

Healthcare Update

Spring 2006

OIG Issues Advisory Opinions

By Daniel J. Mohan



The Office of Inspector General of the Department of Health and Human Services has issued its first two Advisory Opinions of Calendar Year 2006. OIG issued Advisory Opinion 06-01 on March 20, 2006, and Advisory Opinion 06-02 on March 21, 2006. These Advisory Opinions are notable in that OIG rendered an unfavorable opinion on the proposed arrangement described in each of the opinions.

Advisory Opinion No. 06-01. Under the arrangement described in this Advisory Opinion, the requestor, a nation-wide home health agency (the "Agency"), sought an opinion as to whether the Agency's practice of providing individuals with free pre-operative home safety assessments posed a risk of violating applicable provisions of the federal Anti-kickback Statute and the Civil Monetary Penalties Act (CMP).

Under this program, the Agency provided free pre-operative safety assessments for patients scheduled for orthopedic surgery. The patients were referred to the Agency by the physician's office or surgery scheduler. After referral, the Agency contacted the patient to arrange for the assessment. Agency personnel obtained basic information about the patient and the patient's residence, and then provided suggestions to improve safety around the household. No skilled medical care was provided in connection with the assessment. The Agency also represented that it provided each patient with materials to the effect that, if post-operative home health care was necessary, the patient was under no obligation to choose the Agency as its healthcare provider, and provided a list of other available home health agencies for reference.

OIG noted that the provision of free services implicated both the CMP and the AKS. Even though the assessment itself was not a "covered service" under Medicare, home health and other related items and services provided by the Agency were covered services. In analyzing the risk of the proposed arrangement under the CMP, OIG engaged in a three-point analysis:

1. OIG first asked whether the free assessment constituted "remuneration" to patients. OIG concluded that the assessment was a valuable service, in that it could "lead a reasonable beneficiary to believe" that it was receiving a valuable service; and, therefore, the free service constituted "remuneration" to the beneficiary.
2. OIG then asked whether the proposed program was likely to influence the beneficiaries to select the Agency as a provider of Medicare covered services. OIG concluded that the provision by the Agency of free home safety assessments was likely to influence the beneficiaries to select the Agency as a provider of post-surgical home health care and related items and services. In making this determination, OIG relied on the fact that the assessment was recommended by the beneficiary's doctor. OIG further noted that the assessment program

Continued on page 5

Hospital System and Physicians Clash Over On-Call

By Brynne Goncher



In response to declining revenues and increasing expenses, physicians at many hospitals have begun to request payment for providing on-call coverage of the Hospital's emergency department. At the same time hospitals, struggling to meet on-call requirements under the Emergency Medical Treatment and Active Labor Act (EMTALA), and facing similar financial pressures, may be limited in their ability to compensate physicians for on-call coverage. These conflicting interests between hospitals and physicians came to a head in West Virginia when a hospital system and its cardiac surgeons disagreed over certain aspects of the surgeons' on-call coverage, including payment for such services.

On November 14, 2005, seven cardiac surgeons with medical privileges at Charleston Area Medical Center (CAMC), a hospital system composed of three separate hospitals, filed a lawsuit in state court seeking \$2,000 per day for each day spent on-call, whether or not they were actually called

Continued on page 9

INSIDE THIS ISSUE

OIG Issues Advisory Opinions	1
Hospital System and Physicians Clash Over On-Call	1
Changes to Medicare's "Incident To" Regulations Impact Physician Reimbursement	2
News and Events	3
Patient Safety and Quality Improvement Act	4

A blue-tinted portrait of a man with glasses and a goatee, smiling. He is wearing a white shirt and a dark tie with small white dots. The portrait is on the left side of the page, partially overlapping the title.

Deepak Jeyaram

Changes to Medicare’s “Incident To” Regulations Impact Physician Reimbursement

By Deepak J. Jeyaram

For physicians and other licensed practitioners utilizing “incident to” billing for occupational or physical therapy services under Medicare, new federal regulations may impact current and future staffing decisions. Providers should ensure that the person providing those “incident to” services qualifies for Medicare reimbursement under the applicable federal regulations.

As of July 25, 2005, for therapy services to be reimbursed by Medicare, the therapy must be delivered by either a physician or by someone that qualifies as a “therapist” under the federal regulations. Generally, 42 CFR § 484.4 requires that the physical or occupational therapy provider have graduated from physical or occupational therapy program respectively. Therefore, despite extensive training in occupational and physical therapy, chiropractors will be unable to provide “incident to” therapy services and be reimbursed by Medicare, unless the chiropractor meets the specific criteria set forth in the Code of Federal Regulations. The new regulations will affect joint ventures between physicians and chiropractors where chiropractors provide certain therapy services “incident to” services provided by the physician, but are not qualified as a “therapist” under the regulations.

