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SORRENTINO  
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# HEALTH LAW UPDATE

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## Stark Phase III Final Rule

On September 5, 2007 in the *Federal Register*, the Centers for Medicare & Medicaid Services (“CMS”) published the long-awaited third phase of final regulations (“Phase III”) regarding the physician self-referral provisions in Section 1877 of the Social Security Act, commonly known as the Stark Law. Phase III finalizes the second phase interim final rule published on March 26, 2004, which set forth the scope of the prohibition on physician self-referrals and established regulatory exceptions for certain permissible referral arrangements. Generally, the Stark Law: (1) prohibits physicians from making referrals for certain “designated health services” (“DHS”) payable by Medicare to an entity with which they (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payor) for those referred services. The Stark Law, however, authorizes CMS to issue specific regulatory exceptions to this ban on physician self-referrals. CMS (and its predecessor, the Health Care Financing Administration) have exercised this rule-making authority in separate phases. Phase III represents the latest phase of Stark regulations, and will take effect December 4, 2007. Phase III is summarized in the following article.

### Clarifying the Physician Recruitment Exception

The Stark regulations established an exception for payments made to recruit a physician to a hospital’s geographic area in order to facilitate him/her becoming a member of the medical staff, provided certain conditions have been met. Phase III amends this physician recruitment exception by clarifying certain key terms and identifying permissible practice restrictions that may be imposed.

### Identifying the “Geographic Area Served by the Hospital”

The geographic area served by the hospital to which a recruited physician may relocate his or her medical practice was defined in Phase II as an area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75% of its inpatients. Under Phase III, the geographic area served by a hospital is now deemed to be the area comprised of *all* of the contiguous zip codes from which the hospital’s inpatients are drawn when the hospital draws fewer than 75% of its inpatients from contiguous zip codes. In addition, Phase III permits hospitals located in a rural area to determine the relevant geographic area served by the hospital using an alternative test that encompasses the lowest number of contigu-

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If you have any questions regarding the Stark Phase III rulemaking, or would like assistance in submitting an advisory opinion request, please feel free to contact one of our health care attorneys:

Matthew R. Sorrentino, Esq.  
[msorrentino@thslaw.com](mailto:msorrentino@thslaw.com)

Ronnie F. Hess, Esq.  
[rhess@thslaw.com](mailto:rhess@thslaw.com)

Donald H. Lipson, Esq.  
[dlipson@thslaw.com](mailto:dlipson@thslaw.com)

Sandra Jarva Weiss, Esq.  
[sjarvaweiss@thslaw.com](mailto:sjarvaweiss@thslaw.com)

F. Peter Lehr, Esq.  
[plehr@thslaw.com](mailto:plehr@thslaw.com)

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ous (or in some cases, non-contiguous) zip codes from which the hospital draws at least 90% of its inpatients. In addition, if the Secretary of HHS, through an advisory opinion requested by the hospital, determines that the area into which a physician is to be recruited has a demonstrated need for the recruited physician, a rural hospital may also recruit physicians to that area, even though it is outside the geographic area served by the hospital.

### *Recruiting Physicians Who Will Replace a Deceased, Retiring or Relocating Physician*

In the case of an income guaranty made by a hospital to a recruited physician who joins an existing practice, the cost allocated by the practice to the recruited physician cannot exceed the actual additional incremental costs attributable to that recruited physician. Now under Phase III, with respect to a physician recruited to join an existing practice located in a rural area or Health Professional Shortage Area (“HPSA”), in cases where he or she will replace a physician who has retired, relocated outside the geographic area, or died within the previous 12-month period, the cost allocated by the practice to the recruited physician cannot exceed either: (a) the actual additional incremental costs attributable to the recruited physician; or (b) the lower of a per capita allocation or 20% of the practice’s aggregate costs. Phase III, therefore, permits a hospital to offer a more generous income guaranty to a recruiting practice in a rural area or HPSA when the physician will replace a deceased, retiring, or relocating physician.

### *Placing Practice Restrictions on Recruited Physicians*

Perhaps the most important change in Phase III with respect to the physician recruitment exception is the ability of a practice hiring the recruited physician to impose reasonable restrictions on his or her practice, including non-solicitation covenants and liquidated damages pro-

visions. Currently, a practice receiving payment from a hospital to assist in the recruiting of a new physician cannot impose “additional practice restrictions on the recruited physician other than conditions related to quality of care.” CMS made clear that a practice could not impose a covenant not to compete in the employment agreement of the recruited physician. In the Phase III preamble, CMS noted that it intended to include only such restrictions that would have a substantial effect on the recruited physician’s ability to remain in practice in the hospital’s geographic area after leaving the practice. Under Phase III, in the case of recruitment assistance provided by a hospital to a practice, it is prohibited for the practice to impose any practice restrictions that unreasonably restrict the recruited physician’s ability to practice medicine in the geographic area served by the hospital. Thus, a group practice receiving a recruitment incentive from a hospital may still not impose an outright covenant not to compete, but may consider imposing the following restrictions in a recruitment physician’s employment agreement.

