception.)

3. Under the EHR donation exception, physicians are required to contribute 15% of the donor's cost of the donated items and services prior to receipt of the items and services. The final rule revises the timing of these contribution payments. With respect to the initial donation of EHR items and services, the physician must still provide the contribution payment prior to receipt of the donated items and services. However, with respect to items or services provided by the donor after the initial donation (or the donation of replacement items and services), the physician must pay the 15% contribution at reasonable intervals. In commentary to the final rule, CMS suggested that monthly or quarterly intervals may be appropriate.

4. The existing EHR donation exception requires that the recipient not be in possession of "equivalent" items and services to the donated items and services. CMS has historically interpreted this requirement as a prohibition on the donation of replacement technology. As a result, this requirement has presented challenges to, for example, hospitals and physicians that desire to use the exception to replace a physician's EHR system with a system compatible with the hospital's system. The final rule eliminates this requirement.

5. Under the current requirements of the EHR donation exception, the donor (or any person on the donor's behalf) is prohibited from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services with other electronic prescribing or electronic health records systems. In light of the recently released regulations concerning information blocking issued pursuant to the 21st Century Cures Act, CMS has determined that this requirement is not compatible with those regulations and is unnecessary given the prohibitions on information blocking. As a result, the final rule eliminates this requirement.

D. Cybersecurity Donation Exception (42 C.F.R. §411.357(bb)).

In the final rule, CMS adds a new exception that permits entities to donate cybersecurity technology and services to physicians. This exception applies to the donation of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, and reestablish cybersecurity. The elements of the cybersecurity donation exception are as follows:

1. Neither the eligibility of a physician for, nor the amount or nature of, the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties;
2. Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor; and
3. The arrangement is documented in writing.

Importantly, the cybersecurity technology and services covered by this exception may include hardware. In contrast, the donation of hardware is not permitted under the EHR donation exception. There is also no requirement that the recipient contribute any portion of the donor's costs in providing the items and services, unlike the EHR donation exception. CMS provides examples of covered technology and services, which include software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software, data protection and encryption, and email traffic filtering.

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

The final rule adds a new exception that permits an entity to provide a physician up to $5,000 (subject to adjustment for inflation) in a calendar year in exchange for items or services provided by the physician. To comply with this exception, the following requirements must be satisfied:

1. The compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician;
2. The compensation does not exceed fair market value of the items or services provided by the physician;
3. The arrangement would be commercially reasonable even if no referrals were made between the parties;
4. If the compensation is for the lease of office space or equipment, it may not be determined using a formula based on:
    a. a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through use of the equipment, or
    b. a per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the physician to the entity.
5. If the compensation is for the use of premises or equipment, it may not be determined using a formula based on:
    a. a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement; or
    b. a per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises or equipment covered by the arrangement to the party to which the permission is granted.
6. If the remuneration is conditioned on the referral of patients to a particular provider, the arrangement must comply with 42 C.F.R. §411.354(d)(4), which is applicable to compensation from an employer, managed care contracts and personal services arrangements and requires, among other things, that the compensation be set in advance and consistent with fair market value.

The exception permits the physician to provide items or services through employees whom the physician has hired for the purpose of performing the services, through a wholly owned entity or through a locum tenens physician (as defined under the Stark regulations, except that the physician need not be a member of a group practice). Notably, this exception does not require a written agreement. According to CMS, this exception could apply to short-term service arrangements where the parties were unable to document the arrangement. For example, it may apply to the provision of temporary medical director services to fill an unexpected vacancy.

F. Assistance to Compensate a Nonphysician Practitioner (42 C.F.R.§411.357(x)).

Currently, a Stark exception permits hospitals to provide remuneration to a physician to assist with the employment of (or other compensation arrangement with) a nonphysician practitioner (NPP) in certain circumstances. The exception applies to remuneration provided by a hospital to a physician to compensate an NPP to provide "patient care services."

In response to confusion from the health care industry on the application of this exception, CMS updates this exception in the final rule.

