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March 31, 2004

Phase II Stark Law Regulations Provide Guidance But Contain Areas of Concern

by Chris Phillips¹

On March 26, 2004, the Centers for Medicare & Medicaid Services (“CMS”) published an Interim Final Rule with comment period in the Federal Register². The new rule incorporates the existing regulations under the Stark Law³ and provides a comprehensive regulatory scheme covering all aspects of the Stark Law. The new regulations are effective July 26, 2004.

The rule clarifies the application of existing Stark Law provisions and exceptions and also provides a number of new provisions and exceptions. These include (the following summary⁴ assumes familiarity with the Stark Law):

- A definitional provision that hourly physician compensation will be considered fair market value if: (1) it does not exceed the average rate for emergency room physician services in the market, if there are at least three hospitals providing emergency room services in the market (regardless of the physician’s specialty); or (2) it does not exceed one-two-thousandth of the average of the median income in four of six specified surveys for the physician’s specialty (or for general practice if the specialty is not included in the survey).
- An exception providing a period of up to 90 days to bring back into compliance certain arrangements that become noncompliant for reasons beyond the entity’s control.
- Clarification that percentage-based arrangements can be “set in advance” if the methodology is set prospectively and does not change over the course of the

¹ Partner, Kutak Rock LLP. This memorandum does not constitute legal advice and should not be relied upon as such.

² However, the portions of the preamble text addressing reporting requirements and sanctions were accidentally omitted.

³ 42 U.S.C. Section 1395nn.

⁴ The following summary is neither a complete listing of the changes made by the Interim Final Rule nor a complete description of all of the changes that are summarized. For example, many exceptions include language requiring that the arrangement not violate the Anti-kickback Statute (42 U.S.C. Section 1320a-7b(b)).

arrangement in a manner that reflects the volume or value of referrals or other business generated by the referring physician.

- Three specific tests clarifying when the “same building” test for in-office ancillary services is met. These tests appear to prohibit the provision of designated health services under the in-office ancillary services exception in part-time, shared locations used less than one day per week.
- Broadening of the academic medical center exception.
- Narrowing of the exception for remuneration from hospitals unrelated to the provision of designated health services (“DHS”); because of CMS’ restrictive interpretation, this exception will have limited application.
- A new exception for intra-family rural referrals where no other person or entity is available to furnish the services in a timely manner in light of the patient’s condition within 25 miles of the patient’s residence and the referring physician or immediate family member has made reasonable inquiries as to the availability of other persons or entities to furnish the services.
- An amendment to the prepaid plans exception to cover Medicaid managed care plans.
- New exceptions for ownership in certain publicly traded securities and mutual funds.
- An exception for certain unsolicited charitable donations to tax-exempt organizations.
- Compensation arrangement exceptions for remuneration falling within the Anti-kickback Statute safe harbors for referral services and obstetrical malpractice insurance subsidies.
- Compensation arrangement exceptions for professional courtesy offered by an entity to a physician or a physician’s immediate family member or office staff if the professional courtesy is offered to all physicians on the entity’s bona fide medical staff or in the entity’s local community or service area, the items and services provided are of a type routinely provided by the entity, the professional courtesy policy is set out in writing and approved in advance by the entity’s governing body, professional courtesy is not offered to federal health care program beneficiaries absent financial need, and insurers are informed of any coinsurance reductions.
- A compensation exception for retention payments by hospitals or federally qualified health centers in underserved areas (*i.e.*, health professional shortage areas and other areas identified by advisory opinion). Among the requirements of this exception are that the physician has a bona fide firm, written recruitment offer

from another, unrelated hospital or federally qualified health center outside the area and that the remuneration is limited to the lesser of the amount by which the physician's current income is less than the amount specified in the offer or the cost to recruit a new physician to the area.

- A compensation exception for certain items or services of information technology provided by an entity to a physician as part of a community-wide health information system available to all providers, practitioners, and residents of the community who desire to participate.
- Limitation of reporting requirements to requested information.

