The Center for Medicare & Medicaid Services (“CMS”) on March 26, 2004, released an interim final rule (the “Final Rule”) as Phase II of the rulemaking related to the physician self-referral law known as the “Stark Act.”¹ The Final Rule will be effective as of July 26, 2004. This article provides a brief primer on 25 of the key points noted in the Final Rule and the commentary from CMS included as the preamble to the Final Rule.

This primer simply provides an introduction to several important issues articulated in this Final Rule. This does not provide a complete review of any of the specific rules or exceptions and should not be relied upon without a more comprehensive analysis of any specific issue or concern.

1. **Penalties.** CMS noted that the Stark Act provides two types of sanctions for violations. These include non-payment of claims for all violations and civil monetary payments as penalties for knowing violations of the Act. Non-payment applies to any designated health services (“DHS”) furnished to any Medicare patient with regard to a prohibited referral. Certain violations may also give rise to claims under the anti-kickback statute or false claims act.

2. **Indirect Compensation Relationship.** Because the Stark Act applies to indirect as well as direct financial relationships between a physician and a provider of DHS, the definition of an indirect compensation arrangement is important. The Final Rule provides that an indirect compensation arrangement exists if three elements are present. First, an unbroken chain of financial relationships linking the referring physician to the DHS entity. Second, aggregate compensation paid to the referring physician that varies with, or otherwise takes into account, the volume or value of referrals to or other business generated for the DHS entity. Third, the entity furnishing the DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of the fact that the referring physician receives aggregate compensation that varies with or takes into account the volume or value of referrals to or other business generated for the entity furnishing the DHS.²

3. **Aggregate Compensation — Per Click Compensation.** The preamble to the Final Rule clarified that in the case of time-based or unit of service based compensation, aggregate compensation is not deemed to change, as long as the payment amount is fair market value for the items or services actually provided and the payment does not vary over the term of the agreement in any manner that takes into account the DHS referrals or other business generated by the referring physicians.³ This clarifies that as long as the payment for each use is the same and at fair market value and the per-click payment does not increase or decrease with the number of referrals, per-click compensation is a permitted payment structure under certain exceptions to the Stark Act.
4. **Percentage Based Compensation.** The Final Rule clarified that physicians, including independent contractors, may be paid on a percentage of collections basis in many circumstances. Given that this is how many physicians are paid, this is an important change that has been provided by CMS. Here, CMS requires that the formula for calculating payments based on a percentage of compensation must be established with specificity prospectively and must be objectively verifiable, and that any changes over the course of the agreement between the parties may not be based on the volume or value of referrals or other business generated by the referring physician. Thus, a physician can be paid based on a percentage of collections as long as the formula and its process does not change over time based on the volume or value of referrals or services generated.

5. **Covered Services.** The Final Rule clarifies several items and services that may be provided by a physician pursuant to the in-office ancillary services exception. These include: 1) outpatient prescription drugs may be furnished under the in-office ancillary services exception even if they are used by the patient outside the office; 2) external ambulatory infusion pumps that are DME may be provided under the in-office ancillary services exception; 3) chemotherapy and infusion drugs may be provided under the in-office ancillary services exception where the administration or dispensing of the drugs to patients is in the physician’s office; and (4) a new exception was provided for certain DME furnished at a physician’s office for the convenience of the physicians’ patients. (IDTF) or other physician, as opposed to the technical fee provided by a surgery center, are deemed DHS. Thus, brachytherapy services billed by the IDTF or by the radiation oncologist may not be owned by physicians who refer for brachytherapy.

6. **Lithotripsy.** The Final Rule and commentary clarify that lithotripsy will not be considered DHS. However, to the extent that lithotripsy services are billed by a hospital or other entity, any financial relationship between the hospital or entity providing the lithotripsy and the physician must meet an exception under the Stark Act.

7. **Brachytherapy.** CMS again articulated that brachytherapy services provided by an independent diagnostic testing facility (“IDTF”) or other physician, as opposed to the technical fee provided by a surgery center, are deemed DHS. Thus, brachytherapy services billed by the IDTF or by the radiation oncologist may not be owned by physicians who refer for brachytherapy.

