Stark III self-referral prohibitions
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The U.S. Centers for Medicare & Medicaid Services (CMS) have announced, and presented for comment, the third phase of its regulations against physician “self-referral.” The Stark self-referral regulation, as it is commonly known (formally, the Medicare Program: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships regulation or Section 1877 of the Social Security Act) prohibits physicians from referring Medicare patients for certain designated health services (DHS) to an entity with which the physician or a member of the physician’s immediate family has a financial relationship—unless an exception applies. Although the modifications have drawn a fair amount of coverage in the health care press, the “Stark III” regulations provide no new “safe harbor” exceptions and make no significant changes related to the practice of optometry. In most cases, optometrists will simply need to review their existing business arrangements to ensure compliance with the third edition of the rules. However, it is always a good idea for health care providers to pause and make sure they have a clear understanding of the federal regulations that prohibit them from profiting by their patient referrals.

The proposed Stark III self-referral prohibitions will mean few (if any) changes in most optometric practices. However, it is always good for optometrists, like other health care practitioners, to be mindful of the federal regulations that prohibit them from profiting by their patient referrals. Although the final version of the rule could reflect some changes based on public comment, it is generally expected to be finalized pretty much as originally published. The proposed rule builds on an interim Phase II version of the self-referral prohibitions released in 2004. Most provisions of existing contacts that are compliant with existing Phase II rules are “grandfathered” until the end of the contract term (see Section 3 of this article for 1 exception). Although many of the self-referral prohibitions are targeted primarily at hospitals or surgical procedures, it is important for optometrists to be familiar with the regulation and understand the portions that pertain to eye and vision care practice.

The regulation further refines and implements federal legislation sponsored by Rep. Fortney “Pete” Stark (D-CA), which prohibits health care practitioners, who provide services under Medicare or Medicaid, from referring patients to any entity in which they have a financial interest. The regulation bars referrals from practitioners to an entity in which they (or an immediate family member) have an ownership interest when the entity performs ancillary or other designated health care services, such as outpatient or inpatient treatment, or sells products such as medical equipment or nutritional supplies. For example, Stark prohibits a health care provider from referring a patient to a surgical center if the provider is a part owner in the center. It also bars referral fees, sometimes known as “fee-splitting” arrangements, under which a surgeon agrees to provide a predetermined portion of a global surgical fee to the referring primary care provider. However, the rule allows exceptions (or “safe harbors”) for transactions in 3 broad classes (exemptions for specific services and products, transactions in which income is not distributed based on the volume or value of referrals, and transactions in which services or products are reimbursed in ways that the CMS has determined are unlikely to improperly enrich the physician or to encourage unnecessary or fraudulent claims). The Stark regulations specifically provide a safe harbor exemption for eyeglasses and contact lenses, meaning eye care practitioners can refer patients to their own optical dispensaries for postcataract eyeglasses or contact lenses without violating the self-referral prohibitions. It also provides an exception for services personally performed by the physician who “refers” the patient for those services. Most of the Stark provisions specifically relevant to optometry appear to have been included in the first 2 editions of the regulation.
All of the provisions proposed last month as part of the third phase of the regulation are subject to further change after the CMS receives public comment and finalizes the rule. The scope of some exceptions could be limited further or even removed. Few are likely to have any significant impact on day-to-day optometric practice in most offices. The following is a short list of the most significant proposed changes that, in some cases, could affect optometrists:

1. **Narrowing of the in-office ancillary services (IOAS) exception.** Under previous rules, optometrists, in most cases, could provide ancillary DHS at their own location, known as the “centralized building” exception. The CMS solicited and is considering comments on how to limit the IOAS exception so as to curtail perceived abuses. In particular, the CMS notes, with disapproval, that there is often little interaction between the provider who treats patients and the staff who furnish the ancillary services, often in a “separate” location (e.g., laboratory/ dispensary). The CMS requested comments on: (1) whether certain services should not qualify for the IOAS exception (especially those services not needed at the time of the office visit to assist the provider in diagnosis or treatment), (2) whether (and, if so, how) the CMS should make changes to “centralized building” definitions, (3) any other restrictions on the ownership or investment in services that would curtail program or patient abuse. Please note that although this provision has the potential to affect optometric practices with respect to Medicare, it is highly unlikely that the provision allowing postcataract eyeglasses will, in fact, be removed or amended as an exception, as it is not one of the ancillary services that has been the object of abuse and the resulting higher level of scrutiny.