- restrictions on moonlighting;
- covenants prohibiting the solicitation of patients and employees;
- requiring the recruited physician to treat Medicaid and indigent patients;
- requiring that a recruited physician not use confidential or proprietary information of the practice;
- requiring the recruited physician to repay losses of his/her practice that are absorbed by the group in excess of any hospital recruitment payment; and
- requiring the recruited physician to pay a predetermined amount of reasonable damages (i.e., liquidated damages), if the physician leaves the physician practice and remains in the community.

### *Clarification of Relocation*

Phase III clarifies that relocation of a physician’s practice for purposes of the exception means that the recruited physician either: (1) moves his or her medical practice at least 25 miles; or (2) has a new medical practice that derives 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 (i.e., fiscal or calendar year). CMS also exempts from the relocation requirement physicians who, for the prior two years, were employed on a full-time basis by a Federal or State bureau of prisons, the Department of Defense, Department of Veteran Affairs, or the Indian Health Service, provided that the physician did not maintain a separate private practice in addition to such full-time employment. Also exempted from the relocation requirement are those physicians whom the Secretary of HHS, through an advisory opinion, has deemed not to have an established medical practice treating a significant number of patients who are or could become patients of the recruiting hospital.

### *Rural Health Clinics*

In Phase III, CMS clarifies that the aforementioned physician recruitment exception applies to rural health clinics in the same manner as it applies to hospitals.

### **Clarifying the Physician Retention Exception**

The Stark regulations also established an exception for payments by a hospital in an underserved area directly to a physician on the medical staff to retain his or her medical practice in the geographic area served by the hospital. Such retention payments were only permitted when the physician had a bona fide written recruitment offer. CMS now has expanded the retention payment exception to

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permit payments to members of the medical staff in the absence of a bona fide written offer, provided that the physician certifies in writing that, among other requirements, he or she has a bona fide opportunity for future employment that would require relocation of his or her medical practice at least 25 miles to a location outside the geographic area served by the hospital, and provided further that certain other conditions are met. The retention payment exception has also been expanded to permit payments in the case of a physician with a bona fide firm, written offer of employment from, or a bona fide opportunity for future employment with, an academic medical center or physician organization. Finally, CMS has expanded the retention exception to permit a hospital to make a payment to a physician whose current medical practice is not located in a HPSA, provided that the physician's medical practice is located in a rural area or an area with demonstrated need as determined by the Secretary of HHS in an advisory opinion. As with the exception relating to recruitment payments, rural health clinics are also able to make permitted payments to retain physicians.

### Additional and Modified Definitions

Under Phase III, certain terms integral to the Stark Law have been defined or modified, including "rural area," "fair market value," "downstream contractor," and "physician organization."

With respect to "rural area," CMS defines this term as an area that is not an urban area as defined at §412.62(f)(1)(ii).

With respect to "fair market value," CMS created a safe harbor provision for

hourly payments to physicians for their personal services, consisting of two methodologies for calculating hourly rates that would be deemed fair market value for Stark purposes. In Phase III, CMS has eliminated this safe harbor for hourly payments for a physician's personal services. However, fair market value will continue to be an essential element of many Stark exceptions, with fair market value being defined on a case-by-case basis.

Finally, the term "downstream contractor" has been added to the Stark regulations, with the term having the same definition found in the Federal anti-kickback statute safe harbor regulations, in order to make the two laws on patient referrals consistent.

### In-Office Ancillary and Physician Services Exceptions Are Not Applicable to Services Provided by Independent Contractors in Off-Site Locations That Are Not Group Facilities

The general prohibition on self-referrals does not apply to in-office ancillary services or physician services that are furnished: (1) personally by another physician in the same group practice as the referring physician; or (2) under the supervision of another physician in the same group practice as the referring physician. CMS in the Phase III preamble notes that a "physician in the group practice" is considered to be in the group practice only when he or she is performing services in the group practice's facilities. Accordingly, although professional services performed by a member of the group practice may be provided on or off the group practice's site for the purpose of this exception, professional services performed by an independent contractor physician must be performed in the group practice's facilities. Thus, the physician services ex-

ception is not applicable to services provided by independent contractors in off-site locations that are not group facilities. Similarly, in order to satisfy the in-office ancillary services exception, a physician who is an independent contractor with the group practice must perform DHS supervision services *on the premises* of the group practice, regardless of coverage policies. Independent contractor physicians are "physicians in the group practice" only when performing services on the group practice's premises, regardless of whether reassignment or coverage rules would allow an independent contractor physician to perform services off the premises of the billing entity. Therefore, in order to satisfy the requirements of the exception, an independent contractor must supervise services *on the premises* of the group practice.