1. The final rule changes references from "patient care services" to "NPP patient care services" and defines "NPP patient care services" as 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. CMS notes this was a particular area of confusion and clarifies that under this new definition, services provided by an individual who is not an NPP when the services are provided are not NPP patient care services.
2. CMS notes that it received questions from stakeholders regarding whether an NPP may begin their compensation arrangement with the physician before the start of the compensation arrangement between the hospital and physician. These commenters pointed out that nothing in the exception expressly prohibits an entity from reimbursing a physician for money or benefits paid to an NPP that is already employed. CMS states that reimbursement for an already employed NPP is antithetical to the purpose of the exception, which is to increase access to care. Accordingly, the final rule revises the exception to expressly require that the compensation arrangement between the hospital and the physician begins before the physician (or the physician organization in whose shoes the physician stands) enters into the compensation arrangement with the NPP.
3. References in the exception to "referral" are changed to "NPP referral," although CMS made no substantive changes to the meaning of the term.

G. Other Definitions ("commercially reasonable," "fair market value," "volume and value," "isolated financial transactions," "designated health services," etc.).

In the final rule, CMS provides important updates on its interpretation of terms used throughout the Stark law regulations, including the addition of a definition for the term "commercially reasonable." These definitional updates are highlighted below.

1. **Commercially Reasonable (42 C.F.R. §411.351).** Despite the requirement in many Stark law exceptions that the arrangement be "commercially reasonable," CMS had never codified a definition for this term. In the final rule, CMS defines commercially reasonable to mean that:

   > "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

   Importantly, CMS confirms in the definition that an arrangement may be commercially reasonable even if it is not profitable. For example, it may be commercially reasonable to enter into an arrangement that results in a loss to provide services necessary for community need, timely access to health care services, fulfillment of regulatory obligations, the provision of charity care and the improvement of quality and health outcomes. Additionally, CMS advises that when determining commercial reasonableness, the key question to ask is whether the arrangement makes sense, from the perspective of the parties to the arrangement, to accomplish the parties' goals. While the compensation terms are an important part of this determination, according to CMS, the test is not whether the compensation terms alone make sense to achieve the parties' goals.
2. **Fair Market Value (42 C.F.R. §411.351).** The requirement that compensation under certain arrangements be "fair market value" is a fundamental aspect of the Stark law and the related regulations. In prior rulemaking, CMS revised the definition of fair market value to add a reference to the volume or value standard found in many exceptions to the Stark law. In the final rule, CMS is removing references to the volume or value standard in its definitions of fair market value and general market value. According to CMS, the volume or value standard is separate and distinct from the fair market value standard and these concepts should not be connected in the definitions. In the final rule, CMS is modifying the definition of "fair market value" to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space. CMS is also updating its definition of "general market value" to address each of the types of transactions contemplated in the exceptions to the Stark law—asset acquisition, compensation for services, and rental of equipment or office space. The definitions are repeated in full below.

   Fair market value means:

   (1) General. The value in an arm's-length transaction, consistent with the general market value of the subject transaction.

(2) Rental of equipment. With respect to the rental of equipment, the value in an arm's length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) Rental of office space. With respect to the rental of office space, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment 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, and consistent with the general market value of the subject transaction.

General market value means:

(1) Assets. With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

(2) Compensation. With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

(3) Rental of equipment or office space. With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

CMS also cautions stakeholders on the use of salary surveys in determining fair market value. According to CMS, the rates in a salary survey may not always reflect a particular physician's services and extenuating circumstances may command that parties to an arm's-length transaction deviate from the salary surveys. In examples, CMS states that it may be appropriate (and fair market value) to pay above an amount suggested by a salary survey if a particular physician was highly sought-after. On the other hand, fair market value of a physician may be below the salary survey if a geographic area has a particularly low cost of living. This statement is somewhat at odds with CMS' position in the final rule (and reflected in the definition of general market value) that the value of a physician's services should be the same regardless of the identity of the purchaser.

CMS also clarifies its position that salaries at or below the 75th-percentile are not necessarily fair market value. CMS believes that many in the health care industry are under the mistaken impression that compensation at or below the 75th-percentile is always appropriate.

3. **Volume or Value of Referrals or Other Business Generated Standard (42 C.F.R. §411.354(d)).** In the final rule, CMS creates new special rules establishing specific circumstances in which compensation will be deemed to take into account the volume or value of referrals or other business generated. These special rules supersede previous, inconsistent CMS guidance.

