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January 27, 2021 UPDATE

While neither the AKS Final Rule nor the Stark Final Rule addressed in the below Client Resource have been withdrawn by CMS, the effective dates of each of the Final Rules is unclear and may be subject to a regulatory postponement and further review by the new Administration. Following publication in the Federal Register, the Government Accountability Office (GAO) has since found that the effective dates identified in each of the AKS and Stark Final Rules (January 19, 2021) violate the Congressional Review Act (requiring major rules to take effect 60 days after publication in the Federal Register or after Congress receives the rules, whichever is later). As a result, per the GAO, the effective dates for each of the Final Rules should have been a date following President Biden's inauguration, which would subject the Final Rules to the Memorandum for the Heads of Executive Departments and Agencies issued by Chief of Staff Ronald Klain on January 20, 2021. The Memorandum requests that heads of agencies postpone the effective dates for rules that have not taken effect prior to noon on January 20, 2021. As of this update, neither the OIG nor CMS has published further guidance in the Federal Register related to either of the Final Rules.

Something Good from 2020: Greater Stark Law Flexibility

On November 20, 2020, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule entitled, "Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations" (the "Stark Law Final Rule")[1]. With the exception of certain restrictions on group practice compensation methodologies described below, the changes are effective January 19, 2021. In general, the Final Rule offers greater flexibility to physicians and entities that furnish designated health services ("DHS") in ensuring their financial arrangements meet the requirements of a Stark Law exception.

The following is a brief summary of the Stark Law Final Rule.

Changes to Facilitate Compliance. The Stark Law Final Rule makes many significant changes designed to make it easier for DHS entities to comply with the technical aspects of the regulations and to correct errors that do not pose a risk to the Medicare program or patients. These changes include the following:

1. The published version of the Stark Law Final Rule is located at 85 Fed. Reg, 77492 (Dec. 2, 2020). Note that, on that same day, November 20, 2020, the Office of Inspector General ("OIG") issued a final rule entitled, "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements," located at 85 Fed. Reg. 77684 (Dec. 2, 2020).

- *Reconciliation of payment errors*. An entity will be able to reconcile payment errors up to 90 calendar days after the expiration or termination of a compensation arrangement, though payment errors that exceed this 90-day period may not be reconciled through payment by one party to another, stating that parties may not simply "unring the bell" through a correction at some date after the expiration or termination of the arrangement. In the case of an ongoing compensation arrangement, the payment discrepancy can be recovered through an offset against future compensation. However, the introductory explanation makes clear that parties are expected to monitor their arrangements and correct them once an error is discovered, as parties failing to reconcile known payment discrepancies risk establishing a second financial relationship (for example, through the forgiveness of debt or the provision of an interest-free loan).[2]

- *New flexibility as to the writing requirement*. The Stark Law Final Rule permits a required writing to be obtained within 90 consecutive calendar days as long as the arrangement is otherwise fully compliant. (The current regulations permit a missing signature to be obtained within 90 days following the date of a compensation arrangement if the missing signature is the only noncompliant aspect of the arrangement.) However, the introductory explanation makes clear that parties will not be permitted to modify the compensation terms of an arrangement during the first 90 days without documenting the modification in writing, thereby limiting the situations in which parties could rely on this new writing requirement flexibility to those whose compensation terms did not change during the initial 90-day period. The Stark Law Final Rule further states explicitly that the signature requirement may be satisfied by an electronic or other signature that is valid under applicable federal or state law.

- *Limited remuneration exception*. The Stark Law Final Rule creates a new exception providing for limited remuneration to a physician of up to $5,000 per calendar year, as adjusted for inflation, provided that:
    - Compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
    - Compensation does not exceed fair market value;
    - The arrangement would be commercially reasonable even if no referrals were made between the parties;
    - If a lease of office space or equipment, limitations on percentage of revenue and per-unit of service rental charges are met; and
    - If remuneration is conditioned on a physician's referrals, then the requirements of 42 CFR §411.354(d)(4) (relating to directed referrals) apply.