Likewise, physical or occupational therapy services provided “incident to” the services of a chiropractor under the Medicare Chiropractic Demonstration Project will not be reimbursed unless the person who furnishes the service is a “qualified practitioner” under the regulations. Strangely, although a “qualified practitioner” under federal regulations is defined as an individual who has graduated from a physical or occupational therapy program or has equivalent educational credentials, as outlined in 42 CFR §484.4, there is no requirement that the therapist actually hold a license under applicable state law.

The American Chiropractic Association (“ACA”) has been strenuously lobbying the Centers for Medicare and Medicaid Services of the Department of Health and Human Services (“CMS”) to recognize that chiropractors receive extensive education and training in physical therapy and currently provide such services to patients under most state laws. To this point the ACA has been unsuccessful in having CMS revisit the regulations.

Deepak (“D.J.”) Jeyaram is an associate in the firm’s healthcare group. He represents a wide variety of healthcare providers including hospitals, nursing homes and physician group practices. He focuses his practice on healthcare regulatory matters, primarily in administrative appeals and Medicare and Medicaid reimbursement, and aids clients in negotiating and business and contractual relationships between healthcare providers. DJ received his bachelor’s degree from Boston University, cum laude, and his law degree from Emory University.

Healthcare News and Events

Patient Safety and Quality Improvement Act

By **Micelle Madison**



Since 1999, the healthcare industry has evolved to require reporting of medical errors or unanticipated outcomes to the state governments, to accreditation agencies, to managed care companies and employer coalitions.

Are you concerned about the press, the general public or plaintiffs' attorneys gaining access to sentinel event, medical staff peer review and hospital or physician office operations data? In the event that this is a concern for you as a provider, it is important to maximize the benefit of legal protections that prevent improper disclosure. Currently, there are several protections currently provided by state law, quality assurance privilege, peer review privilege and attorney-client privilege. However, the potential of the information being obtained by plaintiff's attorneys or rating agencies is still a very real concern. In order to support the need to protect this sensitive information and promote reporting of medical errors to improve quality care, the federal government took very affirmative and quick action in July 2005.

The Patient Safety & Quality Improvement Act was passed and enacted. Its goal is to

... help create a "culture of safety" by providing peer review protections for information reported on health care errors for the purposes of quality improvement and patient safety.

The "culture of safety" is created by providing a new protection for information obtained and used for patient safety activities. This Act specifically creates privilege and confidentiality protections for "patient safety work product". "Patient safety work product" means any data, reports, records, memoranda, analyses, including root cause analyses, or written or oral statements which:

- (i) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or
- (ii) are developed by a patient safety organization for the conduct of patient safety activities and which could result in improved patient safety health care quality or healthcare outcomes; or
- (iii) Which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

Patient Safety activities occur daily in a hospital setting through the Medical Staff peer review process, the Sentinel Event Process, root cause analyses, and general quality assurance review. Likewise, physician offices that conduct peer review and medical auditing

for quality care may also maintain patient safety work product data. However, in order to obtain the patient safety work product protections the information must be assembled, developed or reported to a patient safety organization.

Patient Safety Organizations could be a private or public entity. At this time, the Department of Health and Human Services ("DHHS") has been tasked to create and publish criteria in order to certify patient safety organizations. Once the criteria are established, the individual organizations can file for certification. Certification will depend upon the criteria set forth by DHHS and the policies and procedures of the entity. Once the entity is certified as a patient safety organization, the information utilized for patient safety and quality improvement activities may be protected by the federal privilege and would not be discoverable for use in civil, administrative, and with certain exceptions, criminal proceedings.

Although the current process for certification has not been published, facilities that are interested in becoming a Patient Safety Organization can begin to evaluate its policies and procedures regarding peer review and quality assurance activities. The policies and procedures should be adapted to comply with the patient safety activities as defined by the regulation and to promote the patient safety and quality improvement activities as set forth by the Patient Safety and Quality Improvement Act. Therefore, begin by taking an inventory of the current policies and procedures related to quality assurance or peer review of the Hospital or physician's office. In addition, review the bylaws for the medical staff to determine if the documents specifically reference patient safety activities.

Individual physician offices may also be considered Patient Safety Organizations, particularly physician offices that have individual peers evaluating the other peer's quality and performance. It is important to determine whether or not the physician office currently has policies and procedures to outline the peer review process in order to obtain not only the state privilege, but in the future, the federal privilege. Accordingly, while the certification criteria have not been established by DHHS, the criteria will be established, and in order to be ready to file for certification, it is important to begin the process now.

OIG Issues Advisory Opinions

Continued from page 1

afforded Agency therapists an opportunity to establish a personal relationship or connection with the beneficiary, which was likely to be a significant factor in the patient's selection of a provider for post-surgical care.