   Under the special rules, compensation will be deemed to take into account the volume or value or referrals or other business generated only if:

   a. the compensation is *from an entity to a physician (or immediate family member of the physician)* and the mathematical formula used to calculate the amount of compensation includes referrals or other business generated by the physician as a variable, and the amount of the compensation *positively correlates* with the volume or value of the referrals to, or generation of business, for the entity; or

   b. the compensation is *from a physician (or immediate family member of the physician) to an entity* and the mathematical formula used to calculate the amount of compensation includes referrals or other business generated by the physician as a variable, and the amount of the compensation *negatively correlates* with the volume or value of the referrals to, or generation of business, for the entity.

   The above special rules have limited application and do not apply to the following exceptions: medical staff incidental benefits, professional curtesy, community-wide health information systems, electronic prescribing items and services, EHR items and services and cybersecurity technology and services. Further, the above special rules do not apply to the compensation rules regarding unit-based compensation.

4. **Remuneration (42 C.F.R. §411.351).** CMS revises the definition of "remuneration" with respect to the carve-out for items, devices and supplies that are used solely for collecting, transporting, processing or storing specimens, or are used for ordering tests or communicating results to the entity providing the items, devices or supplies. Under the revised definition, the items, devices and supplies must "in fact" be used for the above purposes. The final rule modifies the definition to clarify that an item may have multiple uses, but as long as it is actually used only for one of the permitted purposes, it will not be considered remuneration from an entity to a physician. While

not added to the regulatory text, CMS reiterates its belief that the items, devices and supplies subject to this carve-out must be of low value and must have little to no independent value to the physician recipient.

5. **Designated Health Services (42 C.F.R. §411.351).** Under the final rule, CMS revises the definition of DHS to state that services provided to a hospital inpatient are not DHS if providing the service does not increase the amount of Medicare's payment to the hospital under any of the following prospective payment systems: (i) acute care hospital inpatient; (ii) inpatient rehabilitation facility; (iii) inpatient psychiatric facility; or (iv) long-term care hospital.

H. <u>Other Updates</u>.

1. **Indirect Compensation Arrangements (42 C.F.R. §411.357(p)).** In the final rule, CMS modifies its regulations addressing indirect compensation arrangements to incorporate the conditions of the special rules on unit-based compensation when determining whether an indirect compensation arrangement exists. Under the newly revised regulations, an unbroken chain of financial relationships between an entity and a physician will be an indirect compensation arrangement if the physician (or immediate family member of the physician) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the physician for the entity furnishing DHS, and *any* of the following are true:

   a. the individual unit of compensation is not fair market value;

   b. the individual unit of compensation takes into account the volume or value of referrals or other business generated (as defined by the special rules above).

   Additionally, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation based on the volume or value of referrals or other business generated by the referring physician for the entity.

2. **Isolated Transactions (42 C.F.R. §411.357(f)).** In the final rule, CMS makes several changes to the Stark law exception for isolated transactions. The final rule specifies that isolated transactions are one-time transactions; adds as an example of an isolated financial transaction a single instance of forgiveness of an amount owed in settlement of a bona fide dispute; and clarifies that settlement of a bona fide dispute under the isolated transactions exception does not retroactively bring the compensation arrangement that gave rise to the dispute into compliance with Stark. CMS also clarifies in commentary that the isolated transactions exception does not apply to payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services, because this not a payment for a single transaction.

3. **Regulatory Decoupling.** Several Stark exceptions require that the arrangement does not violate the anti-kickback statute for the arrangement to comply with the applicable exception. The final rule removes this requirement from all exceptions except for the fair market value exception (see subsection H.12 below regarding amendments to the fair market value compensation exception). CMS is also removing requirements related to federal or state billing and claims submissions laws and regulations from all the regulatory exceptions.

4. **Denial of Payment for Services Furnished under a Prohibited Referral—Period of Disallowance (42 C.F.R. §411.353(c)).** The Stark regulations provide that a Medicare payment may not be made for DHS furnished pursuant to a prohibited referral unless (i) an entity did not have actual knowledge, and did not act in reckless disregard or deliberate ignorance, of the identity of the physician who made the referral and (ii) the claim otherwise complies with all applicable Federal and State laws, rules, and regulations. In 2008, CMS amended the regulation to define the period during which referrals are prohibited as the "period of disallowance," and to provide that this period begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than:

   a. where the noncompliance is unrelated to compensation, the date the financial relationship satisfies all of the requirements of an applicable exception;

   b. where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or

   c. where the noncompliance is due to the payment of compensation that is insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception.

