The Stark II Regulations are effective July 26, 2004; the Office of Inspector General (OIG) has emphasized the need to implement systems to ensure compliance.

Introduction

More than ten years after Congress enacted its expanded physician self-referral law known as Stark II, CMS has issued the long-awaited second phase of its two-part regulations implementing the law. Although issued in “interim” final form, thus providing for a 90-day comment period, the regulations will be effective on July 26, 2004. Now that there is a complete set of regulations and a definitive compliance date, the health care industry should expect increased enforcement and heightened scrutiny of financial arrangements between referring physicians (or a member of the physician’s immediate family) and entities that provide “designated health services” (“DHS”) payable by Medicare or Medicaid.

Hospitals, physicians and physician groups, imaging centers, home health agencies, long-term care facilities and all other health care providers should understand the implications of the final Stark II regulations, and should carefully analyze current and proposed arrangements with physicians to be sure they can demonstrate compliance. The final regulations give health care entities and physicians considerably more flexibility in structuring their financial arrangements than previously afforded by providing new exceptions and helpful clarification concerning pre-existing exceptions. However, the regulations remain exceedingly complex, requiring careful attention to the regulatory text and interpretive guidance provided by the government both through public forums and in the preamble to the regulations. This Advisory highlights some of the key provisions of the regulations and provides suggestions for important “next steps” health care providers and physicians are strongly advised to take.

Sanctions

As the OIG noted in its recently issued Draft Supplemental Compliance Program Guidance for Hospitals (June 8, 2004), health care entities face “significant financial exposure” under the Stark law. Both physicians that make improper referrals and the entities providing DHS are subject to a variety of sanctions, including nonpayment or refund of amounts improperly billed, civil monetary penalties (up to $15,000 for each item of service billed), damages in the amount of three times the total amount billed and exclusion from Medicare and Medicaid. Physicians and entities also can be fined up to $100,000 for each “scheme” to circumvent the Stark II requirements. In contrast to the anti-kickback statute, the (OIG) has viewed Stark II as a "strict liability" law. This means that these penalties can be imposed if the arrangement does not satisfy a Stark II exception, regardless of whether the referring physician or entity providing services knowingly or intentionally violated the law. Stark II also creates potential liability under the False Claims Act for amounts up to three times the improperly billed amounts and up to $11,000 per improper claim.
Highlights and Major Changes in Phase II

• **Greater clarity for physician compensation:** The Phase II regulations clarify that the "set in advance" requirement of the personal service and fair market value exceptions permit some percentage compensation arrangements (or similar arrangements such as "per click"). A percentage-based compensation scheme is permissible as long as the formula is established prospectively, is objectively verifiable, and is not changed over the course of the agreement based on volume or value of referrals or other business generated by the referring physician. Physicians can also earn productivity bonuses based on work they personally perform. Physicians in a group practice meeting the regulatory definition can also be paid a productivity bonus based on "incident to" services, as well as indirect bonuses and profit shares that may include DHS revenues, as long as the distribution meets certain criteria.

• **"Same building" requirement:** In order to take advantage of the exception for in-office ancillary services, the DHS services must be furnished in the same building where the physician or his or her group provides physician services that are not designated health services (or, in the case of a group practice, a centralized building). The new Phase II regulations simplify the "same building" location rules, replacing a complicated three-part test with three alternative ways for meeting the "same building" requirement. Although CMS believes that "virtually all" legitimate arrangements that complied with the original Phase I three-part test will continue to qualify under one of the new tests, the agency does warn that any previously compliant arrangements that do not meet the new tests should be restructured or unwound.

• **Recruitment/Retention:** The Phase II regulations overhaul the exception for recruitment efforts. Hospitals, and now federally qualified health centers, may pay a physician to relocate to the hospital or center’s geographic area, as long as the relocation meets the 25/75 rule (the physician relocates his or her practice a minimum of 25 miles, or 75% of the physician’s revenues will now come from care provided to new patients) and the other requirements of the exception are met. The regulations also afford special treatment to residents and new physicians. Hospitals may also make payments to medical groups in order to recruit new physicians to join the group, but the payments must meet a number of strict criteria. Phase II also allows limited retention payments to physicians with practices in health professional shortage areas (HPSAs).