2. **Prohibiting percentage compensation arrangements (other than for professional services personally performed by the optometrist).** The proposed rule would prohibit percentage-based compensation not involving revenues directly resulting from personally performed optometric services in many types of contracts beyond personal services. This would include contacts for management services as well as space and equipment leases.

3. **Requiring a DHS entity to “stand in the shoes” of its subsidiaries.** The CMS proposes that it would treat a DHS entity that owns or controls an entity (i.e., its subsidiary) to which an optometrist refers patients for DHS as “standing in the shoes” of its subsidiary, meaning the analysis looks on the parent entity as if it is one and the same as the subsidiary by ignoring the legal structures of different corporate (or other business organizational) entities (e.g., an optometrist refers a patient to a laser surgery center in which the optometrist is part owner).* As a result, whereas current arrangements with a subsidiary often allow the parties to comply with the Stark Law through the use of an indirect compensation analysis, the proposed rule would likely turn many of these relationships into direct compensation arrangements that would have to satisfy the more stringent direct compensation exceptions. The CMS did not propose specific regulatory language but did solicit comments on how to implement this proposal. The CMS also states that the “stand in the shoes” analysis is likely to be implemented in the Phase III regulations with regard to optometrists standing in the shoes of their group practices. Many optometrists will not be affected by this, but clearly some will. (This requirement will be delayed 1 year, taking effect December 4, 2008.)

4. **Alternative criteria for satisfying certain exceptions.** The finalized rule may provide additional flexibility in 1 other area of the Stark regulations. Specifically, the proposed rule asks for comments on creating an alternative method for complying with certain Stark regulations when there has been a technical failure to satisfy a minor procedural criterion, e.g., an inadvertent failure to obtain the required signature on the mandatory written agreement. The standards the CMS suggests for the alternative methodology, however, are very narrow and stringent. The CMS has indicated that, if this amendment were adopted, a number of requirements would be imposed, including (a) the parties self-disclose the violation to the CMS, (b) the CMS determines that the arrangement otherwise satisfied all the relevant requirements, (c) the violation was inadvertent, (d) the parties did not have knowledge of the violation at the time of the referral or the resulting claim, (e) the arrangement did not pose a risk of program or patient abuse, (f) no more than a set amount of time had passed since the time of the original noncompliance, and (g) the arrangement at issue is not the subject of an ongoing federal investigation, enforcement action, or other proceeding. The CMS also noted there would be no appeal or review of a decision to allow the alternative method of compliance and that the CMS would have sole discretion as to whether to make such a determination in the first place (i.e., the parties have no right to receive a determination, and there is no time limit on the CMS’s response).

*The Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS) in October issued an opinion holding that an optometrist could be sanctioned for kickback violations if that optometrist holds an interest in an ambulatory surgical center (ASC), such as a laser center, which provides eye care. (See “HHS-OIG: ODs cannot own eye care ASCs,” AOA News, November 12, 2007. Optometry: Journal of the American Optometric Association will provide an update on this issue in a future “Legal Issues” column.)
5. **Burden of proof on the DHS entity.** The proposed rule would formally incorporate the current CMS policy into the regulations, confirming that, in an administrative proceeding, the entity that submitted a claim that has been denied bears the burden of proving that a violation of the Stark Law did not occur.

6. **Period of disallowance.** The CMS solicited comments on how to define the period of disallowance (e.g., the period during which parties are prohibited from billing Medicare or Medicaid) when there has been a Stark Law violation. The CMS asked for comments on: (1) whether they should use a case-by-case approach or deem certain types of improper financial arrangements to continue for a specified period of time, (2) whether the period of disallowance should terminate when the parties pay back the value of the improper consideration, and (3) whether there should be an additional period of disqualification during which a provider would be prohibited from using an exception once an arrangement fails to satisfy that exception.

The AOA Office of Counsel also notes that although the publication of the Phase III regulation technically ends the current rule-making process for the Stark self-referral prohibitions, the CMS could propose additional self-referral regulations in the future as part of annual Medicare rule changes. The final rule will be accessible on the CMS Web site at [www.cms.hhs.gov/PhysicianSelfReferral](http://www.cms.hhs.gov/PhysicianSelfReferral).