In its 2008 rulemaking, CMS emphasized that these provisions only prescribed an outside date for the period of disallowance, and that parties could determine that the period of disallowance ended earlier than the outside date prescribed by the regulation on the theory that the financial relationship ended prior to this date.

The final rule deletes the provisions added by the 2008 rulemaking. In its commentary, CMS explains that in application, these provisions appear to be overly prescriptive and impractical, and states that the analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship, including the operation of the financial relationship as negotiated between the parties.

5. **Special Rule for Reconciling Compensation (42 C.F.R. §411.353(h)).** The final rule adds a limited "grace period" to reconcile payment discrepancies following the expiration or termination of a compensation arrangement. The new rule permits an entity to submit a claim or bill and permits payment to be made to an entity that submits a claim or bill for a DHS if:

   a. no later than 90 days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and

   b. except for the discrepancies in payments that were reconciled, the compensation arrangement fully complies with an applicable Stark exception.

6. **Ownership or Investment Interests (42 C.F.R. §411.354(b)(3)(vi)).**

   a. **Titular Ownership or Investment Interest.** Under the Stark regulations, a "titular" ownership or investment interest exists if a physician is not able or entitled to receive any of the financial benefits of ownership or investment. Under current Stark regulations, the concept of titular ownership or investment interests applies only to the "stand in the shoes" provisions, which pertain to compensation arrangements--a physician with only a titular ownership or investment interest in a physician organization is not required to stand in the shoes of the physician organization.

      The final rule extends the concept of titular ownership or investment interests to exclude them from "ownership or investment interests" as defined under the Stark regulations. CMS notes that this change should afford greater flexibility and certainty to providers and suppliers, especially in states where the corporate practice of medicine is prohibited. However, CMS cautions that any *compensation* arrangement between a physician and an entity in which the physician or an immediate family member of the physician holds only a titular ownership or investment interest must nonetheless satisfy all the requirements of an applicable Stark exception.

   b. **Employee Stock Ownership Program.** Under current Stark regulations, the definition of ownership or investment interests excludes an interest in an entity arising from a retirement plan offered by that entity to a physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity. CMS notes that in certain cases, employers seeking to offer retirement plans to physician employees may, for federal or state law or taxation reasons, structure a retirement plan using a holding company. CMS uses the example of a home health agency that desires to sponsor a retirement plan for its employees and establishes the plan using a holding company whose primary asset will be the home health agency. To effectuate the retirement plan, the home health agency's assets are transferred to or purchased by the holding company, which then employs the physicians and other staff of the home health agency, and the holding company sponsors the retirement plan for its employees, offering the employees (including physician employees) an interest in the holding company. CMS notes that under current Stark regulations, the physician's interest in the holding company would not be considered an ownership or investment interest because the physician is employed by the holding company, the holding company sponsors the retirement plan, and the physician's ownership interest in the holding company arises through the retirement plan sponsored by the holding company. However, because the physician has an interest in the retirement plan that owns the holding company, and the holding company owns the home health agency, the physician has an indirect ownership or investment interest in the home health agency that would not be excluded under the retirement plan exclusion from the definition of an ownership or investment interest and may not satisfy the requirements of an applicable exception.

      CMS further notes that a common holding company structure involves a holding company owned by its employees, including physician employees, through an employee stock ownership plan (ESOP), which is an individually designed stock bonus plan, or a stock bonus and money purchase plan, qualified under Internal Revenue Code (IRC) §401(a) and designed to invest primarily in qualifying employer securities. Under this structure, the holding company owns a separate legal entity that provides DHS. CMS notes that ESOPs must

be structured to comply with certain safeguards under the Employee Retirement Income Security Act of 1974 (ERISA. Given the statutory and regulatory safeguards that exist for ESOPs, CMS believes that an interest in an entity arising through participation in an ESOP merits the same protection from the Stark law's prohibitions as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity.

