VORYS *On the Horizon in* HEALTH LAW

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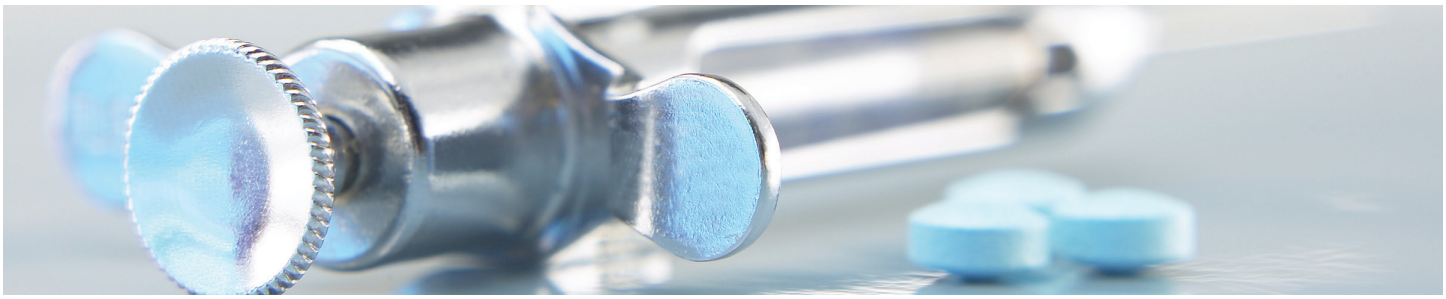

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MEDICARE AND MEDICAID

Final Medicare Anti-Markup Prohibition Takes Effect January 1, 2009

On November 19, 2008, the Centers for Medicare and Medicaid Services' (CMS) published the 2009 Medicare Physician Fee Schedule in the Federal Register (73 FR 69799-69817). This publication included the final Medicare anti-markup rule, which may reduce or eliminate the financial viability of many routine diagnostic testing arrangements. Except for the anti-markup provisions related to purchased technical components (which already existed) and pod labs (which took effect January 1, 2008), the final anti-markup became effective January 1, 2009. CMS' existing anti-markup rules are set out at 42 C.F.R. §414.50, and signal CMS' continued focus on preventing abusive diagnostic imaging arrangements.

The final rule applies to both the professional and technical components of diagnostic tests (excluding clinical diagnostic laboratory tests) that are ordered by the billing physician/supplier ("Supplier") (or by a party related by common ownership or control). In such case, if the professional or technical component is performed or supervised, by a physician that does not "share a practice" with the Supplier, the Supplier is prohibited from "marking up" the charge to Medicare for that purchased component. Instead, payment to the Supplier will be limited to the lowest of: (1) the performing/supervising physician's ("Physician") net charge to the Supplier; (2) Supplier's actual charge; or (3) the Medicare fee schedule amount.

A Physician is deemed to "share a practice" with the Supplier if either of the following two tests are met:

- Substantially All Test: The Supplier will be deemed to "share an office" with the Physician (and the anti-markup prohibition will not apply) if, at the time the Supplier submits the claim to Medicare for the purchased component, the Supplier has a reasonable belief that: (1) the Physician has furnished substantially all (e.g., at least 75%) of his/her professional services through the Supplier for the 12 months prior to and including the month the service was performed, or (2) the Physician is

expected to furnish substantially all (e.g., at least 75%) of his/her professional services through the Supplier during the following 12 months (including the month the service is performed). The Physician may be an employee or independent contractor of the Supplier.

- Site of Service Test: As determined on a case-by-case basis, the Supplier will be deemed to "share an office" with the Physician (and the anti-markup prohibition will not apply) if: (1) the Physician is an employee or independent contractor of the Supplier (or an owner of the Supplier for purposes of purchased technical components only), and (2) the purchased professional component is performed in, or the purchased technical component is conducted and supervised in, the "office of the billing physician/supplier."

