Health Law E-Alert

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STARK PHASE III FINAL RULE JUST RELEASED

On August 27th, the Centers for Medicare & Medicaid Services ("CMS") released the much-anticipated Phase III Stark Final Rule (CMS-1810-F), which is officially titled, "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)" (click the link to access the final rule from the CMS website). The regulations will be effective 90 days after the publication date (which is expected to be September 5, 2007). Below is a summary of the major changes to the regulations identified in this 516-page Phase III final rule:

- No major regulatory changes were made to §411.352 (Group Practices), §411.353 (Prohibition on Certain Referrals by Physicians and Limitations on Billing), or §411.356 (Exceptions to the Referral Prohibition Related to Ownership or Investment Interests). However, certain provisions of these sections were clarified in this preamble.
- Three definitions were added at §411.351 ("downstream contractor," "physician organization," and "rural area"). Also, in the definition of "fair market value," CMS eliminated the safe harbor regarding hourly payments for a physician's personal services.
- Section 411.354 defines "financial relationships" for purposes of the physician self-referral law. A new provision was added in §411.354(b)(3)(v) which specifies that an ownership interest in an entity [the whole hospital or a subdivision of the hospital] does not include a security interest taken by a physician in equipment sold to the entity and financed with a loan by the physician to the entity. However, the security interest is a compensation arrangement.
- A new "stand in the shoes" provision was added to §411.354(c)(2) under which a physician is deemed to "stand in the shoes" of his or her physician organization (defined at §411.351 as a "physician (including a professional corporation of which the physician is the sole owner), a physician practice, or a group practice that complies with the requirements of §411.352." A physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements with the DHS entity that the physician organization has with the DHS entity. As a result, many compensation arrangements that were analyzed under Phase II as indirect compensation arrangements are now analyzed as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements.
- The Phase III changes to the general exceptions in §411.355 for both ownership/investment interests and compensation arrangements are concentrated in the exceptions for academic medical centers and intra-family rural referrals in §411.355(e) and (j), respectively.

- With respect to the academic medical centers exception, CMS clarified that the total compensation from each academic medical center component to a faculty physician must be set in advance and not determined in a manner that takes into account the volume or value of the physician's referrals or other business generated by the referring physician within the academic medical center. In addition, when determining whether the majority of physicians on the medical staff of a hospital affiliated with an academic medical center consists of faculty members, the affiliated hospital must include or exclude all individual physicians holding the same class of privileges at the affiliated hospital.
- CMS amended the exception for intra-family rural referrals to include an alternative test to determine whether a physician may refer a patient to an immediate family member for DHS. Specifically, if, in light of the patient's condition, no other person or entity is available to furnish the DHS in a timely manner within 45 minutes transportation time from the patient's home, a physician is not prohibited from making a referral for the DHS to an immediate family member or to an entity with which the immediate family member has a financial relationship, provided that all other conditions of the exception are satisfied. The Phase II 25-mile test remains an option for complying with the exception.
- Section 411.357 sets out the exceptions for various compensation arrangements. The revisions to the exceptions for physician recruitment in §411.357(e) and retention payments in underserved areas in §411.357(t) are significant.
- Changes relative to physician recruitment:
  - The physician recruitment exception protects certain remuneration that is provided by a hospital to a physician as an inducement for the physician to relocate his or her medical practice into the "geographic area served by the hospital," which CMS defined in Phase II as the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients.
  - Under the revised definition of "geographic area served by the hospital," a hospital that draws fewer than 75 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients may recruit a physician into the geographic area composed of all of the contiguous zip codes from which it draws its inpatients, provided that all other requirements of the exception are satisfied.
  - In addition, the revised definition sets forth a special optional rule for rural hospitals under which a rural hospital may determine its geographic service area using the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients or, if the hospital draws fewer than 90 percent of its inpatients from all of the contiguous zip codes from which it draws inpatients, its service area may include certain noncontiguous zip codes. A rural hospital may also

recruit physicians to an area outside the geographic area served by the hospital if the Secretary has determined in an advisory opinion that the area into which the physician is to be recruited has a demonstrated need for the recruited physician, provided that all other requirements of the exception are satisfied.

