Health Law Alert

HALL RENDER KILLIAN HEATH & LYMAN

July 9, 2007

Hall, Render, Killian, Heath & Lyman is a full service health law firm with offices in Indiana, Kentucky, Michigan and Wisconsin. Since the firm was founded by William S. Hall in 1967, Hall Render has focused its practice primarily in the area of health law and is now recognized as one of the nation's preeminent health law firms serving clients in multiple states. For more information about the law firm please visit us at www.hallrender.com.

Office Locations

Indiana Offices

Downtown
One American Square
Suite 2000
Indianapolis, IN 46282
(317) 633-4884
Contact: Susan Bizzell

North Office
8402 Harcourt Road
Suite 820
Indianapolis, IN 46260
(317) 871-6222
Contact: Jim Willey

Kentucky Office
614 West Main Street
Suite 4000
Louisville, KY 40202
(502) 568-1890
Contact: Rene Savarise

Michigan Office
Columbia Center, Suite 315
201 West Big Beaver Road
Troy, MI 48084
(248) 740-7505
Contact: Michael Philbrick

Wisconsin Office
111 East Kilbourn Avenue
Suite 1300
Milwaukee, WI 53202
(414) 721-0442
Contact: Dave Snow

Contact Us
hallrender@hallrender.com

2008 Medicare Physician Fee Schedule: Summary of Proposed Stark Law Changes

On July 2, 2007, the Centers for Medicare & Medicaid Services ("CMS") posted on its website its proposed revisions to the Medicare Physician Fee Schedule for 2008. Last week we issued a Health Law Alert about a change to the Stark Law regulations proposed by CMS in such posted document that, if finalized, would have an impact on certain under arrangements relationships between physicians and entities that furnish designated health services (DHS). CMS included a number of additional proposed changes to the Stark Law regulations, and solicited comments on other changes CMS is considering related to such regulations.

The expected publication date in the Federal Register is July 12, 2007. In the meantime, the display copy is available online at: http://www.cms.hhs.gov/physicianfeesched/downloads/CMS-1385-P.pdf?agree=yes&next=Accept. Below is a summary of proposals and requests for comments to the Stark regulations.

Restrictions on Unit-of Service (Per Click) Payments in Space and Equipment Leases. Current Stark regulations permit time-based or unit-of-service based payments ("Per-Click Payments") in space and equipment leases, even when the physician receiving the Per-Click Payment is the source of the referral for DHS using the space or equipment that has generated the Per-Click Payment.

CMS has expressed renewed concerns with Per-Click lease arrangements where the physician is "rewarded" for each referral she makes. CMS views such arrangements as potentially leading to overutililtzation of services and other "program abuses." Consequently, CMS proposes to revise the Stark regulations so that space and equipment leases may not provide for Per-Click Payments to a physician lessor for services that utilize the leased space or equipment rendered by the DHS entity lessee to patients who are referred by a physician lessor. CMS also requests public comments as to whether it should prohibit Per-Click Payments to a DHS entity lessor that leases space or equipment to a physician lessee.

Set-in-Advance and Percentage-Based Compensation Arrangements. CMS proposes "to clarify that percentage compensation arrangements: (1) may be used only to pay for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided)." *(Emphasis added.)*

Changes to Reassignment and Physician Self-Referral Rules Relating to Diagnostic Tests (Anti-Markup Provision). In the 2007 Physician Fee Schedule, CMS expressed its concern that the existing purchased diagnostic test (anti-markup) and purchased interpretation requirements had created confusion where a formal reassignment of billing had occurred. CMS also noted its concern with certain arrangements that permit physician group practices to bill for services furnished by a contractor physician in a "centralized building" and those that allow group practices to purchase or otherwise contract for diagnostic testing services and realize a profit when billing Medicare for such services.

CMS now proposes an anti-markup restriction on both the professional and technical components of diagnostic tests. Under this proposal, a purchasing group would be prohibited from charging Medicare more than its actual “net charge” to purchase the professional component (interpretation) even with a formal reassignment of benefits. "Net charge" would be defined to exclude any amount that takes into consideration the cost of equipment or space that is leased to the performing supplier.

Similar restrictions would apply to the technical component of diagnostic tests when the test supplier is not a full-time employee of the billing entity. CMS proposes that these anti-markup provisions would apply to the technical component of diagnostic services performed in centralized buildings and seeks comments as to whether such provisions should exist, and how to effect such provisions. At this time, CMS does not propose to amend the definition of "centralized building" but may address this definition at a later time. The anti-markup provisions would not apply to independent labs that have not ordered the diagnostic test.

