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CMS PROPOSES STARK LAW CHANGES LIBERALIZING 'STAND IN THE SHOES' RULES

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KUTAK ROCK LLP

THE OMAHA BUILDING
1650 FARNAM STREET

OMAHA, NEBRASKA 68102-2186

402-346-6000
FACSIMILE 402-346-1148

www.kutakrock.com

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CMS Proposes Stark Law Changes Liberalizing "Stand In the Shoes" Rules and Addressing Disqualification Period for Noncompliant Arrangements; Solicits Comments on Stark Law Implications of Gainsharing and Physician Owned Medical Device Companies and Proposes Information Reporting Requirement for 500 Hospitals

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Executive Summary

CMS has issued a Proposed Rule that proposes changes to several Stark Law regulations and solicits comments on its recommendations. The proposed changes include the following:

- Two alternative proposals to liberalize the "stand in the shoes" attribution rule under which financial arrangements of physician organizations are attributed to their physicians. Under one proposal, the rule would not apply if the physician was not an owner of the physician organization and the physician's employment or independent contractor arrangement with the organization met the requirements of a specified exception. Under the other proposal, CMS would identify certain nonabusive arrangements that would be excluded from the "stand in the shoes" rule, such as certain mission support payments. In addition, CMS proposed to treat an entity as "standing in the shoes" of its wholly owned subsidiary.

- Clarification of maximum time periods for when a non-excepted financial relationship between a physician and an entity would restrict referrals from the physician to the entity. For example, under the proposal, if the non-excepted relationship involved excessive payment to the physician, referrals would no longer be restricted once the physician has repaid the excess, with interest. However, certain types of arrangements would be evaluated on a facts-and-circumstances basis.

The Proposed Rule also notes that changes to the Stark Law regulations proposed last year that would limit percentage-based compensation to physicians could adversely impact some "gainsharing" arrangements, and solicits comments as to how nonabusive "gainsharing" arrangements might be protected if the limitations on percentage-based compensation go into effect. In addition, the Proposed Rule solicits comments on physician ownership of implant and other medical device companies.

Finally, the Proposed Rule solicits comments on a reporting requirement under which hospitals would be required to report their financial relationships (i.e., ownership or investment interests and/or compensation arrangements) with physicians through an information request that initially would be sent to 500 hospitals. As further discussed below, CMS intends to use the reported information, among other things, to analyze hospitals and physicians' compliance with the Stark Law.

Discussion

On April 14, 2008, the Centers for Medicare & Medicaid Services ("CMS") made available a proposed rule titled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians" (the "Proposed Rule"). The Proposed Rule, which will be published in the Federal Register April 30, 2008, does not make any current changes to the regulations under the Ethics in Patient Referrals Act, 42 U.S.C. Section 1395nn (commonly known as the "Stark Law"), but discusses, and solicits comments regarding, several changes currently under consideration by CMS. Comments on these and other proposed changes must be submitted on or prior to June 13, 2008. Topics addressed include:

- the "stand in the shoes" attribution rules;
- "gainsharing" arrangements;
- the issue of for how physician long a physician is disqualified from making designated health services referrals to an entity when there has been a non-excepted financial relationship; and
- physician-owned implant and other medical device companies.

"Stand in the Shoes". The "stand in the shoes" rule was implemented in 2007 in the Phase III Stark Law regulations. Under this rule, a financial relationship between an entity providing designated health services ("DHS") and a "physician organization" (i.e., a wholly owned PC, group practice or other physician practice) is attributed to the organization's physicians (whether owners, employees, or independent contractors). CMS subsequently delayed until December 4, 2008 the application of this rule to compensation arrangements between a faculty practice plan and another component of the same academic medical center and between an affiliated DHS entity and an affiliated physician practice in the same integrated section 501(c)(3) health care system, recognizing that its application could prevent support payments that are common in those settings.

Physician Organization Stand in the Shoes Proposals. The Proposed Rule proposes two alternative modifications to the physician organization "stand in the shoes" rule and solicits comments on each proposal, as well as on other possible approaches.

Under the first proposal, a physician would be deemed not to "stand in the shoes" of his or physician organization if the physician is not an owner of the physician organization and the compensation arrangement between the physician organization and the physician satisfies the requirements of any of the Stark law regulatory exceptions for bona fide employment relationships, personal service arrangements, or fair market value compensation. (CMS solicits comments on whether a nominal physician owner of a "captive PC" who has no right to profits, a structure used in some states to meet corporate practice requirements, should not be treated as an owner for this purpose.) In addition, a physician would not "stand in the shoes" of his or her physician organization when the academic medical center exception applies. Indirect compensation arrangements with physicians no longer "standing in the shoes" of their physician organizations would be analyzed under the existing indirect financial arrangement rules.

