Update: Physician Self-referral (Stark) Regulations, December 2008

On August 27, 2007, the Centers for Medicare and Medicaid Services (CMS) issued the highly anticipated Phase III Stark Final Rule (Phase III Final Rule). Officially published on September 5, the Phase III Final Rule became effective on Dec. 4, 2007. Also, on Nov. 1, 2007, CMS published the Final Physician Fee Schedule Rule for calendar year 2008, which contained a change to the anti-markup provision of the Stark self-referral law. However, application of the expanded anti-markup prohibition was subsequently delayed (except with respect to certain pathology services), as the result of strenuous objections raised by the AMA and other members of the physician community. Then, in the CY 2009 Physician Fee Schedule Proposed Rule, CMS set forth two principal “options” (with various “sub-options”) for extension of the anti-markup rule. The AMA sent a joint letter with other members of the physician community to CMS opposing both options. Finally, in the CY 2009 Final Rule, published Nov. 19, 2008, CMS issued final anti-markup regulations. This update reviews key elements of the recent additions and modifications to the physician self-referral regulations included in the Phase III Stark Final Rule and the various physician payment schedule rules.

The AMA continues to advocate against further modifications and additions to the self-referral laws. We believe the endless alterations endeavor to regulate every aspect of a physician’s practice. Continually forcing physicians and health care entities to re-structure longstanding relationships previously thought to be acceptable drives up the cost of health care and makes it more difficult for physicians to embrace quality and health information technology initiatives (HIT). The Stark rule remains complex, exceptionally lengthy, at times unclear, and often beyond the scope of the average physician to fully comprehend and attain full compliance. As it is, the law threatens to punish even unintended violations and any deviation of a physician's relationship with an entity, however minor or unintended, could yield dramatic penalties. While physicians have been responding to efforts to improve quality by participating in quality improvement initiatives, the fear of violating one of the complex provisions of the Stark law could inhibit physician participation in many quality improvement initiatives.

Thus, the AMA continues to advocate that CMS refine the regulations to simplify compliance, reduce the risk of making illegal many non-abusive physician relationships that have nothing to do with self-referral, and protect certain physician arrangements that create efficiencies and better quality patient care. We believe that focusing efforts on these laudable goals, rather than further complicating already complex regulations in an attempt to anticipate and restrict every potential physician action for which there might be unsubstantiated anecdotal evidence of abuse, or the potential for abuse, would be of much greater benefit to the health care system as a whole.

The Stark Law and Regulations

Section 1877(a) of the Social Security Act sets forth the physician self-referral law (the Stark Law). The law prohibits a physician from referring Medicare and Medicaid patients to an entity with which the physician or any of his immediate family members has a financial relationship if the entity provides certain designated health services (DHS) reimbursable by Medicare or Medicaid. The Stark Law also prohibits an entity from presenting or causing to be presented a claim for payment under the Medicare or Medicaid programs or a bill to any individual, third-party payor, or other entity for DHS furnished pursuant to a prohibited referral. Under the Stark Law, DHS include, among other things, inpatient and outpatient hospital services, clinical laboratory services, physical and occupational therapy services, and radiology services.

On Jan. 4, 2001, CMS published an interim final rule to the Stark Law (Phase I Rule), which set forth the physician self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created regulatory exceptions for arrangements. CMS published a subsequent interim final rule to the Stark Law with comment period on March 26, 2004 (Phase II Rule), which responded to comments received from the Phase I Rule and created additional regulatory exceptions. As noted above, on Sept. 5, 2007, CMS published the Phase III Final Rule. In addition, CMS proposed extensive changes to the Stark Law in the 2008 Proposed Medicare Physician Fee Schedule Rule that, but for changes to the anti-markup provision of the Stark Law, were not addressed in the Final Physician Fee Schedule Rule.

The AMA submitted extensive comments on the Phase II Rule and the 2008 Physician Fee Schedule Rule. In addition, the AMA joined with a large group of stakeholders to urge withdrawal of proposed changes to the anti-markup provision proffered in the 2009 Proposed Medicare Fee Schedule Rule.

Phase III Final Rule

The Phase III Final Rule includes clarifications and relatively minor modifications to the Phase II Interim Final Regulations that were issued in March 2004. Phase III focuses primarily on closing perceived loopholes, clarifying potentially confusing points, and taking a few small steps toward giving health care entities some flexibility in uncontroversial areas. The Final Rule, among other things, implements the following changes:

- Adds a new "stand in the shoes" provision, under which a physician is deemed to "stand in the shoes" of his or her physician organization. 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.
- Changes the general exceptions for both ownership/investment interests and compensation arrangements, specifically the exceptions for academic medical centers and intra-family rural referrals.
- Provides for greater flexibility in physician recruitment and retention for rural hospitals.
- Clarifies that a recruited physician must relocate his or her practice from outside the geographic area served by the hospital into such geographic area, and either (i) move at least 25 miles or (ii) meet the 75 percent new patient test.

