PUBLICATION

Stark Regulations: Proposed Physician-owned Hospitals Provisions [Ober|Kaler]

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In the proposed Physician Fee Schedule for 2016 [PDF], CMS recommends amending several requirements related to the physician-owned hospital and rural provider exceptions to the Stark law.

As discussed more fully below, CMS proposes to clarify the disclosure requirements for public websites and advertisements for physician-owned hospitals. CMS also proposes certain changes in the manner in which hospitals determine their *bona fide* physician investment level as of March 23, 2010. Overall, these proposals appear designed to provide hospitals with additional flexibility under the physician-owned hospital requirements.

The Affordable Care Act included a number of restrictions and requirements to which physician-owned hospitals must conform in order to continue to avail themselves of the physician-owned hospital and rural provider exceptions. Under one such requirement, physician-owned hospitals must disclose the fact of their physician ownership or investment on any "public website for the hospital" or "public advertising for the hospital." CMS states in the proposed PFS for 2016 that, since the public website and advertising disclosure requirements went into effect on September 23, 2011, it has received a number of inquiries from industry stakeholders and Self-referral Disclosure Protocol (SRDP) submissions seeking guidance on the requirements.

To provide more certainty concerning the forms of communication that require a disclosure, CMS proposes to publish examples of websites that are not considered to be public websites for purposes of the exception, including websites operated by social media outlets on which the hospital may post communications. CMS believes that such websites do not constitute public websites for the hospital" because they are operated by social media or networking services and because a crowd of other users may also become members. Additionally, CMS proposes to identify, by way of example, electronic patient payment portals, electronic patient care portals, and electronic health information exchanges as other websites that do not constitute public websites because they are maintained for the convenience of patients who would likely have already been notified of the hospital's ownership structure. CMS is careful to note that even though a particular site may not be a public website for the hospital, depending on the facts and circumstances, the content on the website may nonetheless qualify as public advertising for the hospital which would require the appropriate disclosure. CMS seeks comments about whether the proposed examples are appropriate, whether different or additional examples should be provided, or whether, instead of the list of examples of websites that are not public websites for the hospital, CMS should provide an inclusive definition of what is considered a public website for the hospital.

Second, CMS proposes to amend its regulations relating to required disclosures for public advertising so they more closely conform to the statutory language by including the phrase *for the hospital* when the regulations reference public advertising. CMS proposes to define *public advertising for the hospital* as "any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital." The definition would exclude, for example, staff recruitment communications, and public service announcements and community outreach issued by the hospital that have a primary purpose of providing public health-related information. CMS reiterated its inability under the statute to exclude certain types of advertising media from the ownership disclosure requirement (i.e., billboard advertising, radio communications) and, instead, proposes that the test is based on a facts and circumstances analysis of the communication.

Third, CMS proposes to specify that it will deem "any language that would put a reasonable person on notice that the hospital may be physician-owned" to be a sufficient statement of physician ownership or investment. CMS provides examples of phrases and even hospital names that would qualify as a sufficient statement of physician ownership or interest. CMS confirms that the statement must be conspicuously located on a web page that is commonly visited by current or potential patients. Rather than specifying a specific font size or location for the statement, CMS merely states that the disclosure statement must be displayed in "a clear and readable manner and in a size that is generally consistent with other text on the website." The clarifications and proposals appear to provide physician-owned hospitals with significant latitude in the format of the disclosure, provided that the disclosure statement is conspicuous and reasonable. CMS seeks comments regarding the proposed examples of language that would satisfy the required disclosures, including alternative standards that could be implemented to deem language sufficient to meet the requirements.

CMS also confirms that submitting disclosures to the SRDP is the appropriate way to address any failure to satisfy these requirements. The earliest possible starting point for the period of noncompliance with both the public website disclosure requirement and the public advertising requirement is September 23, 2011. CMS also proposes to clarify how to calculate the period of noncompliance for both requirements. For the "public website for the hospital" disclosure, CMS notes that the period of noncompliance is simply "the period during which the physician-owned hospital failed to satisfy the requirement" with the earliest possible start date being September 23, 2011. For the "public advertising for the hospital" disclosure, CMS clarifies that the period of noncompliance is "the duration of the applicable advertisement's predetermined initial circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date." CMS seeks comments as to whether additional guidance related to the periods of nondisclosure is necessary.

In addition, CMS proposes significant changes regarding how to determine the *bona fide* investment level. CMS reconsidered its position regarding the exclusion of the ownership or investment interests of non-referring physicians in the *bona fide* investment level. Commentary from industry stakeholders convinced CMS that excluding non-referring and retired physicians from the calculation of ownership interests is overly limiting. Moving forward, CMS proposes to revise its policy to require that the "baseline *bona fide* investment levels and *bona fide* investment levels include direct and indirect ownership and investment interests held by a physician" regardless of whether he or she refers patients to the physician-owned hospital. CMS seeks comment about whether its proposal will reduce the difficulties some physician-owned hospitals face when determining whether a particular physician refers or does not refer in order to establish their baseline *bona fide* investment levels and *bona fide* investment levels.

To support its proposal, CMS seeks to define *ownership or investment* interest, only for 42 C.F.R. § 411.362(a), as "a direct or indirect ownership or investment interest in a hospital." CMS seeks comment on this proposed revision and on alternate ideas that would support public policy but also effectuate the statutory purpose. CMS wonders whether it should remove references to "referring physician" altogether from 42 C.F.R. § 411.354, or whether that phrase need be retained for specific provisions. CMS also proposes delaying the effective date of the final regulations for some period of time to provide physician-owned hospitals time to comply with the new interpretation. CMS suggested delaying the effective date of the changes one year from the date the final regulatory changes are published in the Federal Register, but seeks comments on the exact period of delay.

Finally, CMS seeks comment regarding the overall impact these changes would have on physician-owned hospitals and the specific measures and actions that such hospitals would need to take to become compliant with the proposed revisions.

This article is part of Ober|Kaler's client alert "CMS Drives Change in Quality, Physician Payment, and Stark in Proposed 2016 Physician Fee Schedule." View other installments of the alert at these links:

- Changes Are Afoot for Quality Measures and Physician Payment Provisions
- Stark Regulations: Proposed Physician Recruitment Provisions
- Stark Regulations: Proposed Physician-owned Hospitals Provisions
- Stark Regulations: Technical Revisions
- Proposed 2016 Physician Fee Schedule Would Impact Medicare Shared Savings Program