8. **Group Practice – In-Office Ancillary Services Building Requirements.** The in-office ancillary services exception generally requires that DHS must be provided at a location in which a physician or group practice provides substantial physician services that are unrelated to DHS. The Final Rule enunciates three tests, one of which must be met, to assure that physicians are actually involved in providing physician services unrelated to the DHS at the location.

   First, a group may meet the same building test if the DHS is furnished in the same building in which the referring physician or his group practice has an office that is normally open to patients at least 35 hours per week and the referring physician or a member of the group practice normally provides physician services at the location at least 30 hours per week. Some of these services must be physician services that are unrelated to the DHS.

   Under a second test, a physician could meet the location requirement of the exception if the DHS is furnished in a building where the physician or physician’s group practice has an office that is normally open to patients at least eight hours per week and the referring physician practices medicine in that office at least six hours per week including some physician services unrelated to DHS. Here, the services must be provided in a building in which the patient receiving the DHS usually sees the referring physician or other members of his or her group practice. In essence, a physician cannot send patients from another office to this office for DHS.

   Under a third test, the building where the DHS is furnished must have offices that are open to the patients of the group practice at least eight hours per week and the referring physician or a member of his or her group practice must regularly practice medicine and furnish physician services to the patients at least six hours per week in that office. In addition, the referring physician must be present and order the DHS in connection with the patient visit during the time the office is open. This test reflects a situation where DHS are ordered during a patient visit as opposed to the second test in which the patient typically is seen at that office but does not have to be present at the time the DHS is ordered. This test does not require the DHS to be provided at an office where the patient is regularly seen by the physician or the physician’s group practice.

9. **Mobile Equipment.** CMS continues to take the position that mobile equipment that is located inside the same building may comply with the requirements of the in-office ancillary services exception. In contrast, mobile equipment that is used outside the building such as in a garage or at a loading dock will not qualify under the locational requirements of the exception.

10. **Joint Use of CT and MRI.** Where CT, MRI and other imaging equipment is in the same building as a physician’s...
practice, and the requirements of the in-office ancillary services exception are met, it is possible for physicians to share such equipment. However, the actual billing for the services of the CT or MRI must be done by the group practice or the physician as opposed to by the CT or MRI venture. Additionally, the physician or group practice must meet the supervision and billing requirements of the in-office ancillary services exception. Further, in the event of purchased diagnostic tests, a physician that is billing for services he or she does not perform must comply with the purchased diagnostic test rules which essentially eliminate the ability for the physician to buy a Medicare test from someone at one price and to resell it at a higher price.

11. Rural Exception. While the Final Rule does not change the rural exception, CMS did note that there will be a temporary period of time for a party to come into compliance with the Stark Act if the service was established in a rural area but that rural area subsequently becomes a non-rural area. An entity will have ninety (90) days to come into compliance with an exception to the Stark Act as long as the entity was in compliance with an exception (such as the rural exception) for 180 days preceding the noncompliance. As more areas have become designated as non-rural in the last census, this has become of import.

12. Whole Hospital Exception. The preamble to the Final Rule reiterates that the whole hospital exception applies to a physician’s ownership in the whole hospital. The exception does not apply to subsidiaries of a hospital that provide DHS. Thus, if a hospital has a wholly owned subsidiary that provides DME, home health services or other DHS services, a physician/owner cannot refer through the hospital or to the subsidiary for such services.

13. Equipment and Space Lease Exceptions. In addition to the clarifications related to “per click” payment methods, the Final Rule made three important changes and clarifications to the equipment and space lease exceptions:

(A) Leases or rental agreements may be terminated with or without cause as long as no further agreement is entered into within the first year of the original lease term and any new lease fits on its own terms in an exception.

(B) Month-to-month holdover leases are allowed for up to six months if they continue on the same terms and conditions as the original lease.

