

Legal News Alert is part of our ongoing commitment to providing up-to-the minute information about pressing concerns or industry issues affecting our Health Care clients and colleagues. If you have any questions about this Alert or would like to discuss this topic further, please contact your Foley attorney or any of the following individuals:

Charles B. Oppenheim

Los Angeles, California
310.975.7790
coppenheim@foley.com

Laura J. Gage

Milwaukee, Wisconsin
414.297.5651
lgage@foley.com

Gary D. Koch

Tampa, Florida
813.225.4124
gkoch@foley.com

Lawrence W. Vernaglia

Boston, Massachusetts
617.342.4079
lvernaglia@foley.com

Richard L. Prebil

Chicago, Illinois
312.832.4362
rprebil@foley.com

Lena Robins

Washington, D.C.
202.295.4790
lrobins@foley.com

Stark II Phase III Rules Released

The awaited Stark II, Phase III final rules have just been released by the Centers for Medicare & Medicaid Services (CMS). The rules will become final 90 days after publication, expected on September 5, 2007. The Phase III final rules, which were released August 27, 2007, are 512 pages long, and impact countless aspects of the existing Stark regulations. Among the key changes are: (1) the rules on physician recruitment are relaxed; (2) the “indirect compensation arrangement” concept is scaled back, and physicians instead will be treated as “standing in the shoes” of their practices, so that **arrangements with physician organizations now must meet a direct Stark exception**; (3) the “safe harbor” for determining hourly fair market value compensation for physicians is eliminated; (4) a six-month holdover concept is added to the personal services arrangement exception; and (5) parties can cure non-monetary compensation in excess of the annual limit, in certain cases, if the physician repays the excess compensation to the entity.

These final rules come amidst a recent frenzy of activity on Stark. Just last month, CMS proposed Stark revisions separate from, and in addition to, these Phase III final rules, which would, among other things, prohibit certain **“per click” leases and percentage compensation** arrangements, eliminate many **“under arrangements” joint ventures**, and curtail use of the **in-office ancillary services** exception. Also, CMS recently has announced its intention to mandate that all Medicare-participating hospitals report to CMS details of their financial relationships with their referring physicians, starting with an initial group of 500 hospitals this September. Finally, there also is current legislation pending in the U.S. Congress, which would significantly curtail the Stark exception for physician ownership of hospitals.

Phase III Final Rules

Physician Recruitment. The Phase III final rules make a number of changes that relax the existing rules on physician recruitment. More specifically, the new rules:

- Permit rural hospitals to determine their “geographic service area” using an alternative test that encompasses the lowest number of contiguous (or in some cases,

noncontiguous) ZIP codes from which the hospital draws at least 90 percent of its inpatients

- Permit a more generous allocation of costs to a recruited physician joining an existing practice when replacing a deceased, retiring or relocating physician in a rural areas or Health Professional Shortage Area (HPSA)
- Permit group practices to impose practice restrictions so long as they do not “unreasonably restrict the recruited physician’s ability to practice medicine” in the hospital’s service area
- Permit rural hospitals to recruit physicians into an area outside of the hospital’s geographic service area if it is determined through a CMS advisory opinion that the area has a demonstrated need for the recruited physician
- Exempt from the “relocation” requirement physicians employed full time by a federal or state bureau of prisons (or similar correctional agency), the U.S. Departments of Defense or Veterans Affairs, or facilities of the Indian Health Service, provided that the physician did not maintain a separate private practice in addition to such full-time employment (or any other physician whom the Secretary deems in an advisory opinion did not have an established medical practice with a significant number of patients who are or could become patients of the recruiting hospital)
- Clarify that the additional rules that apply when a recruited physician “joins” an existing practice do not apply when the recruit merely co-locates with an existing practice, but does not join the existing group (i.e., in a “side-by-side” space and expense-sharing arrangement)

Stand in the Shoes. For purposes of determining whether a physician has a direct or indirect compensation arrangement with an entity to which the physician refers, the physician will now be viewed as “standing in the shoes” of his or her physician organization. In other words, **a hospital that contracts with a large medical group will now be viewed as having a direct compensation arrangement with all of the physicians in the group.** On the other hand, if the entity interposed between the physician and the entity to which the physician refers is not a “physician organization,” then the indirect compensation arrangement rules still apply. The new rules define a

“physician organization” to mean a physician, including a professional corporation of which the physician is the sole owner, a physician practice, or a group practice.

On a helpful note, **CMS will “grandfather” existing indirect compensation arrangements entered into prior to the publication date of the Phase III final rule**, if they meet the indirect compensation arrangements exception on the publication date of the Phase III final rule. In other words, such arrangements need not be amended during their current term to comply with the requirements of another exception. Such arrangements may continue to use the indirect compensation arrangement exception during the original or current renewal term of the agreement as if the “stand in the shoes” doctrine does not apply.

Fair Market Value Hourly Payments. In the Phase II regulations, CMS had created a “safe harbor,” within the definition of “fair market value,” for hourly payments to physicians for their personal services that met certain benchmarks. In response to a number of comments with suggestions for changing the methods for determining the hourly fair market value safe harbor, or criticizing the approach, CMS has decided to eliminate the option altogether, noting that it was voluntary, and that there are many ways to demonstrate that compensation is fair market value.

Personal Services Arrangements – Holdovers. CMS has established a six-month “holdover” provision for personal service arrangements that otherwise meet the requirements of the personal services exception. This allows arrangements that continue for up to six months beyond the agreement’s stated expiration date, if they otherwise meet the exception and continue on the same terms and conditions as the immediately preceding agreement. This holdover concept is similar to what CMS did for equipment and space leases in the Phase II rules.

Curing Excess Non-Monetary Compensation. CMS now will make allowances when an entity inadvertently provides non-monetary compensation to a physician in excess of the annual limit (currently \$329 per year), if (1) the value of the excess compensation is no more than 50 percent of the annual limit; and (2) the physician returns the

ABOUT FOLEY

Foley & Lardner LLP is a national law firm providing comprehensive legal services for innovative enterprises in the health care, pharmaceutical, biotechnology, and biomedical sectors. Our Health Care attorneys provide counsel on financial transactions, mergers, acquisitions, affiliations, joint ventures, regulatory and government compliance, and business operations. With offices throughout the United States and the backing of Foley's Health Care Industry Team — consistently ranked as one of the top health care law firms nationally and regionally by Chambers USA — Foley is well-positioned to serve the wide-ranging needs of health care entities across the country.

Foley.com

Foley & Lardner LLP Legal News Alert is intended to provide information (not advice) about important new legislation or legal developments. The great number of legal developments does not permit the issuing of an update for each one, nor does it allow the issuing of a follow-up on all subsequent developments.

If you do not want to receive further Legal News Alert bulletins, please e-mail info@foley.com or contact Marketing at Foley & Lardner LLP, 321 N. Clark Street, Suite 2800, Chicago, IL 60610 or 312.832.4500.

excess amount to the entity by the end of the calendar year in which it was received or within 180 days after received, whichever is earlier.

What To Do Now

These changes are final, and will become effective 90 days after publication (which is expected to be September 5, 2007). In fact, **for compensation arrangements entered into with physician organizations, the new rules are, for all intents and purposes, effective as soon as they are published**, because that is the cut-off date for using the indirect compensation arrangement exception for such arrangements. Thus, providers and physicians are well advised to become familiar with the new rules, and make sure that their financial relationships comply with the new requirements. The Stark Phase III final rule is available on CMS' Web site (<http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/CMS-1810-F.pdf>).