- In the case of an income guarantee provided by a hospital to a physician who relocates his or her practice into a rural area or HPSA and joins a physician practice to replace a physician who retired, died, or relocated (from the service area) during the previous 12-month period, the costs allocated by the physician practice to the recruited physician may be either: (1) the actual additional incremental costs attributable to the recruited physician; or (2) the lower of a per capita allocation or 20 percent of the practice's aggregate costs.
- This Phase III final rule also clarifies that a physician must move his or her medical practice from a location outside of the geographic area served by the hospital to a location within the geographic area served by the hospital.
- In addition, CMS has revised the exception to provide that the relocation requirement will not apply to a physician who: (1) for at least 2 years immediately preceding the recruitment arrangement, was employed on a full-time basis by a Federal or State bureau of prisons (or similar entity operating correctional facilities), the Department of Defense or Veterans Affairs, or facilities of the Indian Health Service, provided that he or she had no private medical practice during the same time period; or (2) the Secretary has determined in an advisory opinion not to have an established medical practice that serves a significant number of patients who are or could become patients of the recruiting hospital.
- In the case of recruitment assistance provided by a hospital to a physician who joins a physician practice, CMS has revised the exception to prohibit the physician practice from imposing on the recruited physician any practice restrictions that unreasonably restrict the recruited physician's ability to practice medicine in the geographic area served by the hospital.
- Finally, the exception in §411.357(e) is now applicable to a rural health clinic in the same manner as it applies to a hospital (or federally qualified health center).

- Changes relative to physician retention:
  - The CMS has expanded the exception in §411.357(t) for retention payments in underserved areas to permit a hospital to make a payment to retain a physician on its medical staff even if the physician does not have a bona fide firm, written recruitment offer, provided that the physician certifies in writing that, among other things, he or she has a bona fide opportunity for future employment that would require the

physician to move his or her medical practice at least 25 miles to a location outside the geographic area served by the hospital, and certain other conditions are satisfied.

- CMS has also expanded the retention payments exception to permit retention 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.
- Also, CMS has expanded the exception to permit a hospital to make a retention payment to a physician whose current medical practice is not located in a HPSA. Under the revised exception, a retention payment may be made to a physician whose current medical practice is located in a rural area or an area with demonstrated need for the physician, as determined by the Secretary in an advisory opinion.

- Changes to the remaining exceptions found in §411.357 include:
  - Under the personal service arrangements exception in §411.357(d), allowing a "holdover" personal service arrangement on terms similar to those in the exceptions for the rental of office space and equipment;
  - Under the nonmonetary compensation exception in §411.357(k), in certain circumstances, upon repayment of nonmonetary compensation in excess of the applicable limit, deeming the nonmonetary compensation to be within the limit, and allowing an entity with a formal medical staff to hold one local medical staff appreciation event per year;
  - Under the exception for charitable donations by a physician in §411.357(j), clarifying that the donation 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;
  - Under the professional courtesy exception in §411.357(s), eliminating the requirement that the entity offering the professional courtesy inform the insurer in writing of the reduction of any coinsurance obligation on the part of the recipient of the professional courtesy, and clarifying that the exception is applicable only to entities that have formal medical staffs;
  - Under the fair market value compensation exception in §411.357(l), clarifying that the exception is applicable to both compensation provided to a physician from an entity and compensation provided to an entity from a physician (but fair market value exception shall not be applicable to space rental); and,
  - Under the compliance training exception in §411.357(o), permitting the provision of training programs for which CME is available, provided that the primary purpose of the program is compliance training.

The Stark Phase III Final Rule will have significant implications for hospitals, physicians and other health care providers. Additional regulatory changes are in store once CMS finalizes its proposed rule in the 2008 Physician Fee Schedule (published in the Federal Register on July 12, 2007). Health care providers are advised to contact legal counsel to review their contractual arrangements for regulatory compliance.

If you have any questions about this or any other health care-related issue, please contact Tricia Ochmann (330.208.1023) or your Vorys lawyer.

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