Arrangements under this exception do not need to be listed in a master list of contracts. Further, an arrangement for items or services under this exception will not violate the prohibition under the fair market value exception on entering into an arrangement for the same items and services during a calendar year. As with the personal services exception, a physician may provide items or

2. That said, CMS does note that not every error or mistake will cause a compensation arrangement to fail to satisfy the requirements of a Stark Law exception or that every error or mistake must be corrected in order to maintain compliance with an exception, providing as examples: "the theft of items, the use of office space that is not included in a lease, and the use of equipment during periods outside those included in a lease would not create a compensation arrangement between the party whose assets have been coopted and the party that took them or used them without permission or payment" or "a slight deviation from the operation of the arrangement as anticipated and documented (where written documentation is required under the applicable exception) that results in the payment of too much or too little compensation under an arrangement—for example, in the case of a single rental payment over the course of an entire lease arrangement that was paid in the wrong amount—may not require reconciliation by the party receiving the overpayment or failing to make the full payment due, especially if the parties are not aware of the discrepancy." See 85 Fed. Reg. at 77587. 3. 85 Fed. Reg, 77492, 77582.

services through an employee, a wholly owned entity, or a locum tenens physician under this exception, but not through an independent contractor, and items, office space, or equipment provided under the exception must be the items, office space, or equipment of the physician.

The introductory explanation notes that this exception can be used in conjunction with the 90-day period for the writing requirement, providing even greater flexibility. The explanation provides the example of a medical director agreement where the parties relied on both exceptions, stating "The 90-day clock would begin when the parties could no longer use (or were no longer using) the [limited remuneration] exception..."[3]

- *Modification of the definition of "set in advance."* Compensation, or a formula for determining compensation, may be modified at any time during the course of a compensation arrangement and satisfy the set-in-advance requirement if the following conditions are all met:
    - All requirements of an applicable exception in 42 CFR §411.355 through §411.357 are met on the effective date of the modified compensation or formula;
    - The modified compensation or formula is determined before the furnishing of the items, services, office space or equipment for which the modified compensation is to be paid; and
    - The formula is set in writing in sufficient detail to be objectively verified before the furnishing of items, services, office space or equipment.

    The introductory explanation states that compensation may be set in advance even if it is not set out in writing before the furnishing of items or services as long as the compensation is not modified at any time during the period for which the parties seek to show the compensation was set in advance, stating that "records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance."

    Depending on the facts and circumstances, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services may be sufficient to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of items or services. The set-in-advance requirement does *not* require that the modified compensation remain in place for at least one year from the date of amendment, and there is no prohibition on the number of times the parties may modify the compensation.

- *Clarification of exclusive use requirement.* The Stark Law Final Rule clarifies that the "exclusive use" requirement in the space and equipment lease exceptions means that the lessee and any other lessees must use the space or equipment to the exclusion of the lessor. Thus, lessees can share the use of space or equipment with anyone except the lessor without violating the "exclusive use" requirement in the space and equipment lease exceptions.

- *Relaxed practice signature requirement in physician recruitment agreements.* The Stark Law Final Rule modifies the physician recruitment exception to provide that the practice does not need to sign if all compensation is paid to and retained by the physician or paid to the practice but paid in full to the physician. This could apply, for example, if a physician joins a practice during the repayment period of an existing recruitment agreement.

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3. 85 Fed. Reg, 77492, 77582.

- *Expansion of fair market value exception.* The Stark Law Final Rule modifies the fair market value compensation exception to clarify that it can apply to leases of office space or equipment, reversing CMS's prior position that these are not items or services. The revised fair market value exception states that the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year and includes the existing limitations on percentage-based and per-unit compensation. However, the inclusion of leases under the fair market value compensation exception will permit leases of office space for less than one year, which are not allowed under the lease exception. Under current regulations, parties wishing to enter into a lease for a period of less than one year would need to structure it as a one-year lease that provides for termination without cause.

- *Clarification regarding pass-through payments.* The introductory explanation to the Stark Law Final Rule states that a physician or entity acting as a pure pass-through by taking money from one party and passing the exact same amount of money to another party does not in and of itself result in the intermediary having a financial relationship.