- Enumerates certain "practice restrictions" that will be permissible in physician recruitment arrangements (e.g., reasonable liquidated damages and non-solicitation provisions).
- Provides relief for inadvertent violations of the self-referral prohibition under certain circumstances. For example, the Phase III Final Rule permits parties that inadvertently exceed the limit on non-monetary compensation to continue to satisfy the requirements of the exception if the excess non-monetary compensation did not exceed 50 percent of the permitted amount and is repaid within 180 days of its receipt or the end of the calendar year, whichever is earlier.
- Eliminates the compensation safe harbors within the definition of Fair Market Value.
- Clarifies that a lease agreement may be amended multiple times after the first year of the agreement provided that the rental charges are not changed.
- Clarifies that to be a "physician in the group practice," an independent contractor physician must have a direct contractual relationship with the group.
- Expands the Non-Monetary Compensation exception to address circumstances of noncompliance, and to allow an entity with a formal medical staff to provide one local medical staff appreciation event each year.

Phase III did not offer any big surprises to the health care community. Rather than implementing additional burdens on physicians and health care entities, the Phase III Rules, in many cases, clarified and relaxed certain confusing and narrow requirements. Unlike the potentially dramatic Stark rule changes that were addressed in the proposed revisions to the 2008 Physician Fee Schedule Rule, CMS did not use the Phase III Final Regulations to make significant changes.

2008 Medicare Physician Fee Schedule Final Rule

Contrary to the Phase III rule, the 2008 Proposed Physician Fee Schedule Rule presented a number of substantial, burdensome modifications to the Stark laws. The majority of these proposals were not ultimately included in the Final Rule. The issues that were proposed, but not included in the Final Fee Schedule Rule, were: burden of proof in denial of payment appeals; obstetrical malpractice insurance subsidies; per-click payments; the period of disallowance for noncompliant financial relationships; ownership or investment interest in retirement plans; "set in advance" and percentage-based compensation arrangements; "stand in the shoes" provisions; alternative criteria for satisfying certain exceptions; services furnished "under arrangements;" and changes to the In-Office Ancillary Services exception. While CMS declined to include these issues in the Final Physician Fee Schedule Rule, they made it clear that final rules on many of these issues are forthcoming.

The AMA aggressively advocated against the majority of these proposed changes as most represent inappropriate and burdensome attempts to regulate every aspect of physician practices. We informed CMS that the proposed changes would force physicians and health care entities to re-structure longstanding relationships previously thought to be acceptable, driving up the cost of health care at the very time we should be looking for ways to make it more affordable. In addition, we made clear our belief that the Stark laws already pose significant obstacles to physicians, group practices, and integrated health systems, despite benefits that

often result from referrals between the components of integrated systems. The AMA will continue to oppose these and any other future changes to the Stark laws that will create additional ambiguity, complexity, and barriers to the delivery of care.

The only proposed revision of the physician self-referral regulations that *was* made final in the 2008 Physician Fee Schedule Final Rule is the proposal related to anti-markup provisions for diagnostic tests. Here, CMS expanded the anti-markup rule to apply to some services provided within a group practice based on new site-of-service distinctions more restrictive than those permitted for Stark law purposes. Application of the expanded anti-markup prohibition was subsequently delayed (except with respect to certain pathology services) as the result of strenuous objections raised by the physician community.

2009 Medicare Physician Fee Schedule Final Rule

The CY 2009 Medicare Physician Fee Schedule Proposed Rule proposed that the anti-markup provisions would apply to all cases where the Technical Component (TC) or the Professional Component (PC) of a diagnostic testing service is either purchased from an outside supplier, or performed or supervised by a physician who does not share a practice with the billing physician or supplier. CMS proposed two alternatives for determining whether the performing or supervising physician “shares a practice” with the billing physician or supplier. The first alternative proposed that a physician who is employed by or contracts with a single physician or physician practice “shares a practice” with that physician or physician practice. The second alternative proposed that the anti-markup limitation would apply to non-purchased TCs and PCs that are performed outside the office of the billing physician or supplier. The physician community requested that CMS withdraw the delayed portions of the 2008 Physician Fee Schedule and any further proposed revisions.

In the Final Rule, CMS has decided to finalize the first alternative with some modifications as well as retaining, with modifications, the “site-of-service” approach that was proposed in the second alternative. Thus, where the performing physician (the physician that supervises the TC, performs the PC, or both) performs “substantially all” (at least 75 percent) of his or her professional services for the billing physician or other supplier, none of the services furnished by the physician on behalf of the billing physician or other supplier will be subject to the anti-markup limitation. If the performing physician does not meet the “substantially all” requirement found in the first alternative, an analysis under the second alternative—the “site-of-service” approach—can be done on a test-by-test basis. Under this approach, only TCs conducted and supervised in, and PCs performed in, the office of the billing physician or other supplier by an employee or independent contractor physician will be free from the anti-markup limitation.