Based on this analysis, the final rule excludes from the definition of "ownership or investment interests" an interest in an entity arising from an ESOP qualified under IRC §401(a). CMS notes that, as with the current retirement interest exclusion, employer contributions to the ESOP on behalf of an employed physician will be considered part of the physician's overall compensation and will have to meet the requirements of an applicable Stark exception.

7. **Special Rule on Compensation Arrangements (42 C.F.R. §411.354(e)).** In commentary to the final rule, CMS advises that it has reconsidered its policy on temporary noncompliance with the signature and writing requirements of various Stark compensation arrangement exceptions. CMS explains that under the CMS Voluntary Self-Disclosure Self-Referral Disclosure Protocol (SRDP) it has reviewed numerous compensation arrangements that fully satisfied all the requirements of an applicable Stark exception except for the writing or signature requirements, and that, in many cases, there are short periods of noncompliance with the Stark law at the outset of a compensation arrangement because the parties begin performance before reducing the key terms and conditions to writing. CMS believes that as long as the compensation arrangement otherwise meets all the requirements of an applicable exception and the parties memorialize the arrangement in writing and sign the written documentation within 90 days, the arrangement does not pose a risk of program or patient abuse.

   The amended rule for noncompliance with the writing or signature requirements of an applicable exception for compensation arrangements replaces the current special rule for compensation arrangements addressing writing requirements and the current rule for temporary noncompliance with signature requirements, and adds a new rule on electronic signatures. The amended rule provides as follows:

   a. Application. The rule applies only to compensation arrangements.

   b. Writing requirement. Where the Stark regulations require a compensation arrangement to be in writing, this requirement may be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties.

   c. Signature requirement. In the case of any signature requirement, this requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law.

   d. Special rule on writing and signature requirements. Where a compensation arrangement must be in writing and signed by the parties to satisfy a Stark exception, the writing requirement or the signature requirement is satisfied if:

      i. The arrangement between the entity and the physician fully complies with an applicable Stark exception except with respect to the writing or signature requirement of the exception; and

      ii. The parties obtain the required writing(s) or signature(s) within 90 days immediately following the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them.

   CMS commentary stresses that permitting parties up to 90 days to satisfy the writing requirement of an applicable exception does not amend or affect the requirement under various Stark exceptions that compensation must be set in advance (see subsection H.8 below regarding amendments to the "set in advance" requirement), noting that to establish compliance with the Stark law in reliance on the special rule on writing and signature requirements, the amount of or formula for calculating compensation must be set in advance and the arrangement must satisfy all other requirements of an applicable exception, other than the writing or signature requirements.

8. **Special Rules on Compensation – "set in advance" (42 C.F.R. §411.354(d)(1)).** The current Stark regulations provide that compensation is considered "set in advance" if aggregate compensation, a time-based or per-unit of service based (whether per use or per service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items or services for which the compensation is to be paid. Under current regulations, the formula for determining the compensation must be objectively verifiable, and the formula may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

   The final rule amends these requirements to underscore that this rule is merely an optional "deeming provision" and not a requirement, and to codify requirements that must be met for modifying compensation and satisfying the requirement that it is "set in advance." Under the amended rule:

a. Compensation is deemed to be "set in advance" if aggregate compensation, a time-based or per-unit of service-based (whether per use or per-service) amount, or a specific formula for calculating compensation is set out in writing before the furnishing of the items, services, offices space, or equipment for which the compensation is to be paid, and the formula for determining the compensation must be objectively verifiable.

b. Compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is "set in advance" if all of the following conditions are met:

    i. All requirements of an applicable Stark exception are met on the effective date of the modified compensation (or the formula for determining the modified compensation).

    ii. The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid.

    iii. Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. The parties do not have the 90-day "grace period" under the special rule on writing and signature requirements to reduce the modified compensation terms to writing.

CMS' commentary notes the following points with respect to this amendment:

- Except for the writing and signature requirements, a compensation arrangement must satisfy all the requirements of an applicable exception, including the set in advance requirement, during the initial 90 days of the arrangement (and thereafter).
- Any modification of the compensation terms of an arrangement during the initial 90 days (or thereafter) must meet all the conditions of the final rule for the compensation to be set in advance.
- The modified compensation (or formula for determining the compensation) must be sufficiently set forth in writing *before* the furnishing of items, services, office space, or equipment for which the modified compensation is to be paid, even if the modification occurs during the first 90 days of the arrangement.
- According to CMS, there are many document types that may be used (alone or in combination) to establish that compensation is set in advance, including: emails, text, internal notes to file, similar payments between the same parties for similar items or services under prior arrangements, generally applicable fee schedules, and/or documents showing a pattern of payments to or from other similarly situated physicians for similar items or services.