Certain Services Not Increasing Reimbursement Not DHS. Significantly, the Stark Law Final Rule provides that, for services furnished to inpatients by a hospital, a service is not a DHS payable by Medicare if furnishing the service does not increase Medicare's payment to the hospital under any of the following prospective payment systems:

  - Acute-care hospital inpatient;
  - inpatient rehabilitation facility;
  - inpatient psychiatric facility; or
  - long-term care hospital.

This change will substantially reduce the potential liability of hospitals for services provided to inpatients where the hospital's nonexcepted financial relationships are with physicians who do not admit the patient, but order items or services that are included in the DRG, such as hospitalists and intensivists.

Clarification of "Fair Market Value" and "Commercially Reasonable." The Stark Law Final Rule defines "fair market value" to mean, in general, the value in an arm's length transaction consistent with the general market value of the subject transaction.[4] "General market value" is defined to mean, with respect to assets, the price an asset would bring on the date of acquisition as a result of bona fide bargaining between a well-informed buyer and seller not otherwise in a position to generate business for each other; with respect to compensation, 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 not otherwise in a position to generate business for each other; and with respect to space or equipment rental, the price the 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 not otherwise in a position to generate business for each other.

4. The regulations also provide, consistent with the statute, specified rules for rental of equipment, which must not take into account its intended use, and for office space rent, which should not take into account the space's intended use or 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.

The introductory discussion explains that this means that a hospital may not value a physician's services at a higher rate than a private equity investor or another physician practice simply because the hospital could bill for DHS referred by the physician at higher rates under the outpatient prospective payment system.

The Final Rule creates a separate definition of "commercially reasonable," reflecting that the fair market value requirement and commercial reasonableness requirement are separate and distinct. Under this new definition, "commercially reasonable" means that the 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. The introductory explanation gives as examples arrangements entered into to meet community need, provide timely access to healthcare services, fulfill licensor or regulatory obligations, provide charity care, and improve quality and health outcomes. However, an arrangement for a criminal purpose (such as one that violates the Anti-kickback Statute) cannot be commercially reasonable.

Settlements. The revised regulations clarify that an isolated financial transaction can include a single instance of forgiveness of an amount owed in settlement of a bona fide dispute. However, the commentary makes clear that where there is a settlement of a nonexcepted financial relationship, while the settlement itself qualifies for an exception, the nonexcepted financial relationship does not qualify based on the settlement.

Thus, for example, a hospital owed money under a nonexcepted arrangement by a physician group that disputes the obligation to pay could settle for a lesser amount that is fair market value in light of the circumstances and treat the settlement as an isolated transaction, but would still have a noncompliant arrangement during the time the arrangement was in effect.

Definition of Indirect Compensation Arrangement Significantly Revised. Under the revised definition, the "takes into account" language is removed. Instead, the second of the three conditions for an indirect compensation arrangement is met where the referring physician (or an immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or family member) has a direct financial relationship that varies with the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the individual unit of compensation received by the physician or immediate family member meets one of the following three tests:

- It is not fair market value for items or services actually provided;
- It includes the physician's referrals to the entity furnishing DHS as a variable resulting in an increase or decrease in the physician's or family member's compensation that positively correlates with the number or value of the physician's referrals to the entity; or
- It includes other business generated by the physician for the entity as a variable resulting in an increase or decrease in compensation positively correlating with the physician's generation of the other business for the entity.

"Positively correlating" means that the compensation increases as referrals or other business increase.

In general, only the exceptions at 42 CFR §411.355 and §411.357(p) (the indirect compensation exception) can be used with indirect compensation arrangements. However, indirect compensation arrangements involving an MCO or IPA and a referring physician can also use 42 CFR §411.357(t) (and §411.357(n) if the MCO or IPA is the entity furnishing DHS, and, in value-based arrangements, 411.357(aa) is also available.