### New "Stand in the Shoes" Provision Added

In the Phase III preamble, CMS notes that it received public comments claiming that the indirect compensation arrangements definition in Phase II and the corresponding exception added an unnecessary step when determining compliance with Stark. The public comments reflected a belief that it would be easier, more efficient, and consistent with Stark to examine the relationship between the hospital and the group practice for compliance with a Stark exception. CMS was urged to consider that a referring physician would "stand in the shoes" of his or her group practice. This approach would enable analysis of an arrangement between a DHS entity and the group practice (for example, a lease of office space, personal service arrangement, or fair market value arrangement) under the various direct com-

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pensation arrangements exceptions, without using the indirect compensation arrangements definition or exception. Therefore, under Phase III, a physician stands in the shoes of his or her physician organization and is deemed to have the same compensation arrangements with the DHS entity as the physician organization has with that entity. As a result, many compensation arrangements that were analyzed under Phase II as indirect compensation arrangements are now, under Phase III, analyzed as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements.

### Clarification of the “One Year” Rule

To satisfy the requirements of many compensation arrangements exceptions, compensation must be “set in advance,” consistent with fair market value, and not take into account the volume or value of referrals or other business generated by the referring physician. In the Phase III preamble, CMS responded to public comment asking whether an agreement between an entity furnishing DHS and a referring physician could be amended during the first year of the agreement and still satisfy the “set in advance” requirement, by stating that such amendments would be permissible under the “set in advance” definition if they are made for bona fide reasons unrelated to the volume or value of referrals or other business generated between the parties.

### Shared Facility Arrangements

In the Phase III preamble, CMS noted that it received public comment on whether physicians could use facilities simultaneously (eg., an imaging suite, clinical laboratory, or physical therapy office) and simply share the costs and administration of the DHS without having to separately lease the

facilities for specific blocks of time determined in advance. CMS responded that a physician sharing a DHS facility in the same building must control the facility and the staffing (ex., the supervision of the services) at the time the DHS is furnished to the patient. As a practical matter, CMS noted that this likely necessitates a block lease arrangement for the space and equipment used to provide the DHS. CMS cautioned that shared facility arrangements must be carefully structured and operated (ex., with respect to billing and supervision of the staff members who provide the DHS in the facility). CMS further noted that common per-use fee arrangements are unlikely to satisfy the supervision requirements of the in-office ancillary services exception and may implicate the Federal Anti-Kickback Statute.

### Amending the Professional Courtesy Exception

Phase III eliminates the requirement that the entity offering the professional courtesy inform the insurer in writing of a reduction of any co-insurance obligation on the part of the recipient of the professional courtesy, and clarifies that the professional courtesy exception is applicable only to entities that have formal medical staffs.

### Clarification of the Fair Market Value Compensation Exception

Phase III clarifies that the exception is applicable to both compensation provided to a physician from an entity and compensation provided to an entity from a physician.

### Clarifying the Compliance Training Exception

Phase III permits the provision of compliance training programs to physicians (or to the physician’s immediate family member or office staff) for which CME is available, provided that the primary purpose of the program is compliance training.

### Charitable Donations by a Physician Exception

Phase III clarifies that any donation meeting the exception may neither be *solicited nor offered* in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity.

### Non-Monetary Compensation Exception

The non-monetary compensation exception allows non-cash compensation from an entity in the form of items or services that does not exceed an aggregate of \$300 per calendar year, provided certain conditions are met. Phase III amends this exception to provide that, in certain circumstances, upon repayment of non-monetary compensation in excess of the applicable limit, such compensation shall be deemed to be within the limit. Phase III also allows an entity having a formal medical staff to provide one local medical staff appreciation event per year for the entire medical staff, however, any gifts or gratuities provided in connection with such event are subject to the limit on non-monetary compensation.

### “Holdover” Arrangement for Personal Services Arrangements

Phase III amends the personal service arrangements exception to allow a “holdover” arrangement on terms similar to those in the exceptions for the rental of office space and equipment.

### Security Interests Held by Physicians

Phase III clarifies that certain security interests held by a physician, and property sold or loaned to hospitals, are deemed compensation and not ownership arrangements in the hospital.