

Client Newsletter

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OIG Issues Supplemental Compliance Program Guidance for Hospitals

On January 27, 2005, the United States Department of Health and Human Services Office of Inspector General (“OIG”) issued a “Supplemental Program Guidance for Hospitals” (“Guidance”). The document supplements the OIG’s 1998 Guidance for the hospital industry. Among the compliance issues addressed in the Guidance, the OIG highlights areas of potential concern under the Federal Anti-Kickback Statute and also addresses the importance of self-assessment of compliance programs.

The Guidance reminds hospitals to be aware of the Federal Anti-Kickback Statute, and be mindful that compliance with the statute is a condition of payment under Medicare and other Federal health care programs. The Guidance highlights several known areas of potential risk under the Anti-Kickback Statute. These areas include: (1) joint ventures; (2) compensation arrangements with physicians; (3) relationships with other health care entities; (4) recruitment arrangements; (5) discounts; (6) medical staff credentialing; and (7) malpractice insurance subsidies. Of particular note, in its discussion of compensation arrangements with physicians, the OIG provides clarification on the issue of exclusive contracts between hospitals and traditional hospital-based physicians (e.g., anesthesiologists, radiologists and pathologists). The Guidance acknowledges that depending upon the circumstances, an exclusive contract between a hospital and hospital-based physician (or group) may have substantial value to both the physician and the hospital, which may have nothing to do with the value or volume of business flowing between the hospital and the physician(s). The Guidance states that in an appropriate context, “an exclusive arrangement that requires the hospital-based physician or physician group to perform reasonable administrative or limited clinical duties directly related to the hospital-based professional services at either no charge or at a reduced charge, would not violate the Anti-Kickback Statute, provided the overall arrangement is consistent with fair market value in an arms-length transaction, taking into account the value attributable to the exclusivity.” The Guidance states that the OIG’s position in this regard should not be construed as requiring hospital-based physicians to perform administrative or clinical services at either no charge or at a reduced charge.

The Guidance also addresses the importance of a hospital's self-assessment of its compliance program. The Guidance encourages hospitals to regularly review the implementation and execution of their compliance program. In undertaking such an assessment, however, a hospital should not exclusively rely upon various outcome indicators (e.g., billing and coding error rates, identified overpayments and audit results). The Guidance lists the following factors the OIG has observed in effective compliance programs for hospitals: (1) designation of a compliance officer and compliance committee; (2) development of compliance policies and procedures, including standards of conduct; (3) developing open lines of communication; (4) appropriate training and education of staff; (5) internal monitoring and auditing to avoid the submission of incorrect claims to federal healthcare program payors; (6) response to detected deficiencies; and (7) enforcement of disciplinary standards.

The Guidance is available at <http://oig.hhs.gov/authorities/docs/cpghosp.pdf>.

Charitable Immunity Cap Not Applicable in Discrimination Lawsuit against Hospital

The Massachusetts Supreme Judicial Court recently issued an opinion in the matter of *Ayash v. Dana Farber Cancer Institute*, in which it declared for the first time that the Massachusetts Charitable Immunity Cap of \$20,000.00 is not applicable to discrimination claims brought under Massachusetts General Laws, c. 151B. In the same case, the Court also reaffirmed the confidentiality of proceedings, reports and records of medical peer review committees.

In November of 1994, a research fellow at Dana Farber Cancer Institute ("Dana Farber") administered an overdose of a highly toxic chemotherapy drug to two breast cancer patients who were enrolled in an experimental protocol. One of the patients died as a result of the overdose. The Plaintiff, Dr. Lois Ayash, the Protocol Chair and the Principal Investigator, was informed two months later by a Dana Farber Data Manager that the death was a result of an overdose. Dr. Ayash immediately reported the overdosing errors to Dana Farber's Human Protection Committee and the patients' families. The hospital also began an investigation into what caused the overdoses.

