

New Stark Phase II Regulations Released

April 19, 2004

On March 26, 2004, the Centers for Medicare & Medicaid Services ("CMS") published the second part of the final rule ("Phase II") implementing certain provisions of the federal physician self-referral prohibition or "Stark law" (42 U.S.C. § 1395nn). Phase II comes more than three years after "Phase I," and more than a decade after the original Stark law was amended and expanded in "Stark II". Phase II was published as an Interim Final Rule with a 90-day comment period, and will be effective on July 26, 2004.

Phase II continues CMS's stated intent to interpret the Stark law's prohibitions narrowly and the exceptions broadly, and to provide "bright lines" relating to the law. The Phase II regulations address statutory provisions not previously dealt with, creates new obligations, and modifies select provisions of Phase I.

Some of the key provisions include:

New exception for arrangements that have temporarily fallen out of compliance with another exception. Previously compliant arrangements that fall outside an applicable exception for reasons beyond the parties' control will now be protected for up to 90 days in a new "temporary noncompliance" exception. The parties must act quickly to remedy the non-compliance, and this exception may be used only once every three years with respect to the same referring physician.

New physician retention exception. If a physician practicing in an underserved area receives a bona fide written offer from a facility located more than 25 miles from the geographic area of the facility where the physician currently provides services, the facility where the physician currently provides services is allowed to offer the physician a retention bonus in an amount equal to the lesser of the amount required to match the other facility's offer or the reasonable cost of recruiting another physician.

Changes to the physician recruitment exception. For hospitals, one of the most anticipated sections of Phase II is the exception governing physician recruitment arrangements. This exception allows hospitals to pay remuneration to induce a physician to relocate to the hospital's geographic area and become a medical staff member. Both the 1995 final rule governing Stark I, and the 1998 proposed rule governing Stark II imposed additional requirements, including that the recruited physician must "relocate" to the hospital's geographic area. The Phase II final rule adopts most of the requirements in the 1995 and 1998 provisions referenced above, but also elaborates on them and offers some new twists. The Phase II recruitment exception can now be used by hospitals and Federally Qualified Health Centers ("FQHCs"), but not by other organizations such as physician practices (although medical group practices have other exceptions that can generally be used to promote recruitment goals). To qualify for the exception, the recruit's medical practice, and not his/her residence, must be relocated. Under Phase II a recruit's practice will be deemed to have been relocated if its physical location is moved at least 25 miles, or if at least 75% of the recruited physician's revenues are provided to "new" patients who were not seen at the previous practice site. The geographic service area is defined as the lowest number of contiguous zip codes from which the recruiting hospital derives at least 75% of its inpatients. The recruitment exception has also been modified to clearly indicate that recruits cannot be prohibited from establishing privileges at a hospital other than the recruiting hospital.

The most significant change on the recruitment front is that the Phase II rule now provides a narrow exception for recruitment arrangements into existing medical practices. The physician recruitment provision under Phase II explicitly provides an exception for recruiting arrangements with medical practices. Key requirements of this practice-affiliated recruitment exception include:

- Written agreements executed by the recruit and the recipient of the payments;
- Payments to the practice or physician other than the recruit are limited to the incremental costs incurred due to the recruited physician;
- No direct or indirect consideration of referrals in determining the amount of recruitment support;
- Prohibitions on the imposition of other restrictions such as non-competes; and
- The recruitment arrangement must not violate the anti-kickback law.

Clarifications related to leases. Providers now have some greater flexibility in lease arrangements. Among other clarifications, leases may be terminable without cause as long as the parties do not enter into

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a new agreement during the first year of the original term of the agreement. Month to month holdovers are now expressly allowed under the same terms as the original lease for up to 6 months following a term that is at least 1 year. Subleases are acceptable as long as neither the lessee nor the sublessee share the space with the lessor or anyone related to the lessor.

Physician production bonuses based on personal performance. The Phase II regulations clarify that all physicians (including independent contractors and employees) can be paid productivity bonuses based on work personally performed by the physicians.

"Per Click" arrangements permitted. CMS now says that percentage based compensation arrangements can fit the Stark "personal services" exception's requirement that compensation be "set in advance," as long as the percentage fee is specifically set in advance, is objectively verifiable; and is not changed over the course of the agreement based on the volume or value of referrals or other business produced by the referring physician.

New safe harbor for fair market value determination. Although CMS does not require fair market value determination by any specific method, the Phase II Regulations now provide a safe harbor for determining hourly rates for services provided by physicians. The safe harbor provides that CMS will consider an hourly rate for physician services as fair market value if it is either equal to or less than the average hourly fee for emergency department physician services in the relevant market and there are at least three hospitals in such market that provide physician services, or based upon an average of the 50th percentile national compensation level for physicians in the same specialty (or general practice if the relevant specialty is not listed in the surveys) in at least four of the six physician compensation surveys by companies listed by CMS.

Clarification of the "same building" requirement of the in-office ancillary exception. Under the in-office ancillary services exception, designated health services must be furnished in the "same building" in which the referring physicians provide their regular medical services or, in the case of a group practice, in a central building. Phase II redefines the meaning of the "same building." The Phase II regulations state that a building will be considered the "same building," if it satisfies one of three tests comprised of elements related to the number of hours the office is open, the number of hours physician services unrelated to DHS are provided, and the presence of the referring physician.

New intra-family rural referral exception. Referrals from a physician to an immediate family member or an entity with which an immediate family member has a financial relationship are protected if: the referred patient lives in a rural area (as defined by statute); no other provider within 25 miles of the patient's residence is available to supply the services promptly considering the patient's condition (the referring physician has a duty to inquire about this availability); with respect to those services provided to a patient in his home, no other provider is available to furnish such services in a timely manner; and the financial relationship does not violate any state or federal laws related to billing/claims submission, including the anti-kickback statute.

New professional courtesy exception. A provider may now give free or discounted health care to a physician, a physician's family member or office staff so long as the arrangement does not violate the anti-kickback statute or any federal or state laws related to billing or claims submission and the provider offers the courtesy service to all physicians on its medical staff or in its local community/service area without regard to the value or volume of referrals, routinely provides such health care items or services, sets forth its professional courtesy policy in writing and the provider's governing body has approved it in advance, does not offer the courtesy service to any person who is a federal health care program beneficiary absent a showing of financial need, and informs any insurer in writing of a reduction of a coinsurance obligation if such a reduction is involved.

New exception for community-wide health information systems. Entities may provide information technology items or services that permit access to or sharing of electronic health records and other medical information systems to physicians to enhance the community's overall health if the items or services are available to enable the physician to participate in a community-wide health initiative and are not provided in any way that takes into account the value or volume of referrals, the information is available to all providers who are interested, and the arrangement does not violate the anti-kickback statute or any federal or state law related to billing or claims submission.

The Phase II final rules become effective July 26, 2004. Interested parties may provide comments to CMS until June 24, 2004.

For Further Information

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