We encourage all physicians, physician groups, and health care entities to re-examine their diagnostic testing arrangements in light of the final anti-markup rules. Contact your Vorys attorney for further details regarding the potential impact of the anti-markup prohibitions on your diagnostic testing arrangement.

FRAUD AND ABUSE

OIG Approves Physician Group's Proposal To Hire Part-time Employees

On December 15, 2008, the Office of Inspector General issued Advisory Opinion No. 08-22[1] in which it advised that a Group Practice[2] proposal to employ two part-time physicians to perform endoscopies on its premises would not generate payments prohibited by the federal "anti-kickback" statute.

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration either in return for or to induce referrals for, or purchases of, services, if those services will be paid for by Medicare or other federally funded health care programs. 42 U.S.C. § 1320a-7b(b). The anti-kickback statute, however, does not apply to "any amount paid by an employer to a bona fide employee for employment in the provision of covered items and services." 42 U.S.C. § 1320a-7b(b)(3)(B). The safe harbor regulations specifically provide that the term "remuneration" as used in the anti-kickback statute, does not include:

> Any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

42 C.F.R. § 1001.952(i).

The Group Practice proposed to employ two physicians on a part-time[3] basis to perform endoscopies on the Group Practice's premises. The Group Practice certified that the two part-time physicians would be its bona fide employees within the meaning of 26 U.S.C. § 3121(d)(2). The Group Practice also certified that the part-time employees would perform endoscopies, services for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs. The Group Practice further certified that the employees would be paid a salary based on the fair market value of the professional services each provided while employed by the Group Practice.

Based on these certifications, the OIG concluded that the proposed employment arrangement satisfied the criteria of the employee safe harbor contained in 42 U.S.C. § 1320a-7b(b)(3)(B) and 42 C.F.R. § 1001.952(i)[4] and, therefore, the wages paid to the part-time physician employees would not constitute prohibited remuneration under the anti-kickback statute.

OIG Advisory Opinion 08-22, while seemingly clear on its face, should be compared to and read in light of the OIG's earlier Advisory Opinion No. 08-10 issued on August 26, 2008. Indeed, while Advisory Opinion No. 08-22 concluded that in a part-time employment relationship payments made by the Group Practice to the employee physician for services furnished by the physician is not a kickback, the OIG concluded that similar payments may be considered an illegal kickback if paid to an independent contractor or for the lease of space and equipment, or in an arrangement with some combination of these factors.[5]

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[1] "OIG Advisory Opinion No. 08-22," Department of Health & Human Services, Office of the Inspector General, December 15, 2008, http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-22.pdf.

[2] The Group Practice which made the proposal to the OIG certified that it satisfied all the criteria of a group practice as set forth in 42 C.R.F. § 411.352.

[3] Each of the part-time physicians continued to operate an independent medical practice, at separate premises.

[4] The OIG specifically limited its opinion to the proposal's compliance with the employee safe harbor of the anti-kickback statute in 42 U.S.C. § 1320a-7b(b)(3)(B) and 42 C.F.R. § 1001.952(i). The OIG did not express any opinion about its compliance with the physician self-referral law contained in 42 U.S.C. § 1395nn(e)(2) and 42 C.F.R. § 411.357(c).

[5] In Advisory Opinion No. 08-10, the OIG held that a proposal between a group practice providing cancer treatment services in a free-standing facility and certain groups of area urologist groups that had made referrals to such facility could result in prohibited remuneration under the Anti-Kickback Statute. Under the proposal, the group practice would enter into a series of written agreements whereby the urologist groups would lease, on a part-time basis, the space, equipment and personnel services to perform the cancer treatments, specifically intensity-modulated radiation therapy ("IMRT"). Despite the fact that the leases and personal service agreements were compliant with relevant safe harbors contained in the anti-kickback statute, the OIG noted that the proposed arrangements were a form of impermissible "joint venture." The OIG concluded that "we are unable to exclude the possibility that the parties' contractual relationship is designed to permit the [physician group] to do indirectly what it cannot do directly; that is, pay the [urologist groups] a share of the profits from referrals." See Advisory Opinion No. 08-10.