Modification of Directed Referral Requirement. The Stark Law Final Rule modifies the directed referral requirement at 42 CFR §411.354(d)(4) to specify that it applies in cases of a bona fide employment relationship, personal service arrangement, or managed-care arrangement and that neither the existence of the compensation arrangement nor the amount of the compensation can be contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. However, the physician may be required to refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier, subject to the exceptions for patient choice, insurer determination, and medical judgment.[5]

Changes to When Compensation "Takes into Account" Referrals or Other Business. The Stark Law Final Rule adds new subsections 42 CFR §411.354(d)(5) and (d)(6), addressing when compensation takes into account the volume or value of referrals and other business generated, respectively.[6] Under subsection (d)(5), compensation from an entity furnishing DHS to a physician (or immediate family member) takes into account the volume or value of referrals only if the formula used to calculate the physicians' (or family member's) compensation includes the physician's referrals to the entity as a variable resulting in an increase or decrease in the compensation that positively correlates with the number or value of referrals, and compensation from the physician takes into account the volume or value of referrals only if it negatively correlates with the number or value of referrals.

Subsection (d)(6) operates similarly with respect to other business generated. New subsections (d)(5) and (d)(6) cannot be overridden by application of subsections (d)(2) and (d)(3), which are the existing rules relating to what takes into account referrals or other business.

Clarification of Payments by a Physician Exception. The Stark Law Final Rule modifies the payments by a physician exception to provide that it cannot be applied in situations to which the exceptions in 42 CFR §411.357(a) through (h) are applicable, but can be applied in situations where one of the remaining regulatory exceptions in 42 CFR §411.357 could apply, including the fair market value exceptions sections, based in part on the rationale that the first eight exceptions are based on statutory exceptions and the payments by a physician exception were intended to be a catchall for situations not covered by those exceptions.

EHR and Cybersecurity. The Stark Law Final Rule modifies the electronic health records exception to permit cybersecurity software and services to be provided under that exception, to remove the blocking

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5. The requirements contained in 42 CFR §411.357(d)(4)(iv) if any compensation paid to a referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier are added to the academic medical center exception, the employment exception, the personal services exception, the physician incentive plan exception, the isolated financial transaction exception, the fair market value exception, and the indirect compensation arrangements exception.

6. However, subsections (d)(5) and (d)(6) do not apply for purposes of 42 CFR §411.357(m) (medical staff incidental benefits), (s) (professional courtesy), (u) (community-wide health information systems), (v) (electronic prescribing items and services), (w) (electronic prescribing items and services) and (bb) (cybersecurity technology).

provision, to permit payment of the physician's 15% share of costs (other than initial costs) at reasonable intervals, and to remove the prohibition on replacement technology and the sunset provision.

In addition, the Stark Law Final Rule creates a new exception for cybersecurity technology, including hardware, and related services. This exception, as well as its corresponding Federal Anti-Kickback Statute safe harbor, are discussed in more detail here.

Restrictions on Group Practice Allocation Methodologies. The Stark Law Final Rule revises the special rules for profit shares and productivity bonuses applicable to group practices, effective January 1, 2022 (in order to give group practices sufficient time to revise their distribution methodologies to comply with the revised rules). As revised, the group, or each subgroup, must treat all DHS income of the group or subgroup consistently (however, different methodologies can be used by different subgroups).

The introductory explanation also clarifies CMS's position that DHS income and not DHS revenue is to be allocated; CMS takes the position that dividing up revenue could result in incentivizing referrals. Additionally, the Stark Law Final Rule will permit profits from DHS that are directly attributable to a physician's participation in a value-based enterprise to be distributed to the participating physician.

We recommend that physician organizations who rely on group practice status for purposes of compensating their physicians review their existing profit-share and productivity bonus allocation methodologies in 2021 and, to the extent those existing methodologies only apply to DHS revenue or treat various types of DHS income inconsistently, develop strategies to cause the existing methodologies to comply with the revised special rules prior to January 1, 2022.

Value-Based Arrangements Exceptions. The Stark Law Final Rule also contains exceptions for value-based arrangements. These are addressed separately in our recent white paper.

If you have questions regarding the Stark Law Final Rule or their applicability to your business arrangements, please reach out to a member of Kutak Rock's National Healthcare Practice Group.