(C) The exclusive use test will be considered met “as long as the lessee (or sublessee) does not share the rented space or equipment with the lessor during the time it is rented or used by the lessee (or sublessee).” Here, CMS stated:

The statutory lease exceptions provide that the lessee must use the leased space or equipment “exclusively” when the lessee is using the space or equipment... we believe a fair reading of the exclusive use provision in the context of the lease exceptions is that the rented space or equipment cannot (or any subsequent sublessee). In other words, a lessee (or sublessee) cannot “rent” space or equipment that the lessor will be using concurrently with, or in lieu of, the lessee (or sublessee). Thus, for example, if a DHS entity rents examination rooms from a physician practice, the physician practice may not use those same examination rooms while the lessee (or a sublessee) is using or renting them.

14. Shared Employees. The regulations commented negatively on situations in which a DME supplier and a physician share employees and each pay for certain of the employees’ services. The preamble to the Final Rule stated “If the salary paid by the DME supplier covers any portion of the employee's work that benefits the physician (for example, work for which the physician would otherwise have incurred costs), that portion of the employee's salary could be remuneration to the physician that would create a financial relationship between the physician and the DME supplier.”

15. Fair Market Value - Medical Director and Other Services. The Final Rule provides much greater latitude for medical director compensation and other such relationships which should be at fair market value. Specifically, the Final Rule states that:

An hourly payment for a physician’s personal services (that is, services performed by the physician personally and not by employees, contractors, or others) shall be considered to be fair market value if the hourly payment is established using either of the following two methodologies:

(a) The hourly rate is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market.

(b) The hourly rate is determined by averaging the 50th percentile national compensation level for physicians with the
same physician specialty (or, if the specialty is not identified in the survey, for general practice) in at least four [national compensation surveys] and dividing by 2,000 hours.\textsuperscript{23}

These two specific methodologies give physicians and group practices greater comfort that compensation can be structured to be in the range of fair market value.

16. **Physician Recruitment.** Under the previous Stark Act regulations, the physician recruitment exceptions only allowed payments directly to a recruited physician. However, most specialist physicians are recruited into groups. Thus, the Final Rule sets forth standards by which a physician can be recruited into a group and the hospital can assist in providing recruitment assistance in the form of remuneration to that group. The new regulations also provided for a certain amount of assistance in providing “retention” payments. Additionally, the Final Rule permits “cross-town” recruitment of residents and physicians who have been in medical practice less than one year without regard to any change in location of their practice because such physicians are not deemed to have an established practice.\textsuperscript{24}

Finally, the Final Rule modifies language regarding a recruited physician maintaining staff privileges at other hospitals to clarify that recruitment payments should not be used to lock physicians into using solely the recruiting hospital. However, the preamble to the Final Rule states that “reasonable credentialing restrictions on physicians becoming competitors of a hospital would not violate “the requirement that a recruited physician be permitted to establish staff privileges at other hospitals.”\textsuperscript{25} This potentially leaves the door open for the use of certain economic credentialing tactics by hospitals.

17. **Isolated Transactions.** Under the isolated transactions exception of the Stark Act, it was commonly believed that installment payments were not permitted. Under the new regulations, installment sales are permitted as long as the total aggregate payment is set before the first payment is made and the total payment does not take into account the amount of direct or indirect referrals or the business generated between the referring parties. Further, the outstanding balance must be guaranteed by a third party, secured by a promissory note or subject to a similar measure to ensure payment even in the event of default by the purchaser or obligated party. These tests are intended to assure that the installment balance due to the selling physician does not provide an incentive to make referrals.

18. **ASC Implants and Radiology Services.** The Final Rule clarifies that an ASC may bill for implants implanted in an ASC as long as the implantation of the device occurs during a surgical procedure rather than before or after it. Similarly, the Final Rule clarifies that radiology services provided as part of the ASC composite rate for an ASC procedure is not defined as D H S. The exception does not allow the ASC to bill for brachytherapy seed implants or the imaging portion of brachytherapy services. Radiology services that are furnished at an ASC that are not paid for as part of the ASC composite rate are treated the same as any other radiology services. Hence, there is not an exception for other separately billable radiology services.\textsuperscript{26}

19. **Nuclear Medicine.** Nuclear medicine services continue to not be classified as D H S. Further, certain interventional radiology procedures remain not covered as D H S. However, to the extent they are billed as a hospital inpatient or outpatient service, such services would be considered D H S.