• **"Safe harbor" for fair market value:** As part of CMS’s efforts to provide "bright-line" rules, the new regulations include a "safe harbor" for establishing the fair market value of hourly payments to physicians for personal services. The safe harbor specifies two methods for determining an hourly rate (average hourly rate for emergency room physicians in the relevant market or averaging the 50th percentile compensation for the same physician specialty in at least four national compensation surveys divided by 2,000 hours); if either method is used, the compensation will be deemed "fair market value."

• **New exceptions:** The new regulations allow a limited "grace period" for temporary lapses in compliance, but this exception is available only once every three years with respect to the same referring physician and is subject to other conditions. Donations to a tax-exempt organi-
Compliance Program Guidance for Hospitals, mentioned above, also emphasizes the need for providers to implement systems to ensure all conditions for any applicable exceptions are met. New agreements or structures may need to be put in place, or existing agreements or structures modified, to address the regulatory requirements. More specific “next steps” physicians and organizations should take are:

1. Review, inventory and document all existing ownership, investment and compensation relationships between the entity providing DHS (which may include the physician group itself) and referring physicians or physician groups (or an immediate family member of a referring physician). Some of the key areas that should be reviewed are:

   • Employment arrangements
   • Medical director arrangements
   • Management contracts
   • Joint ventures
   • Space and/or equipment leases
   • Recruitment arrangements
   • Financial arrangements of any kind (compensation or investment) that may involve an immediate family member of a referring physician

2. For physician practices, document that the practice meets all the criteria to be treated as a “group practice” and that criteria for the in-office ancillary exception are satisfied.

3. Ensure that productivity bonuses are derived based on work personally performed and that other applicable compensation requirements are satisfied. Document the amount of the payment

• Documentation and Reporting: Under the proposed regulations, entities subject to Stark II would be required to report annually about their financial relationships with physicians. The new rules significantly ease this burden, requiring instead that entities maintain information regarding all financial relationships subject to Stark II and submit certain information to CMS or the OIG upon request. This new provision highlights the importance of maintaining appropriate documentation both of current and future relationships between referring physicians and entities providing DHS.

Steps to Ensure Compliance

This Advisory highlights only a portion of the changes contained in the final Stark II Phase II regulations. As discussed above, the effective date of the regulations is July 26, 2004. Accordingly, hospitals, physicians and physician groups, home health agencies, long-term care providers and other health care entities should immediately begin to review, inventory and document their existing financial and contractual arrangements with physicians (or with immediate family members of physicians). The OIG’s Draft Supplemental Compliance Program Guidance for Hospitals, mentioned above, also emphasizes the need for providers to implement systems to ensure all conditions for any applicable exceptions are met. New agreements or structures may need to be put in place, or existing agreements or structures modified, to address the regulatory requirements. More specific “next steps” physicians and organizations should take are:

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2. For physician practices, document that the practice meets all the criteria to be treated as a “group practice” and that criteria for the in-office ancillary exception are satisfied.

3. Ensure that productivity bonuses are derived based on work personally performed and that other applicable compensation requirements are satisfied. Document the amount of the payment
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and the methodology used to calculate the bonus.

4. Review any leasing or rental arrangements to assess and amend provisions, as necessary, concerning payments during a holdover period.

5. Ensure you have a signed written agreement in place and satisfy other conditions if you plan on relying on the exceptions for recruitment, indirect compensation arrangements, personal services, rental and equipment leases, or fair market value arrangements.

6. Document that compensation paid under any employment or personal services contracts is the fair market value for those services (particularly if the compensation does not fall within the new "safe harbor" for determining fair market value).

7. Compile a "master list" of all "personal services" arrangements. Draft agreements, or revise existing agreements as necessary, to ensure compliance with the personal services or fair market value exceptions. Ensure there are appropriate cross-references to all agreements for services provided by the same referring physician or group.

8. Be cautious about extending "professional courtesy" services under the professional courtesy exception; consider other relevant legal issues, like the anti-kickback statute and private inurement.

9. Implement a policy to document instances of temporary noncompliance, the reasons for the noncompliance and the steps taken to bring the arrangement back into compliance within the 90-day "grace period."

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Nothing in this Advisory constitutes legal advice, which can only be obtained as a result of personal consultation with an attorney. The information published here is believed to be accurate at the time of publication, but is subject to change and does not purport to be a complete statement of all relevant issues.

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Wiggin and Dana is planning to hold Stark II compliance discussion sessions in its New Haven and Hartford offices. Please email mdebarge@wiggin.com or call 860.297.3702, if you are interested in attending, and we will send you confirmation of the details shortly.

Please contact one of the following attorneys for further information or assistance with your Stark II compliance efforts.

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