9. **Exceptions for Rental of Office Space and Rental of Equipment (42 C.F.R. §411.357(a) and (b)).** The Stark law and regulations include exceptions to its referral and billing prohibitions for certain arrangements involving the rental of office space or equipment. Among other things, the exception requires the office space or equipment to be used exclusively by the lessee when being used by the lessee. In the final rule, CMS states that disclosures to the SRDP have included several arrangements where multiple lessees use the same rented office space or equipment either contemporaneously or in close succession to one another while the lessor is excluded from using the premises or equipment, but where the disclosing parties assumed that the arrangements violated the Stark law because the arrangements did not satisfy the exclusive use requirement of the applicable exception. To clarify CMS' longstanding policy that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment, the final rule provides that for purposes of the Stark law exceptions relating to rental of office space and rental of equipment, "exclusive use" means that the lessee (and any other lessees of the same office space or equipment) uses the office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor), and further that the lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or the equipment.

10. **Exception for Physician Recruitment (42 C.F.R. §411.357(e)).** The Stark law and regulations include an exception for remuneration from a hospital, federally qualified health center or rural health clinic to a physician to induce the physician to relocate to the geographic area served by the hospital to become a member of the hospital's medical staff. Under current Stark regulations, remuneration provided by a permissible recruiting entity to a physician, either indirectly to a physician practice or directly to a physician who joins a physician practice, the physician practice is required to sign the written recruitment agreement. CMS has previously declined to relax this signature requirement.

    In commentary to the final rule, CMS states that it has reconsidered its position, noting that it has seen arrangements in the SRDP in which a physician practice hiring a physician recruited by a recruiting entity did

not receive any financial benefit as a result of the recruitment arrangement. Examples of such arrangements include arrangements under which (i) the recruiting entity paid the recruitment remuneration to the recruited physician directly, (ii) remuneration was transferred from the recruiting entity to the physician practice but the practice passed all of the remuneration to the recruited physician; and (iii) the recruited physician joined the physician practice after the period of an income guarantee but before the physician's "community service" repayment obligation was completed. In each of the arrangements, CMS states that it does not believe that a compensation arrangement of the type the statute is intended to protect against (that is, the type of financial self-interest that impacts a physician's medical decision making) existed between the physician practice and the recruiting entity because the physician practice is not receiving a financial benefit from the recruitment arrangement.

Accordingly, the final rule modifies the signature requirement under the physician recruitment exception to require the physician practice to sign the writing documenting the recruitment arrangement only if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

11. **Exception for Payments by a Physician (42 C.F.R. §411.357(i)).** Under the Stark regulations, a compensation arrangement constituting a "financial relationship" for purposes of the Stark law does not include payments made by a physician (or his or her immediately family member):

    a. to a laboratory in exchange for the provision of clinical laboratory services, or

    b. to an entity as compensation for any other items or services furnished at a price consistent with fair market value and not specifically excepted by another Stark exception related to ownership/investment interests or compensation arrangements set forth in 42 C.F.R. §411.355 through §411.357, including, but not limited to, the fair market value exception at 42 C.F.R. §411.357(l).

    In response to comments that this regulation unreasonably narrows the scope of the exception set forth in the Stark statute, the final rule amends the regulation so that clause (2) above refers only to the Stark exceptions for compensation arrangements set forth in 42 C.F.R. §411.357(a) through (h).