Joint Ventures. Several aspects of the new regulations are relevant to joint ventures:

- Although the rule deletes regulatory language providing an exception for clinical laboratory services furnished in an ambulatory surgical center or end-stage renal disease facility or by a hospice if included in the applicable composite rate, the preamble notes that this language was deleted because it is redundant—services included in a composite rate are not DHS. Implants furnished by a referring physician or member of his or her group practice and billed by the ASC may qualify for a separate exception, but the exception does not apply to brachytherapy seeds.
- The rule confirms that where services are provided by a hospital through an “under arrangements” arrangement with a physician-owned entity, the “under arrangements” arrangement will be treated as a compensation arrangement and not as an ownership or investment interest in the hospital.
- The regulations addressing the “whole hospital” and rural exceptions reflect the specialty hospital moratorium that is currently in effect.

Overview. Although the law and regulations are complex, the basic concept of the Stark Law is simple. Certain items and services, including hospital services and many ancillary items and services, are defined as “designated health services”.⁵ If a physician (or an immediate family member) has a financial relationship with an entity, the physician cannot refer a designated health service to the entity, and the entity cannot bill for the designated health service, unless an exception applies. Violation can result in severe financial penalties, exclusion and potential False Claims Act liability.

A financial relationship can be direct or indirect. A relationship is direct if it is between the physician and the entity directly and indirect if there is one or more intervening parties. For example, if a hospital leases office space to a physician group practice, there is an indirect financial relationship with the physicians of the group practice. If the lease is to an individual

⁵ The regulations generally define DHS as such services payable, in whole or in part, by Medicare. However, in certain contexts the term is used to refer to all such services regardless of payor source. The application of the Stark Law prohibition to Medicaid services is complex, and the Interim Final Rule reserves this subject for future rulemaking.

physician or his or her wholly owned professional corporation (which the regulations treat as equivalent to the physician), there is a direct financial relationship.

The preamble to the Interim Final Rule indicates that indirect compensation arrangements are to be evaluated based on whether they meet the requirements of the regulatory indirect compensation arrangement exception and not based on the other exceptions, which apply to direct compensation arrangements and/or to ownership/investment relationships (whether direct or indirect). However, there appears to be inconsistency in CMS' approach to this issue, because several of the exceptions state by their terms that they apply to arrangements with physician groups. Clarification of this point from CMS prior to the effective date of the regulations would be helpful.

The regulations include two "catch-all" provisions that appear intended to cover compensation arrangements that are not described by any of the other exceptions. If a compensation arrangement involves an entity paying a physician or physician group for items or services, it may qualify for the "fair market value" exception. This exception is available whether or not the arrangement is of a type that is described in another exception. If a compensation arrangement involves a physician paying an entity for items or services, it may qualify for the exception for "payments by a physician for items or services". However, this exception is only available if the arrangement is not of a type that qualifies for another exception.

Indirect Financial Arrangements. Because so many financial arrangements between physicians and DHS providers involve intervening entities (in particular, physician group practices), the application of the indirect financial arrangement rules deserves particular attention. These rules can be summarized as follows:

(1) A financial arrangement must be direct or indirect. If a financial arrangement is not directly between the physician and the entity and it does not fall within the definition of an indirect ownership or investment interest or an indirect financial arrangement, it is not a financial arrangement for Stark Law purposes.

(2) An indirect ownership or investment interest requires that the physician (or an immediate family member) indirectly own an interest in the DHS provider (for example, a physician owns an interest in a limited liability company that owns an interest in a DHS provider) and the DHS provider "has actual knowledge of, or acts in reckless disregard or deliberate ignorance of" this fact. Common ownership does not constitute an indirect ownership or investment interest, but satisfies one of the requirements for an indirect compensation arrangement.

(3) An indirect compensation arrangement requires that three conditions be met. First, there must be an "unbroken chain" of financial relationships between the physician (or an immediate family member) and the DHS provider. Second, the physician (or immediate family member) must receive aggregate compensation under the closest compensation arrangement to the physician (or family member) in the chain that varies with, or otherwise reflects, the volume or value of referrals to, or other business generated by the referring physician for, the entity furnishing the DHS. Third, the DHS 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 that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician.

The regulations and preamble clarify that if aggregate compensation will vary based on referrals, the second part of this test is met. For example, if a physician group leases an MRI to a hospital on a per-click basis and will use the MRI, the second part of the test is met with respect to physician owners of the group. (Whether the second part of the test is met with respect to physician employees of the group depends on whether their compensation from the group varies with or otherwise reflects rentals received under the lease.)