20. **Brachytherapy.** The CMS regulations continue to clarify that a brachytherapy facility which bills a technical fee cannot be owned by referring physicians. For example, CMS states that a urologist who refers to a brachytherapy facility may be more inclined to order brachytherapy if he has a financial interest in the facility.\textsuperscript{27} Here, one needs to likely distinguish between the surgical facility fee billed for an ASC to provide the location for the services and the actual brachytherapy services and seeds themselves billed by an ID T F or radiation oncologist.

21. **Professional Courtesy.** The Final Rule provides an exception for professional courtesy discounts offered by an entity to a physician or a physician’s immediate family member or office staff that meet six conditions. These conditions include the requirement that the professional courtesy be offered to all physicians on the entity’s bona fide medical staff or in the entity’s local community or service area without regard to the volume or value of referrals or other business generated between the parties.\textsuperscript{28}

22. **Charitable Donations.** A new exception is created in the Final Rule for “bona fide” charitable donations made to an exempt entity.\textsuperscript{29}

23. **Dialysis Related Drugs.** CMS expanded the list of separately reimbursable drugs used for dialysis which will not be
considered DHS as long as such drugs are not self-administered. These new drugs include albumin and levocarnitine as well as several other drugs. The preamble to the Final Rule indicates however that CMS will closely monitor this area for potential abuse. Further, the preamble states: “we want to emphasize that this exception applies only to drugs that are not self-administered except when the facility furnishes EPO or Aranesp to the patient who dialyzes at home.”

24. Fair Market Value Exception. The preamble to the Final Rule clarifies that the fair market value exception is a narrowly applicable exception that only applies to items and services provided by physicians (i.e., amounts paid to physicians). Hence, this exception is not available for a number of relationships where items and services are provided by non-physician entities (i.e., a hospital or IDTF and paid for by physicians). There is a separate exception which applies to payments made by physicians. However, this exception does not apply to certain types of relationships where a separate exception is specifically available (i.e., space and equipment leases).

25. Bone Densitometry Services. In Phase I of the Stark Act rules, CMS included only one of the nine possible CPT codes used to bill for bone densitometry services on the list of DHS. The commentary to the Final Rule indicates that this was done because certain bone densitometry tests were believed to be for screening purposes and were thus not diagnostic tests. The Final Rule has changed the treatment of bone densitometry services to define all bone densitometry services as “radiology and certain other imaging services” which are considered DHS. Further, because CMS has determined that all bone densitometry tests are not screening tests, the exception for certain screening procedures does not apply to such services.

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These 25 issues represent certain of the most significant issues included in the Final Rule. Health care providers and entities providing DHS should evaluate their relationships to ensure that they remain in compliance with the Stark Act and the myriad of exceptions thereunder. Scott Becker is a partner and co-chair of the McGuireWoods LLP Health Care Department. Krist Werling is an associate in the McGuireWoods LLP Health Care Department. Should you desire further guidance on any of these issues, please contact Scott Becker, 312.750.6016, or Krist Werling, 312.750.8911.

Endnotes

1 42 USC 1395nn (2004).
2 The Final Rule did not make any significant changes to the services which are defined as DHS, these continue to include: (1) laboratory services, (2) physical therapy, occupational therapy, and speech-language pathology services, (3) radiology and certain other imaging services, (4) radiation therapy services and supplies, (5) DME, (6) parenteral and enteral nutrients, equipment and supplies; (7) home health services, (8) prosthetics, orthotics and prosthetic devices and supplies, (9) outpatient prescription drugs, and (10) inpatient and outpatient hospital services. 42 C.F.R. §411.351 (2004).
3 42 C.F.R. §411.354.
4 42 C.F.R. §411.354(d)(1).
5 42 C.F.R. §411.354(d).
7 42 C.F.R. §411.354(a).
9 42 C.F.R. § 411.355(b)(4).
16 42 C.F.R. § 411.355(b).
17 Medicare Carriers Manual § 3060.5.
18 42 C.F.R. § 411.353(f).
23 42 C.F.R. § 411.351.
24 42 C.F.R. § 411.357(e).
28 42 C.F.R. § 311.357(s).
29 42 C.F.R. § 311.357(j).
33 42 C.F.R. § 411.355(h).