3. Finally, the OIG asked whether the Agency knew, or should have known, that the proposed arrangement was likely to influence the patient's selection of the Agency for post-operative care. OIG answered this question in the affirmative. OIG opined that the structure and operation of the arrangement "appears calculated" to generate post-operative business for the Agency.

Thus, OIG concluded that the arrangement potentially violated the CMP, and that no statutory exemption was available with respect to this arrangement. OIG further determined that, based on the foregoing rationale, the arrangement potentially violated the Anti-Kickback Statute.

Advisory Opinion No. 06-02. The proposed arrangements described in this advisory involved arrangements between physician groups and a DME manufacturer/supplier. The requestor was a DME and an orthotics manufacturer and supplier (the "Supplier"), which sought an opinion from OIG on two programs that the Supplier sought to institute:

1. The first program related only to non-federal patients. Under this program, physicians and physician groups would become DME suppliers for items and services sold or leased to the physicians by the Supplier.
2. The second program covered items and services furnished to both federal healthcare program beneficiaries and to patients who were not covered by a federal healthcare program. Under this program, the Supplier would act as the DME supplier, and it would bill Medicare, Medicaid and commercial payors for goods and services provided under this program.

OIG stated that, although the DME Supplier sought to characterize the programs as separate arrangements for regulatory analysis and compliance purposes, OIG felt that they were sufficiently related that it would consider them together for the purposes of the opinion. OIG further stated that, taken individually or collectively, the programs posed a "significant risk" under the Anti-Kickback Statute.

Under the first program, the DME Supplier would provide the following to the physician group:

- (i) DME and orthotics for sale or rent by the physicians to patients;
- (ii) A technician to assist the group in fitting patients for DME and orthotics, instructing patients in the use and maintenance of the products, obtaining pre-certification for the products, and managing product inventory; and

- (iii) Billing and collection services.

OIG asserted that this proposed arrangement amounted to a "contractual joint venture." In a "Special Fraud Alert" issued by OIG on _____, OIG made public its very strong reservations about arrangements that it characterized as "contractual joint ventures." Further, OIG asserted that the fact that the program was limited to non-federal healthcare program business, did not "save" the program from Anti-Kickback Statute risk. The opportunity for the physicians to order the DME Supplier's products for federal healthcare program beneficiaries under program No. 2 provided a "nexus" between federal healthcare program business in this program. Therefore, the Anti-Kickback Statute was implicated by the arrangement, and because the proposed arrangement shared many characteristics of the "suspect" contractual joint venture arrangements described by OIG in its special fraud alert, OIG concluded that this arrangement raised significant issues under the Anti-Kickback Statute.

Under the second program, the DME Supplier would sell or lease DME and orthotics to federal and non-federal healthcare program beneficiaries, billing Medicare, Medicaid or the appropriate commercial payor for the items. In connection with this program, the DME Supplier would (i) lease storage space from the physician groups for its products, (ii) pay the physician group for "inventory management services," which fee would be based on a percentage of the revenue from the sale of products and services to non-federal healthcare program beneficiaries, and (iii) provide a technician to the group, for a flat fee to be paid by the group, to provide the same or similar services described under Program No. 1 to patients who received DME or orthotics under Program No. 2.

OIG identified several questionable features of this program. First, OIG expressed concern about the percentage-based fee for the "inventory management services" provided by the physician group. OIG noted its historical position that percentage-based compensation arrangements are "inherently problematic" under the Anti-Kickback Statute. OIG did not specifically express, but clearly was troubled by, the appropriateness of management services provided by the physician group under these arrangements in consideration for the percentage-based fee. OIG also questioned the technician arrangement, and the relationship between this arrangement and the technician arrangement under Program No. 1. Finally, OIG reiterated its long-standing concern with the propriety of "consignment closet" arrangements, and the potential that rents paid to physician groups for these arrangements included disguised kick-backs.

Based on the foregoing analysis, OIG concluded that the proposed programs represented a "significant risk" of fraud and abuse.

Conclusion. While the glacial pace at which OIG continues to issue advisory opinions is troubling, the fact that the first two opinions of the year issued by OIG were negative opinions is significant.

Continued on page 6

OIG Issues Advisory Opinions

Continued from page 5

These opinions are consistent with OIG's increasingly tougher review of proposed arrangements under the Anti-Kickback Statute, particularly physician arrangements, and increasingly vigorous enforcement activity in this area. In addition, note that the proposed arrangement described in Advisory Opinion 06-02 raise significant issues under the Stark II Statute as well. While OIG does not render opinions on Stark II compliance, any parties contemplating a business relationship involving "designated health services" must structure the relationship so as to meet a Stark II exception.

Dan Mohan is a partner in the firm's healthcare group. He specializes in corporate and regulatory matters and represents a broad array of healthcare providers, including hospitals and healthcare systems, physician group practices, home health agencies, post-acute care providers, diagnostic imaging centers and outpatient surgery centers. Dan received his bachelor's degree from the University of Virginia and his law degree from the University of Georgia.