(4) If an indirect compensation arrangement exists, the parties should evaluate whether the requirements of the indirect compensation arrangement exception are met. These requirements are as follows:

(a) The compensation received by the referring physician (or immediate family member) must be fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the DHS entity.

(b) The compensation arrangement must be set out in writing and signed by the parties and must specify the services covered by the arrangement (but a bona fide employment relationship need not be in writing but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer).

(c) The compensation arrangement cannot violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

In the MRI lease example given above, the arrangement could meet the requirements of the exception because the regulations state that unit-based compensation (including time-based or per unit of service based compensation) will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.

The new regulations are helpful in that they provide several new exceptions and offer greater clarity as to the application of existing exceptions. However, DHS providers will need to review and in some cases amend their existing arrangements with referring physicians by July 26 in order to be able to continue to receive DHS referrals from those physicians. Because of the inconsistency noted above, a conservative position would be to structure indirect compensation arrangements so that the compensation arrangement with the group meets the requirements of an exception *and* the indirect compensation arrangements with group physicians meet the requirements of the indirect compensation arrangement exception. In order to demonstrate that it

is not “in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician”, a prudent approach would be to require that the contracting group represent and warrant that its payments to physicians and immediate family members will meet this standard (such a representation would not provide absolute protection, but would be helpful in the event of a Stark Law challenge to the arrangement).

Physician Recruitment. An area addressed in the Interim Final Rule that merits particular review is physician recruitment. Many hospitals have entered into recruitment arrangements with physicians and/or groups that provide for payments and/or forgiveness of obligations over extended time periods. Because the new regulations impose specific limitations on permitted recruitment arrangements, benefits provided after July 26 may result in a non-expected financial arrangement under the Stark Law. These specific limitations were not defined in previous guidance, and many parties entered into arrangements not meeting the new requirements in good-faith reliance on the guidance available to them at the time. It would be helpful for CMS to provide relief for hospitals in this situation in order to avoid disruption of contractual arrangement entered into by the parties in good faith and possible limitation of services to Medicare patients. In the absence of such relief, it may be necessary for many existing recruitment agreements to be amended.

Hospitals and federally qualified health centers (“FQHCs”)⁶ should note the following specific requirements of the recruitment exception:

- The physician must be recruited to the “geographic area served by the hospital”, defined as the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. This definition may not include locations within a hospital’s service area that are in zip codes with relatively low populations, and could, for example, disqualify recruitment of a physician to a rural outreach location or to a commercial area with physician offices but few residents.
- The physician must move his or her medical practice at least 25 miles; or the physician’s new medical practice must derive at least 75% of its revenues from professional services furnished to patients (including hospital inpatients) not seen or treated by the physician at his or her prior medical practice site during the preceding three years, measured on an annual basis (fiscal or calendar year) (there is a “reasonable expectation” rule during the start-up period). However, residents and physicians who have been in practice one year or less will not be subject to the relocation requirement if they establish their medical practices in the geographic area served by the hospital. Legitimate recruitment agreements should generally meet the 75% test.
- If the recruited physician joins an existing practice, additional requirements apply, among them the following:

⁶ The recruitment exception is limited to payments by hospitals and FQHCs.

- If payments are made directly to the practice, the practice must sign the agreement.
- All remuneration must cover actual costs or be retained by or passed on to the recruited physician—in other words, the practice cannot profit from the recruitment agreement. In income guarantees, only additional *incremental* costs can be retained by the practice (thus, existing overhead costs cannot be allocated to the recruited physician). Records of the actual costs and passed-through amounts must be maintained for a period of at least five years and made available to the Secretary of the Department of Health and Human Services upon request. Hospitals and FQHCs should ensure that these records requirements are incorporated into recruitment agreements.
- The practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care. The preamble makes it clear that this requirement prevents recruitment of a physician to a practice that imposes a noncompetition restriction or penalty on the recruit.

Conclusion. While the new regulations offer welcome clarification and flexibility in a number of areas, several areas require clarification. Because the effective date is less than four months away, CMS should provide additional guidance as soon as possible. (The Interim Final Rule provides a 90-day comment period; providers should consider whether to take advantage of this opportunity.) In addition, relief for providers that entered into binding agreements in reliance on existing guidance would be appropriate. In the absence of such relief, providers will need to review, and in some cases renegotiate or terminate, existing arrangements with referring physicians and physician groups prior to the July 26 effective date.

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