Burden of Proof Where a Claim is Denied Based on a Prohibited Referral. CMS proposes to clarify existing regulations to provide that in any appeal of a denial of payment for DHS because the service was furnished pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral. In other words, the burden of proof is not on CMS or its contractors to show that the service was not furnished pursuant to a prohibited referral, but rather is on the billing provider (i.e., hospital, physician group or physician).

Services Furnished "Under Arrangements". (This information regarding "under arrangements" services was included in our Health Law Alert last week, and is repeated here for convenience.) CMS proposes to revise the definition of "entity" in the Stark Law regulations to include both the entity that submits the claim to Medicare for the DHS and the entity that performs the DHS (i.e., the under arrangements services provider). CMS continues to believe that there is a high risk of overutilization and increased program costs associated with services provided under arrangements by certain hospital/physician joint ventures, including imaging joint ventures. CMS goes so far as to state its belief that that "[t]here appears to be no legitimate reason for [joint venture under arrangement services] other than to allow referring physicians an opportunity to make money on referrals for separately payable services."

If the proposed change is finalized in its current form, then it is likely to require restructuring or unwinding of under arrangements joint ventures in which the supplier of services is at least partially owned by physicians who refer to the hospital. However, until CMS clarifies when a person or entity is deemed to have "performed" a designated health service, it is unknown to what extent, if any, the proposed change would impact other arrangements, such as management contracts of provider-based departments.

Providers that have entered, or are considering entering, into an under arrangements services agreement should be aware that these proposed regulations, if finalized, may prohibit or otherwise necessitate the restructuring or termination of such arrangements.

Solicitation of Comments on Potential Changes to the In-Office Ancillary Services Exception. At this time, CMS has not proposed changes to the in-office ancillary services exception, but it indicates its interest in making it more restrictive. CMS believes that Congress included the exception to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. "At the time of enactment, a typical in-office ancillary services arrangement might have involved a clinical laboratory owned by physicians located on one floor of a small medical office building. Under such an arrangement, a staff member would take a urine or blood sample to the clinical laboratory, create a slide, perform the test, and obtain the results for the physician while the patient waited." CMS believes that, today, services furnished pursuant to the exception are not so closely connected to the physician practice.

For example, a group practice provides pathology services furnished in a centralized building that is not physically close to any of the group's other offices and, in some cases, the technical component of such services is furnished by laboratory technologists who are employed by an entity unrelated to the group. The professional component of the pathology services may be furnished by contractor pathologists who have virtually no relationship to the group practice. CMS states that, "[i]n sum, these types of arrangements appear to be nothing more than enterprises established for the self-referral of DHS." Even when ancillary services are furnished in the same building as the group practice's office, CMS is concerned that there may be little interaction between the physicians who are treating patients and the staff that provide the ancillary services.

CMS specifically seeks comments on: (1) whether certain services should not qualify for the exception (for example, therapy services that are not provided on an incident to basis, services that are not needed at the time of the office visit in order to assist the physician in his or her diagnosis or plan of treatment, and complex laboratory services); (2) whether, and, if so, how the definitions of "same building" and "centralized building" should be changed; (3) whether nonspecialist physicians should be able to use the exception to refer patients for specialized services involving the use of equipment owned by the nonspecialists; and (4) any other restrictions on the ownership or investment in services that would curtail program or patient abuse.

"Stand in the Shoes" Relationships. CMS proposes to amend regulations to provide that where a DHS entity owns or controls an entity to which a physician refers patients for DHS, the DHS entity would "stand in the shoes" of the entity that it owns or controls and would be deemed to have the same compensation arrangements as the entity under its ownership or control. For example, where a hospital is the sole member of a medical foundation, the hospital would stand in the shoes of the foundation, and any direct relationship between the medical foundation and physicians with which it contracts would also be a direct compensation arrangement between such physicians and the hospital. CMS finds it necessary to collapse this chain of financial relationships to prevent parties from circumventing application of the Stark Law by simply inserting an entity or contract into the chain linking a DHS entity and the referring physician. CMS indicates that it will address the issue of whether a physician stands in the shoes of his or her group practice in a separate rulemaking.

