New Federal Rules on Physician Self-Referral Prohibition (Stark Law, Phase III)

Stanley W. Stead, M.D., M.B.A., Chair
Committee on Economics

On September 5, 2007, the Centers for Medicare & Medicaid Services (CMS) published the long-awaited third phase of its final rulemaking (the Phase III rule) regarding the federal physician self-referral prohibition, known as the "Stark Law." The amendments reflected in the Phase III rule go into effect on December 4, 2007.[1] Phase III contains many technical changes and subtle details, along with substantive changes that will require physicians and their counsel to re-evaluate and likely restructure their relationships with "designated health service" (DHS) organizations in the immediate future.

Phase III is a final rule wholly separate from the self-referral provisions contained in the recent Proposed CY 2008 Medicare Physician Fee Schedule (the "Fee Schedule Rule").[2] Confusingly, Phase III requirements significantly differ from and in some topics directly conflict with the Fee Schedule Rule, particularly as providers attempt to comply with the "strict liability" statute. In addition, commentary in the Phase III rule reveals that CMS may be considering yet another future rulemaking to address further issues raised by stakeholders. This brief article serves to point out key Phase III changes that may apply to anesthesiologists practicing in surgical anesthesia, critical care and pain medicine.

Anesthesiologist Referrals to DHS Still Not Excluded

Three years ago, ASA requested confirmation from CMS that anesthesiologists do not refer patients to DHS organizations by providing surgical anesthesia services under the Stark Law and regulations. ASA specifically asked that CMS confirm that anesthesiologists do not refer patients for inpatient or outpatient hospital services when they provide surgical anesthesia services and asked CMS to specifically address the case of freestanding outpatient facilities. CMS *declined* to make this change. In the commentary in Phase III, CMS noted that the consultation exclusion granted to pathologists, radiologists and radiation oncologists is statutory and that CMS lacks the authority to extend it. Furthermore CMS was not persuaded that any special regulatory exception is warranted for "DHS referrals made by an anesthesiologist to an entity with which he or she (or his or her immediate family member) has a financial relationship."[3]

Elimination of Safe Harbor Method for Establishing Fair Market Value of Personal Services

Many anesthesiology practices receiving support from hospitals and other entities have relied upon a "fair market value" (FMV) to establish an appropriate level of support (stipends). Previously, under Phase II rule, FMV was considered by CMS to be a "safe harbor" for establishing compensation for physicians' personal services. Typically compensation was based on the average of the "50th percentile national compensation level for physicians in the same specialty,"[4] using at least four of six specified salary surveys, and dividing the result by 2,000 hours to establish an hourly rate. Phase III eliminates this "safe harbor" method. CMS acknowledges, however, that "references to multiple, objective and independently published salary surveys remain a prudent practice for evaluating fair market value." CMS emphasized that FMV is essential to many Stark Law exceptions and "the appropriate method for determining fair market value for purpose of the physician self referral law will depend on the nature of the transaction, its location and other factors."[4] The abolition of the "safe harbor" provision means that each compensation agreement between physicians and DHS will need to take into account the particular nature and environment of the agreement. Rather than relying on a particular valuation methodology, "ultimately, fair market value is determined based on facts and circumstances."[5]

FMV Exception

Until now, FMV exceptions currently applied only to FMV compensation paid to a physician or group for items or services by a DHS. Phase III now extends the exemptions for payments made by a physician or group of physicians to a DHS hospital or health entity.[6] Office space rent is under additional scrutiny as are equipment leases of less than one year. For physician payments to a DHS to qualify as FMV

Stanley, W. Stead, M.D., M.B.A., is CEO, Stead Health Group, Inc., and Clinical Professor of Anesthesia and Pain Management, University of California-Davis, Encino, California.

exceptions, agreements must satisfy the more stringent requirements of §411.357(a), requiring a written agreement and stated term length. In the 2008 proposed fee schedule rule, CMS proposes to amend the office space and equipment rental exceptions to exclude per unit of service or "click" rental payments.[2] CMS is seeking more transparency in physician payment to health entity arrangements.

Group Practice Compensation

Physician compensation within group practices receives more flexible treatment than individual physicians under the Stark Law. Generally, in the case of group practices, members of a group practice cannot be compensated in any way that directly or indirectly relates to the volume or value of their referrals for a DHS. Physicians may, however, be paid a share of group profits or bonuses based upon services personally performed or "incident to" as long as the determination of the bonus or profit share is not directly related to the volume or value of physician referrals. "Incident to" services are defined as those services performed by ancillary personnel under supervision of a qualified Medicare provider. "Incident to" does not include medical direction of nurse anesthetists.