> *Example*: Suppose a hospital has a below-market lease with a practice owned by a physician who employs a second physician for a flat, fair market value salary. Currently, the Stark referral prohibition would apply to both physicians. Under the first proposal, only the owner would "stand in the shoes" of the practice and be subject to the referral prohibition.

This approach would generally protect a non-financial relationship between a hospital and an affiliated entity that employs physicians, as long as the employment agreements are structured to meet the requirements of the employment exception and compensation to the employed physicians does not vary with or take into account referrals to the hospital.

Further, the "stand in the shoes" rule would not apply to compensation from a component of an academic medical center to an affiliated physician organization through a written contract limited to providing services required to satisfy the academic medical center's obligations under the Medicare graduate medical education rules.

CMS states that it is also considering, and solicits comments on, an approach under which only owners of a physician organization would "stand in the shoes" of that physician organization.

Under the second proposal, CMS would not revise the "stand in the shoes" provisions, but instead would except specified types of compensation arrangements that CMS determines do not pose a risk of program or patient abuse. If this approach is taken, it is likely that there would be an exception applying to mission support payments in "integrated health care delivery systems." CMS solicits comments about this proposal that "identify with specificity the types of compensation agreements that should be permitted". It also solicits comments regarding the definition of "integrated health care delivery systems," and discusses some possible approaches.

Entity Stand in the Shoes Proposals. In a proposed rule published on July 12, 2007 (the "July 2007 Proposals"), CMS proposed certain changes to the Stark Law regulations and solicited comments on other changes. The July 2007 Proposals proposed an entity "stand in the shoes" rule, providing that, where one DHS entity owns or controls another DHS entity, the first entity would "stand in the shoes" of the second. In the Proposed Rule, CMS proposed instead that a DHS entity would be deemed to "stand in the shoes" of an entity in which it has a 100% ownership interest, whether or not the owned entity provides DHS. CMS also solicited

comments as to whether it should deem a DHS entity to "stand in the shoes" of an organization that it controls.

Interplay between Physician Organization and Entity Stand in the Shoes Proposals. The Proposed Rule also proposes rules for coordinating the application of the entity and physician "stand in the shoes" rules designed to ensure that at least one compensation arrangement remains between the DHS entity and the referring physician.

The Proposed Rule would also clarify that a physician is considered the same as a PC of which he or she is the sole owner. CMS expressed concern that its current guidance that a physician "stands in the shoes" of his or her wholly-owned PC might be misconstrued as not requiring a physician who practices in a physician organization through a PC to "stand in the shoes" of the physician organization, as intended.

Period of Disallowance. In the July 2007 Proposals, CMS solicited comments regarding how long a noncompliant relationship should cause referrals from the physician to the entity to be disqualified. In the Proposed Rule, CMS proposed the following maximum disqualification periods:

- Where the noncompliance is not related to compensation (for example, a signature is missing or an agreement is not in writing), the period of disallowance would end no later than the date the arrangement was brought into compliance (for example, by obtaining a missing signature or executing a written agreement).

- Where the noncompliance is related to the payment or receipt of excess compensation, the period of disallowance would end no later than the date the excess compensation (including interest, as appropriate) is returned and all other requirements of the applicable exception are met.

- Where the noncompliance is related to the payment or receipt of insufficient compensation, the period of disallowance would end no later than the date the shortfall (that is, the amount, including interest, as appropriate, necessary to bring the arrangement into compliance from the date of its inception) was paid to the party to which it is owed and all other requirements of the applicable exception are met.

CMS did not explain when interest would or would not be "appropriate".

In light of this guidance, DHS entities should seek to include contractual language in arrangements with physicians in a position to refer that would obligate those physicians to make to the DHS entity any payments that are determined to be necessary to correct the arrangement if it is determined to be non-fair market value for Stark Law purposes.

CMS did not propose a prescribed period of disallowance for arrangements that are noncompliant for reasons that are related to compensation but which do not involve only the payment or receipt of excess compensation or a shortfall in compensation paid or received. Rather, the appropriate period of disallowance for such arrangements would need to be

determined on a case-by-case basis. In addition, CMS declined to propose that the parties to a noncompliant financial relationship would be prohibited for some period of time thereafter from using a particular exception (e.g., the exception most closely applicable to the noncompliant relationship), as considered in the July 2007 Proposals, but may revisit this issue.

Gainsharing Arrangements. In the July 2007 Proposals, CMS proposed requiring that percentage-based compensation arrangements be used only for paying for personally performed physician services and that such arrangements must be based on the revenues directly resulting from the physician services. In the Proposed Rule, CMS noted that this proposal, which it said was "under active consideration," would prevent typical gainsharing arrangements between physicians and hospitals to which they refer for DHS. However, CMS is considering whether to issue an exception specific to gainsharing arrangements, and solicited comments as to whether to establish an exception for gainsharing arrangements, and, if so, what safeguards should be included in the exception.

