CMS Issues Phase II Stark II Regulations

On March 26, 2004, the U.S. Centers for Medicare & Medicaid Services (“CMS”) published the long-awaited Phase II, Stark II physician self-referral regulations (the “Regulations”). The Regulations were published as an interim final rule with a ninety-day public comment period and an effective date of July 26, 2004. The Regulations offer slightly more flexibility through the addition of certain limited exceptions and more liberal interpretations of certain requirements, while establishing certain bright line rules that may make it more difficult to qualify certain arrangements for exceptions to the Stark self-referral ban.

I. Important Revisions and Additions

The Regulations’ highlights include:

- **In-Office Ancillary Services — the “Same Building” Requirement:** The “same building” standard maintains the “single postal address” criterion (despite comments urging a more liberal approach) and creates more difficult to satisfy tests for part-time physician offices. A physician group now must maintain a physician office that furnishes physician services unrelated to the furnishing of designated health services (“DHS”) in the same building as the DHS facility in accordance with one of the following three tests: (1) office is open to patients 35 hours per week and referring physician or group members regularly practice at location at least 30 hours per week; (2) office is where patient usually receives physician services, is open to patients at least 8 hours per week and is where referring physician furnishes services (some unrelated to DHS) at least 6 hours per week; or (3) office is open to patients 8 hours per week and referring physician or group member furnishes services at the location at least 6 hours per week (referring physician must be present and order DHS during a patient visit or group member must be present while DHS is furnished). This revision does not affect a physician group’s ability to provide DHS in a “centralized location” occupied by the group on a full-time basis. The Regulations sole impact is on DHS facilities leased by a group on a part-time basis, which must be in the “same building” as a physician office occupied by the group in accordance with the new tests.

- **Physician Recruitment:** The Regulations “substantially modify” the proposed recruitment exception in the following respects: (1) focuses on relocation of recruited physician’s medical practice rather than physician’s residence; (2) eliminates relocation requirement for residents and physicians who have been in medical practice less than one year; (3) permits recruitment by federally qualified health centers (“FQHC”) in addition to hospitals, but not to nursing homes or home health agencies; (5) permits certain recruitment payments made through existing group practices (rather than directly to a physician), provided that the group does not impose practice restrictions on the recruited physician (such as a non-compete agreement) except conditions related solely to quality; and (6) bars hospitals from “locking in” referrals by restricting the recruited physician’s ability to join other medical staffs and refer to other hospitals (except as permitted under the employment and risk sharing exceptions). CMS declined to extend the exception to teaching hospital faculty recruitment in light of existing academic medical center, personal services and employment exceptions. In the case of income guarantees made by a hospital to a physician who joins a practice, costs allocated by the practice to the physician may not exceed actual incremental costs. In addition, CMS reversed its prior position that the fair market value compensation exception might also apply to re-
recruitment arrangements. Thus, hospitals and FQHCs must fit their recruitment arrangements within the four corners of the recruitment exception.

• **Physician Retention**: The Regulations establish a new compensation arrangement exception for retention payments provided by a hospital or FQHC directly to a physician on its medical staff to retain the physician's medical practice in the same geographic area if the physician has a bona fide written offer from an unrelated hospital or FQHC at least 25 miles away and outside the geographic area served by the hospital or FQHC and certain other technical requirements are satisfied.

• **“Set in Advance”**: CMS has modified its interpretation of “Set In Advance” to permit percentage compensation if the methodology for calculating the compensation is set in advance and does not change over the course of the arrangement in any manner that reflects the volume or value of referrals or other business generated by the referring physician.

• **Declining Unit-Based Compensation May Satisfy Fair Market Value Standard**: The preamble to the Regulations acknowledges that there may be circumstances, particularly in the context of equipment leases, in which per-use or unit-of-service payments that decrease as volume increases most accurately reflect fair market value and do not take into account the volume or value of referrals or other business generated for purposes of the Stark Act. Compliance with the fair market value criterion will be evaluated on a case-by-case basis.

• **“Fair Market Value” Safe Harbor for Hourly Compensation**: The Regulations create safe harbors for two types of hourly physician compensation methodologies. Such methodologies will be deemed to satisfy the “Fair Market Value” standard if: (1) the hourly payment is less than or equal to the average hourly rate for emergency room physician services in the relevant physician market, provided there are at least three hospitals providing emergency room services in the market; or (2) the hourly rate is established by averaging the fiftieth percentile salary for the physician’s specialty under four national salary surveys and dividing the resulting figure by 2000 hours.

• **Productivity Bonuses**: CMS has clarified that personally performed DHS is not a “Referral” and that “Other Business Generated” does not include personally performed professional services. However, “Other Business Generated” does include any corresponding technical component of a service billed by a DHS entity. Therefore, all physicians, whether employees, independent contractors or academic medical center physicians, can be paid productivity bonuses based on professional services they personally perform.