Phase III now defines "incident to" services to mean those services that meet the requirements of section 1861(s)(2)(A) of the Social Security Act, the "incident to" billing rule in §410.26, and the relevant manual provisions,"[5] thus allowing a productivity bonus for supplies, including drugs, as long as they qualify and are billed on an "incident to" basis. For example, pain physicians in a group practice may receive a productivity bonus for supplies (including drugs), assuming that they properly qualify and are billed on an "incident to" basis. Note that "incident to" services cannot be billed in a hospital setting.

The "Stand in the Shoes" Provision Converts Indirect Compensation to Direct

Physician practices have used their medical groups as an intermediary to accept payments from a DHS to individual physicians and remain in compliance with Stark regulation. Previously if a health entity had a financial relationship with a physician's medical practice, this was not regarded as a direct compensation arrangement with the individual physician. Rather, if there were a chain of financial relationships involving at least one additional entity interposed between the physician and the health entity, it was considered a potential indirect compensation agreement. This may no longer be valid; instead, a new test is used in analyzing financial relationships.

Phase III introduced a new definition ("stand in the shoes") of their "physician organization" in analyzing financial relationships. Under section §411.354, "a physician is deemed to 'stand in the shoes' of his or her own physician organization." If the only intervening entity between the physician and the DHS is the "physician organization," the financial relationships that were indirect may now be considered direct. In the case of an anesthesiology group, an office lease between the hospital and the anesthesiology group now must comply with the lease exception, rather than rely upon the indirect compensation exception. Moreover, when a medical director agreement exists between the hospital and the anesthesiology group, it must comply with the personal services or FMV exception. In the case of academic medical centers, the academic medical center exemption may apply. Fortunately CMS does not require change to any current indirect compensation arrangements entered into prior to September 5, 2007.[7] They may remain in effect during the original term or the current renewal term.

Academic Medical Center (AMC)

AMCs may face additional regulatory burden under Phase III. There are three principal changes effecting AMCs: first, compensation from each academic medical center need not separately satisfy an FMV test, but the compensation paid to all AMC components must be applied on an aggregate (medical school and faculty practice plans); second, in determining whether the majority of its medical staff are faculty members, the hospital may include or exclude certain types of privileges (e.g., courtesy), but the criteria must be uniform; and lastly, compensation between AMC components and faculty members may not take into account referrals or other business generated for any AMC component.

Physician Recruitment

Hospitals frequently provide recruitment support to anesthesiology groups. Under Stark Phase II, payments made by hospitals intended to induce physicians to relocate their medical practice to the geographic areas served by the hospital in order to become a member of the medical staff are permitted. Phase III now requires that the recruited physician move the practice from outside the geographic service area to a location inside the service area of at least 25 miles or utilize a more complex calculation of how the physician's revenues are derived.[8] More liberal allowances are made for rural hospitals. Payments made to an existing physician group for recruitment continue to be protected if the hospital payments take into account only the incremental costs associated with the recruited physician. Phase III now recognizes medical groups' imposition on noncompete clauses and other practice restrictions for group members as long as they are "reasonable."[8] CMS notes that state law may be an important source of guidance in this area.

Retention Payments in Underserved Areas

Hospitals have made "retention payments" to induce anesthesiologists to continue to practice in a particular area, particularly when the anesthesiologist was being recruited by

another hospital. Currently payments from a hospital to a physician with the intention to retain the physician in the facility service area are permitted in underserved areas. Phase III expands the criteria of an underserved area to be met if at least 75 percent of the physician's patients reside in a "medically underserved area" or are members of a medically underserved population.[9] In addition, Phase III permits retention payments to be made to physicians in the absence of a written recruitment offer from a competing location as long as the offer is *bona fide* under certain constraints.[6]

Professional Courtesy

In the past, CMS required that DHS entities notify the applicable insurer when there was a reduction of the coinsurance obligation (professional courtesy) to physicians or their immediate family members. Phase III has deleted this requirement that the DHS entity notify an insurer when the professional courtesy was extended. In addition, CMS clarified this ruling, noting that it only applies to entities with formal medical staffs (hospitals) with written professional courtesy policy approved by the governing body.[10] Physician-to-physician professional courtesy is unlikely to be prohibited unless the recipient physician is a source of DHS referrals to the physician extending the courtesy.[10]

Conclusion

The Phase III regulations further implement the federal physician self-referral statute (Stark Law). While the provision provided some changes to the actual text of the Stark Law and the commentary provided significant clarification statements by CMS, it also provided insight into the way enforcement authorities may interpret the statute.

References:

1. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51012-51099 (September 5, 2007) (to be codified at 42 CFR Parts 411 and 424).
2. Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B payment Policies for CY 2008, 72 *Federal Register*, 38122-38395 (July 12, 2007)
3. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51021 (September 5, 2007).
4. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51015 (September 5, 2007).
5. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51016 (September 5, 2007).
6. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51057 (September 5, 2007).
7. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51087 (September 5, 2007).
8. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51048 (September 5, 2007).
9. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51096 (September 5, 2007).
10. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 *Federal Register*, 51064 (September 5, 2007).