    To explain these amendments, CMS' commentary distinguishes between the *statutory* exceptions found in the Stark statute, which include the exception for payments by physicians (and which are codified at 42 C.F.R. §411.357(a) through 42 C.F.R. §411.357(i) of the Stark regulations), and the *regulatory* exceptions in the Stark regulations issued pursuant to the authority of the Secretary of the Department of Health and Human Services under the Stark statute (and which are codified at 42 C.F.R. §411.357(j) *et seq*. of the Stark regulations). CMS takes the position that the *statutory* exception for payments by a physician was not meant to apply to compensation arrangements that are specifically excepted by other *statutory* exceptions in the Stark statute: given the placement of the exception for payments by a physician as the final statutory exception in the Stark statute, CMS believes that this exception functions as a catch-all to protect certain legitimate arrangements that are not covered by the preceding exceptions set forth in the Stark statute. However, CMS states that it no longer believes that the *regulatory* exceptions should limit the scope of the exception, and accordingly amends the exception to refer only to the statutory exceptions codified in the Stark regulations at 42 C.F.R. §411.357(a) through (h), stating that, as a matter of statutory construction, the exception for payments by a physician is not available to protect any type of arrangement that is specifically addressed by another statutory exception in the Stark statute. The final rule also removes the reference to exceptions in 42 C.F.R. §§411.355 and 411.356.

    CMS commentary further states that "items or services" furnished by an entity under the exception for payments by a physician may not include cash or cash equivalents. That is, the physician may not make in-kind "payments" to the entity in exchange for cash from the entity. At the same time, CMS states its belief that if a physician pays an entity $10 in cash for a gift card worth $10, or if a physician or an entity acts as a pure pass-through, taking money from one party and passing the *exact* same amount of money to another party, this would not constitute a financial relationship for purposes of the Stark law.

12. **Exception for Fair Market Value Compensation (42 C.F.R. §411.357(l)).** In the past, CMS has taken the position that the exception for fair market value compensation does not apply to arrangements for the rental of office space. In commentary to the final rule, CMS advises that it has reconsidered this policy, stating that through its administration of the SRDP, it has seen legitimate, nonabusive arrangements for the rental of office space that could not satisfy the requirements of the exception for rental of office space because the term of the arrangement was less than one year, and could not satisfy the requirements of the exception for timeshare arrangements because the arrangement conveyed a possessory leasehold interest in the office space. To provide flexibility to stakeholders to protect such nonabusive arrangements, the final rule amends the fair market value compensation exception to permit parties to rely on the exception for fair market value compensation to protect arrangements for the rental or lease of office space. With respect to this change, CMS notes, among other things, that:

a. the exception may be used for the *lease* of office space and not only for the *use* of office space;

b. CMS is adding the phrase "even if no referrals were made between the parties" to the commercially reasonable requirement in the exception;

c. the amended regulation permits parties to rely on the fair market value compensation exception and a new exception for limited remuneration to a physician (see subsection E above regarding this new exception) to protect an arrangement for the same items, services, office space, or equipment during the course of a year; and

d. the amended regulation requires that any arrangement including a directed referral requirement must satisfy all the conditions of the special rules on compensation relating to directed referral arrangements at 42 C.F.R. §411.354(d)(4).

At the same time, CMS notes that it remains concerned about potential abuse that may arise when rental charges for the lease of office space or equipment are determined using a formula based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in office space (a "percentage-based compensation formula") or per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (a "per-click compensation formula"), because these arrangements may incentivize overutilization and patient steering. To address this risk, the amended rule incorporates prohibitions on percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for the lease of office space similar to the restrictions found elsewhere in the Stark regulations.

The final rule removes from the fair market value compensation exception the requirement that the arrangement does not violate any Federal or State law or regulation governing billing or claims submissions. CMS advises that it is no longer convinced that this requirement is needed as a substitute safeguard to prevent program or patient abuse, and the final rule removes this requirement from all regulatory exceptions. However, the final rule retains the requirement that an arrangement under the fair market value compensation exception must not violate the anti-kickback statute. Although the final rule deletes this requirement elsewhere in the Stark regulations, CMS commentary states that it continues to believe that the requirement functions as an important safeguard that substitutes for certain requirements included in other statutory exceptions but omitted from the fair market value compensation exception.

CMS notes the following additional points:

- Parties will be able to renew the arrangement on the same terms and conditions any number of times, provided that the terms of the arrangement and the compensation for the same office space do not change.
- Parties are not required to renew their arrangement in writing. Renewals effectuated through course of conduct or by verbal agreement are permitted under the exception for fair market value compensation. However, parties retain the burden of proof to establish that the terms of the arrangement and the compensation for the same items, office space, or services did not change during the renewal arrangement.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group

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