• **Additional Flexibility for Group Practice Compensation Arrangements**: Although several commentators urged CMS to modify the employment, personal services and fair market value compensation exceptions to provide the same flexibility as exists under the Phase I Regulations’ “Special Rules for Productivity Bonuses and Profit Shares” for physicians in a “group practice,” CMS has interpreted the Stark Act to require a number of important distinctions reflected in the chart below:

<table>
<thead>
<tr>
<th>Terms of exception</th>
<th>Group practice physicians</th>
<th>Bona Fide employment</th>
<th>Personal service arrangements</th>
<th>Fair market value</th>
<th>Academic Medical Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Must compensation be “fair market value”?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Must compensation be “set in advance”?</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Scope of “volume or value” restriction.</td>
<td>DHS referrals</td>
<td>DHS referrals</td>
<td>DHS referrals or other business</td>
<td>DHS referrals or other business</td>
<td>DHS referrals or other business</td>
</tr>
<tr>
<td>Scope of productivity bonuses allowed.</td>
<td>Personally performed services and “incident to,” plus indirect bonuses and profit shares that include DHS revenues under “Special Rules”</td>
<td>Personally performed services</td>
<td>Personally performed services (but not DHS technical component)</td>
<td>Personally performed services (but not DHS technical component)</td>
<td>Personally performed services (but not DHS technical component)</td>
</tr>
<tr>
<td>Are overall profit shares allowed?</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Written agreement required?</td>
<td>No</td>
<td>No</td>
<td>Yes, minimum 1 year term</td>
<td>Yes (except for employment), no minimum term</td>
<td>Yes, written agreement(s) or other documents</td>
</tr>
</tbody>
</table>
• **“One Year Term”:** The Regulations liberalize the one year term requirement under various lease and compensation exceptions to allow “without cause” termination provisions, provided that the parties do not enter into the same or a substantially similar arrangement during the remainder of the first year of the original term.

• **Temporary Compliance Lapses:** The Regulations create a “grace period” exception to accommodate situations in which parties to an arrangement: (1) fall out of compliance with an exception through events outside their control; or (2) are unable to comply with an exception for temporary periods of time. In particular, the new exception applies to arrangements that have fully satisfied another exception to the self-referral prohibition for a least 180 consecutive days, but have fallen out of compliance with such exception for reasons beyond the control of the DHS entity. The temporary compliance lapse exception lasts up to 90 days and applies to DHS furnished during the exception period. By the end of the 90 day exception period, parties must either comply with another exception or have terminated their otherwise prohibited arrangement. Note: the exception may not be used by a DHS entity more often than once every three years with respect to referrals from the same referring physician.

• **New Exceptions:** The Regulations create new exceptions for charitable donations by a physician; obstetrical malpractice insurance subsidies; professional courtesy; and community-wide health information systems.

• **Miscellaneous Revisions:** Other notable features include the following:
  – The Regulations clarify that common ownership or investment interest in an entity does not, in and of itself, establish an indirect ownership or investment interest by one common owner or investor in another common owner or investor, i.e., physician-hospital joint ventures do not automatically create a financial relationship between the parties.
  – The Regulations expand the “consultation exception” in the “referral” definition to permit services and tests to be performed or supervised by another physician in the same group practice as the consulting pathologist, radiologist or radiation oncologist.
  – Radiology procedures performed immediately after an invasive procedure to confirm placement of an item are excepted from the definition of “radiology services.”
  – The “exclusive use” provision of the “rental of office space” exception is modified to allow sublease arrangements.
  – DHS entities that have more than one compensation relationship with a physician must cross-reference each relationship in their physician contracts (except employment contracts) or reference and maintain a “master list” of compensation arrangements.
  – The “isolated transaction” exception now allows for installment payments and commercially reasonable post-closing adjustments to purchase price that do not take into account the volume or value of referrals or other business generated by the referring physician.

• **Open Issues:** The preamble specifically reserves two issues for future rulemaking: (1) application of the Stark Act to Medicaid referrals and (2) potential inclusion of nuclear medicine procedures in the DHS definition.

II. Impact/Counseling Tips

While most of the regulatory changes involve clarifications or minor extensions of prior exceptions, a few “action steps” are recommended:

• Hospitals should examine their recruitment and retention arrangements to ensure compliance with the Regulations’ limited exceptions.

• “Shared ancillary services” arrangements under which group practices lease physician office space on a part-time basis may need to be restructured to ensure compliance with the in-office ancillary services exception’s “same building” requirement.
• When feasible, DHS entities should document that their hourly compensation arrangements with physicians qualify for the new “fair market value” safe harbor.

• Physicians and DHS entities should keep in mind that the Regulations open the door to certain new types of compensation arrangements, including percentage-based and declining unit of service compensation arrangements, installment sales, post-closing purchase price adjustments and productivity bonuses based on services personally performed by independent contractor and employed physicians.

• Given the additional flexibility for group practice compensation arrangements, physician practices and other entities that provide physician services should carefully evaluate whether they satisfy the “group practice” definition and, if not, consider restructuring to qualify for group practice treatment. In particular, hospitals that directly employ physicians may find it prudent to establish a physician practice affiliate.

Once the final, clarified Regulations take effect, health care providers should expect increased enforcement by the OIG.

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