Obstetrical Malpractice Insurance Subsidies. CMS is concerned that the current obstetrical malpractice insurance subsidies exception, which applies only to practitioners engaged in obstetrical practice in a primary care health professional shortage area, is overly restrictive. CMS has received reports of patient difficulty obtaining obstetrical care in some communities in states where obstetrical malpractice premiums are high. Accordingly, CMS is interested in whether the exception would more effectively ensure beneficiary access to care, without risking Medicare program abuse, if the requirements of the exception were revised to expand its application. CMS seeks public comments on several proposed new requirements of the exception, as well as comments describing access to care problems.

Solicitation of Comments on the Period of Disallowance for Noncompliant Financial Relationships. CMS seeks public comments about how to determine the "Period of Disallowance". The Period of Disallowance refers to the period during which a physician may not refer DHS to an entity and the entity may not bill Medicare for such DHS referrals, where the Stark Law implicated a certain financial arrangement and the parties failed to meet the requirements of a relevant Stark exception. At this time, CMS does not propose to prescribe the "Period of Disallowance for various types of noncompliance, but is seeking public comments only.

Generally, CMS believes the Period of Disallowance should begin with the date that the financial relationship failed to comply with the Stark Law and regulations and should end on the date the financial relationship either ended or came into compliance. However, in some situations, it is not clear when the relationship ended; for example, when a physician pays a below fair market value lease rate, it may raise the inference that such below market rate was paid to induce referrals after the lease expires.

In light of such ambiguities, CMS seeks additional comments on whether it should:

- define the Period of Disallowance on a case by case basis or deem certain types of financial relationships to continue for some prescribed period of time;
- curtail a prescribed Period of Disallowance where the parties have repaid the prohibited compensation; and
- disqualify the parties from using a certain exception for a period of time when the parties previously relied on the exception but did not meet all of its requirements.

Alternative Criteria for Satisfying Certain Exceptions. CMS also addresses the issue of inadvertent violations of the Stark Law in which an agreement fails to satisfy certain procedural or "form" requirements of an exception (e.g., a missing signature on a lease or personal service agreement), but which is otherwise substantively in compliance with such exception. While CMS states that it has no statutory authority to waive violations of the Stark Law, it is considering whether to amend the regulations to provide an alternative method of satisfying the requirements of an exception where there has been such an inadvertent violation of the law.

CMS proposes that to demonstrate compliance with such alternate criteria, (a) the facts and circumstances must be self-disclosed by the parties to CMS, (b) CMS must determine that the arrangement otherwise satisfied all the relevant requirements except for the procedural or "form" requirement, (c) the violation must have been inadvertent (i.e., the result of an innocent or unintentional mistake), (d) the parties must not have had 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.

CMS states that there would be no appeal or review of a decision to allow the alternative method of compliance, and that parties have no right to receive such a determination by CMS. CMS is soliciting comments on whether to adopt this policy and relevant details, including whether the determination should be made pursuant to an advisory opinion. This proposed policy would complement the exception for certain arrangements involving temporary noncompliance.

Ownership or Investment Interest in Retirement Plans. CMS proposes to revise the definition of ownership and investment interests to exclude an interest in a retirement plan offered by the entity to the physician (or her immediate family members) or as a result of the physician's (or her immediate family member's) employment with the entity. The purpose of the change is to clarify that where a physician has an interest in a retirement plan offered by Entity A through the physician's (or an immediate family member's) employment with Entity A, CMS intended to except from the definition of ownership or investment interests any interest the physician would have in Entity A by virtue of her interest in the retirement plan. CMS did not intend to exclude from the definition of ownership or investment interest any interest the physician may have in Entity B through the retirement plan's purchase of an interest in Entity B.

Written comments on these proposed regulations may be submitted to CMS no later than 5:00 p.m. August 31, 2007. Comments may be mailed to Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1385-P, Post Office Box 8018, Baltimore, Maryland, 21244-8018; submitted electronically at http://www.cms.hhs.gov/eRulemaking; or by other methods listed in the proposed regulations.

If you need additional information about the proposed regulations or need assistance in preparing comments to such regulations or in the review of a proposed or existing arrangement, please contact Gregg Wallander at (317) 977-1431 or gwally@HallRender.com; Susan Bizzell at (317) 977-1453 or sbizzell@HallRender.com; Adele Merenstein at (317) 977-1469 or amerenstein@HallRender.com; or Erin Abraham at (317) 977-1470 or eabraham@HallRender.com.

This publication is intended for general information purposes only and does not and is not intended to constitute legal advice. The reader must consult with legal counsel to determine how laws or decisions discussed herein apply to the reader's specific circumstances.