Hospital System and Physicians Clash Over On-Call

Continued from page 1

into the hospital to provide services. The surgeons claimed, in a separate statement, that CAMC paid neurosurgeons \$3,000 per on-call day, creating unequal pay between specialties, and that CAMC threatened to take away their medical staff privileges if they refused to serve on trauma call. In addition, they asserted CAMC imposed work conditions that were harmful to patients when it limited cardiac surgeries to only one of its three campuses, CAMC General Hospital. The surgeons claimed CAMC imposed such policy to maintain CAMC General Hospital's certification as a trauma center, but such location was not equipped to handle cardiac surgeries. The surgeons alleged that CAMC Memorial Hospital was better equipped to handle such surgeries. In the suit, the surgeons requested an injunction requiring CAMC to allow them to transfer patients to CAMC Memorial Hospital.

CAMC filed its own suit in federal court alleging the surgeons violated federal antitrust laws by fixing prices, entering into agreements for the purpose of restraining price competition, and refusing to serve on cardiovascular trauma emergency call until CAMC accepted the price agreed upon by the surgeons. CAMC asserted that the surgeons were putting it in the position of having to pay more than fair market value for the surgeons, which could be characterized as an attempt to induce referrals, putting them in danger of prosecution under the Federal Anti-Kickback Statute and the Ethics in Patient Referrals Act (Stark II).

Each side argued that the other was being unreasonable. The cardiac surgeons claimed that the argument was really about patient safety, that CAMC General Hospital's trauma unit was dangerous, and that they would not work at the hospital until the hospital gave them the equipment and trained staff they needed. CAMC countered that the surgeons were merely concerned about money.

On February 8, 2006, one day prior to the a scheduled hearing in state court, CAMC and the surgeons entered into a settlement agreement in which each side agreed to drop the lawsuit filed against the other. While the settlement agreement was confidential, reports noted that the executive board of CAMC passed guidelines for transferring patients from CAMC General Hospital to CAMC Memorial Hospital. No information was given as to whether the surgeons received payment for on-call coverage, and if so, whether they were compensated for each on-call day or only for those days in which they actually were required to come into the emergency department.

Regardless of which side is right, this situation illustrates a continuing problem that hospitals and physicians across the nation are encountering. Hospitals and physicians face conflicting economic and legal demands. Physicians continue to encounter increasing demands on their professional time, many of which are not reimbursed. Hospitals are expected to maintain on-call coverage under EMTALA, but compensating physicians for on-call coverage may put additional financial strain on the hospital, while subjecting all parties to potential risks under federal and state anti-kickback and self-referral laws. These arrangements raise a host of legal, financial and political issues for the institution and the physicians. The parties must be sensitive to structuring these arrangements in compliance with applicable healthcare statutes and regulations while meeting the economic and administrative needs of the parties.

Brynne Goncher is an associate in the firm's healthcare group. She represents healthcare providers in various business and regulatory matters including corporate structuring, joint ventures, mergers and acquisitions, federal and state regulatory compliance, including the federal Anti-Kickback Statute, Stark II, EMTALA and HIPAA, physician employment matters, licensing and Certificate of Need, Medicare and Medicaid reimbursement, investigations, audits, and appeals, and medical staff bylaws. Brynne received her bachelor's degree from the University of Pennsylvania, her master's of public health degree from Emory University, Rollins School of Public Health, and her law degree from Emory University, School of Law.

Healthcare Update

Spring 2006

MMM Healthcare Attorneys

Leslie A. Allen.....	404.504.7631	lallen@mmmlaw.com
Ward S. Bondurant.....	404.504.7606	wbondurant@mmmlaw.com
Brynne R. Goncher	404.504.7658	bgoncher@mmmlaw.com
Richard L. Haury, Jr.....	404.504.7713	rhaury@mmmlaw.com
Deepak J. Jeyaram	404.495.3656	djeyaram@mmmlaw.com
Daniel J. Mohan.....	404.504.7610	dmohan@mmmlaw.com
Michelle M. Madison	404.504.7621	mmadison@mmmlaw.com
John H. Northey III (N.C. Office)	704.554.5031	jnorthey@mmmlaw.com
Robert C. Threlkeld.....	404.504.7757	rthrelkeld@mmmlaw.com

This newsletter is provided solely for informational and educational purposes and presents only highly condensed summaries relating to the topics presented. Therefore, it should not be relied upon as a complete record for purposes of regulatory compliance, nor as legal advice. Addressees and other readers are urged to consult their attorneys and advisors about any questions they may have. For additional information on any of the topics in this newsletter, please contact the authors or Robert R. Joseph, newsletter editor.