OIG Finds Safe Harbor Inapplicable To Physician Investments In Rural Medical Practice

In an Advisory Opinion issued on December 29, 2008, the Department of Health and Human Services Office of Inspector General ("OIG") determined that a medical practice did not comply with the safe harbor for investments in group practices because one of the twenty-three physician owners only performed administrative duties and did not treat patients for the practice. See OIG Advisory Opinion 08-24 (December 29, 2008). Given that the safe harbor was not satisfied, OIG found that the proposed arrangement could implicate the anti-kickback statute if the requisite intent existed. Because the proposed arrangement was in compliance with all of the other requirements of the safe harbor for investments in group practices, however, the OIG noted that it would not impose civil monetary penalties or administrative sanctions.

Under the facts of the proposed arrangement, twenty-three physician and podiatrist investors formed a limited liability company to operate a medical practice (the "Practice") in a rural Health Professional Shortage Area ("HPSA"). The Practice provides physician consultation on a walk-in urgent care basis, as well as various clinical laboratory and diagnostic radiology services through shared office space, facilities, equipment, and personnel. The Practice's investors include twenty-two licensed physicians or podiatrists who treat patients at the Practice (although none on a full-time basis) and one licensed physician who provides administrative, but no clinical services to the Practice (holding a 1% investment interest).

The OIG addressed the applicability of the anti-kickback safe harbor for investments in group practices set forth in 42 C.F.R. § 1001.952(p) to the proposed arrangement. This safe harbor has four requirements: (1) the equity interests in the group must be held by licensed health care professionals who practice in the group; (2) the equity interests must be in the group itself, and not some subdivision of the group; (3) the practice must meet the statutory definitions of "group practice" and must be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation and profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers; and (4) revenues from ancillary services, if any, must be derived from "in-office ancillary services."

Because 1% of the ownership interests in the Practice were held by a physician who would not provide clinical services at the Practice, the OIG found that the anti-kickback safe harbor for investments in group practices did not apply. However, based on "the totality of facts and circumstances," the OIG found that the investor's stake in the Practice did not "pose any appreciable additional risks to Federal programs or beneficiaries . . . [because] [h]is returns are directly proportional to his investment interest, and he provides substantial services integral to the Practice's operation and administration, thus minimizing the risk that his small equity interest reflects referrals." As the proposed arrangement was in compliance with all of the other requirements of the safe harbor, and the investors certified compliance with the Stark law, the OIG concluded that it would not impose civil monetary penalties or administrative sanctions in this instance.

HOSPITAL ACCREDITATION AND REGULATIONS

EMTALA Risk To Hospitals That Divert Ambulances

On January 12, 2009, the US Supreme Court declined to hear a case interpreting when a hospital may become subject to EMTALA while an individual is en route to a hospital in an ambulance that is not owned by the hospital. Sociedad Espanola de Auxilio Mutuo y Beneficencia v. Morales, U.S., No. 08-169, Review Denied 1-12-09. The Court's decision leaves intact a decision by the First Circuit Court of Appeals which held that an individual may "come to" an emergency department for EMTALA purposes without physically arriving on the hospital's grounds if the individual is en route to the emergency department and it has been notified of her imminent arrival.

In this case, paramedics in an ambulance not owned by the hospital contacted the hospital emergency department physician twice to facilitate admission of a pregnant Morales to the hospital. The hospital was not on diversionary status. During the second call, the emergency department physician allegedly asked about Morales's insurance status and, upon learning that Morales had no medical coverage, abruptly terminated the call. The paramedics interpreted this action as a refusal to treat Morales and took Morales to a different facility for treatment.

The First Circuit Court of Appeals reversed the District's Court ruling for Summary Judgment on behalf of the hospital. It was undisputed that the paramedics clearly requested treatment for Morales. The narrow issue before the Court of Appeals was whether Morales had "come to" the hospital for EMTALA purposes while she was still en route by virtue of the paramedics seeking to facilitate her admission by calling ahead.