Physician-Owned Implant and Other Medical Device Companies. In the Proposed Rule, CMS noted the possibility that overutilization, substandard care, and increased program costs may arise from physician ownership of implant and other medical device companies. While noting that in many circumstances such arrangements will result in a non-excepted indirect financial arrangement, CMS solicited comments "as to whether our physician self-referral rules should address POCs [physician-owned companies] and similar physician-owned companies more specifically, or whether the concerns surrounding POCs and similar organizations, to the extent that they are not addressed by the statute and our current rules, are better addressed through enforcement of the False Claims Act, the anti-kickback statute and similar fraud and abuse laws, other public laws, and through other applicable Federal, State, and local regulations."

Reporting Proposals. In addition to the Stark Law proposals discussed above, the Proposed Rule also solicits comments on a proposal that would require hospitals (including but not limited to specialty hospitals) to report information concerning their financial relationships (i.e., certain ownership or investment interests and/or certain compensation arrangements as further explained below) with physicians through use of an information collection instrument created by CMS known as the "Disclosure of Financial Relationships Report" ("DFRR"). According to CMS, the information collected as a result of the DFRR instrument will be used to analyze hospitals and physicians' compliance with the Stark Law and to assist CMS in future rulemaking (e.g., possibly in the rulemaking that finalizes the July 2007 Proposals).

CMS intends to initiate its DFRR reporting process by requiring 500 hospitals to submit the information required by the DFRR instrument. These 500 hospitals include 210 hospitals that were not involved in CMS' study of physician-owned specialty hospitals and 290 hospitals that were involved in that study but did not respond to a similar voluntary collection instrument during that study.

The draft DFRR instrument requires hospitals to provide information concerning both physicians' ownership or investment interests in the hospital and physicians' compensation arrangements with the hospital. The draft DFRR requires hospitals to indicate whether they are physician-owned and, if so, to report, among other things, the following information: the class

and amount of stock, and the direct or indirect ownership percentage, held by each physician investor; payments made by each physician-investor based on his or her direct or indirect ownership interest (e.g., initial investments, assessments, capital calls and loan guarantees); physician-investor distributions; and whether the physician-investor's risk of loss or liability is limited or eliminated by an agreement or other understanding (e.g., a stop-loss agreement, a back-up guarantee, or disproportionate guarantee by a physician investor). The draft DFRR also requires hospitals to report certain information concerning the following compensation arrangements with physicians: office space rental arrangements; equipment rental arrangements; personal service arrangements; physician recruitment arrangements; isolated transactions (e.g., one-time sale of property or sale of a practice); non-DHS related compensation arrangements; payment-by-physician arrangements; physician-hospital charitable donation arrangements; and non-monetary compensation arrangements and/or medical staff incident benefits granted to a physician that exceed published limits.

Currently, CMS is proposing a deadline to complete the DFRR instrument of 60 days from the date that appears on the cover letter or email transmission of the DFRR instrument. CMS notes that it is authorized to impose civil monetary penalties of up to $10,000 for each day beyond the deadline, but that it will work with entities to facilitate their compliance with the reporting requirements. CMS also notes that hospitals may receive an extension of time to submit the requested information upon a showing of good cause.

In the Proposed Rule, CMS solicits comments on the following topics with respect to the DFRR reporting process:

- Whether the collection effort should be recurring, and, if so, whether it should be implemented on an annual or some other periodic basis;
- Whether CMS is collecting too much or not enough information, and whether CMS is collecting the correct (or incorrect) type of information;
- The amount of time and costs associated with completion of the DFRR;
- The amount of time CMS should give hospitals to complete and submit the DFRR;
- Whether CMS should direct the DFRR instrument to all hospitals, and, if so, whether CMS should stagger the collection so that only a certain number of hospitals are subject to it in any given year; and
- Whether hospitals, once having completed the DFRR, should have to send in yearly updates and report only changed information.

Hospitals and physicians and other providers implicated by the Stark Law should consider submitting comments on the topics set forth above with respect to the DFRR reporting process. Additionally, hospitals and physicians should review the DFRR instrument, evaluate their contractual management procedures to ensure they can adequately and timely respond to

the DFRR instrument and evaluate their financial relationships to ensure that they comply with the Stark Law.

Questions regarding this memorandum may be directed to any of the following, or to the member of the firm who handles your health care matters:

Jennifer Brown
jennifer.brown@kutakrock.com
(479) 695-1932

Robert Cohen
robert.cohen@kutakrock.com
(402) 231-8738

Bryan Looney
bryan.looney@kutakrock.com
479-695-1953

Chris Phillips
chris.phillips@kutakrock.com
(402) 231-8787