The Court found CMS guidance unclear. On one hand, CMS guidance states that, if an individual is not on hospital property, EMTALA is not applicable. On the other hand, CMS guidance advises that a hospital may divert a non-hospital owned ambulance to another facility if the hospital is on diversionary status. In Morales, a critical fact for the Court was that the hospital was not on diversionary status. The Court interpreted CMS guidance to mean that, when a non-hospital owned ambulance seeks care for an individual en route to an emergency department that is not on diversionary status, the individual may have "come to" the emergency department for EMTALA purposes.

The Court was concerned that a contrary interpretation would mean that a hospital could redirect any individual in a non-hospital owned ambulance for virtually any reason, including concerns regarding the individual's economic status. The Court found that the statute and its implementing regulations must be interpreted in light of

the overall purpose of the EMTALA statute - to ensure that individuals of every socioeconomic class would be treated fairly when undergoing medical emergencies regardless of their insurance status or ability to pay and to prohibit the "dumping" of financially undesirable individuals presenting with emergency conditions. The court also noted that its decision was consistent with a Ninth Circuit case, Arrington v. Wong, 237 F.3d 1066 (9th Cir. 2001), construing an earlier but materially identical version of the current EMTALA regulation.

The Joint Commission New And Revised 2009 Accreditation Requirements

The Joint Commission accredits and evaluates more than 15,000 health care organizations and programs in the United States. The Joint Commission's accreditation process seeks to improve safety and quality of care by helping health care organizations identify and correct problems. To achieve these goals, the Joint Commission publishes standards and requirements for the accreditation of health care organizations. On January 5, 2009 the Joint Commission released revised accreditation standards aimed at adding clarity to existing standards and including provisions applicable to specific health care settings. The most significant revisions include the addition of the following new requirements:

Environment of Care

EC.02.02.01 EP 14, 15. "The hospital checks radiology staff, according to timeframes it defines, for radiation exposure using exposure meters or badge tests. The dates of the checks and amount of exposure are documented. . . . The radiologic services, including ionizing radiology procedures, are free from hazards for patients and staff." This new standard imposes specific requirements, where the former standard merely mandated that an organization manage risks related to hazardous materials and waste.

Human Resources

HR.01.04.01 EP 3. "The hospital orients staff on the following: Relevant hospital-wide and unit-specific policies and procedures. Completion of this orientation is documented." Because the former standard merely required an organization to provide orientation to staff, this new requirement defines the specific areas of orientation.

Leadership

LD.04.04.01 EP 5. "The hospital identifies and documents its quality improvement projects. The hospital documents the following: what quality improvement projects are being conducted; the reasons for conducting these projects; and the measurable progress achieved on these projects." By requiring an organization to identify and document its quality improvement projects, this new requirement sets more specific guidelines to the former standard that required leaders to establish priorities for performance improvement.

Provision of Care

PC.03.01.01 EP 11. "For hospitals that use Joint Commission accreditation for deemed status purposes: The following equipment is available in the operating room suites: A call-in system; Cardiac monitor and equipment; Ventilator; Defibrillator; Suction equipment; Tracheotomy set; Manual breathing bags." Instead of merely requiring an organization to have operative and high-risk procedures, as stated in the former requirement, this new provision requires specific equipment to be available in order to enhance safety and quality of care.

In addition to the above-referenced requirements, the Joint Commission has published the remaining revisions on their website.[1] Compliance with these new requirements will be evaluated by surveyors beginning January 1, 2009, but will not be scored until July 2009. This delay is consistent with the Joint Commission's policy to provide six months notice of changes and will allow the Joint Commission to further evaluate the revisions.

[1] Available at: http://www.jointcommission.org/ NR/rdonlyres / 6F82A3A7-22A6-43C4-AF65-8EAC2670541A/0/ HospitalNewandRevisedRequirementsinResponsetoCMSDeemingApplication_20090106.pdf.