The overdoses became the subject of intense media coverage. In particular, the Boston Globe published several articles about the overdoses and the subsequent investigation by Dana Farber. On March 23, 1995, the Boston Globe published an article entitled "Doctor's Orders Killed Cancer Patients", in which it stated that the erroneous order for the chemotherapy was countersigned by "Dr. Ayash, leader of the team." In fact, Dr. Ayash, did not countersign the order, nor was she the "leader of the team." Dana Farber, however, did initiate a corrective action proceeding against Dr. Ayash, as a result of her failure, as the Chairperson of the Protocol and the attending physician of the overdose victims, to immediately explore the possibility of an overdose after the patient's death. Dr. Ayash was assigned to "administrative duty" by the hospital and the Boston Globe identified Dr. Ayash as the subject of a Dana Farber "internal disciplinary process". Ultimately, the Dana Farber Board of Trustees recommended a sanction of oral reprimand for Dr. Ayash.

In November of 1995, Dr. Ayash filed a Complaint against Dana Farber with the Massachusetts Commission Against Discrimination (“MCAD”), alleging gender discrimination in an unrelated matter. Dr. Ayash eventually removed the case to the Superior Court. Shortly thereafter, Dr. Ayash was informed by Administrators at Dana Farber, that clinical positions previously offered to her would no longer be available. Dr. Ayash was also informed that once her appointment at Dana Farber expired in June of 1997, her employment would not be renewed. As a result, Dr. Ayash amended her Complaint to include unlawful retaliatory discharge against Dana Farber.

Dr. Ayash’s lawsuit included claims against Dana Farber for invasion of privacy and breach of the implied covenant of good faith and fair dealing. She also sued the Boston Globe for libel and defamation. A jury returned a verdict in favor of Dr. Ayash against Dana Farber in the amount of \$1.2 million dollars for lost compensation, emotional distress and punitive damages. (Dr. Ayash also received a \$2.9 million verdict against the Boston Globe and one of its reporters). Dana Farber, however, was successful on a post-trial motion in having the damages awarded against it, reduced to \$20,000.00 in accordance with the Massachusetts Charitable Immunity Cap. The Plaintiff appealed and the Massachusetts Supreme Judicial Court took direct appellate review.

The Supreme Judicial Court upheld the \$1.2 million dollar verdict and found that the Charitable Immunity Cap of M.G.L. c. 231, §85K, does not apply to damages awarded pursuant to a successful claim of unlawful retaliation under General Laws, c. 151B. The Court ruled that the Charitable Immunity Cap applies only in limited circumstances where damages flow from a tort “committed in the course of any activity carried on to accomplish directly a Defendant’s charitable purposes.” The Court ruled that the Charitable Immunity Cap does not apply to most statutory violations unless there is a “tort” within the meaning of the statute. The Court noted that chapter 151B is a comprehensive statute enacted to provide judicial and administrative remedies for destructive acts of discrimination in the workplace. The Court held that it cannot be said that claims arising under General Laws, c. 151B, are causes of action in tort. Therefore, the Court found that the Charitable Immunity Cap does not apply to claims under General Laws, c. 151B. However, because the trial court record did not distinguish the jury’s award for the retaliation claim against Dana Farber, the Court ordered a new trial on damages.

In its discretion, the Court also reaffirmed that proceedings, reports and records of a medical peer review committee are statutorily protected from disclosure by Massachusetts General Laws, c. 111, §§ 203 and 204(a). Dr. Ayash attempted to argue that Dana Farber’s inadvertent or intentional release of peer review information to the Boston Globe was the equivalent of an invasion of privacy. Dana Farber continually denied that it or any of its agents leaked any confidential peer review information to the Boston Globe. Nevertheless, the Court held that the peer review statute did not create a private right of action for a physician under investigation to sue for invasion when protected peer review information is either inadvertently or intentionally released to the public. The Court, therefore, vacated the judgment against Dana Farber for invasion of privacy.

OIG Determines Joint Venture Raises Anti-Kickback Concerns

On December 17, 2004, the United States Department of Health and Human Services Office of Inspector General (“OIG”) concluded that a proposed pathology joint venture could generate prohibited remuneration under the Federal Anti-Kickback Statute. Under the proposed arrangement, a company would be established to manage off-site pathology laboratories for certain physician groups. The company would offer turn-key pathology lab operations to dermatology, gastroenterology, and urology group practices at a “centralized location.” Through a series of agreements, the company would establish the laboratory, manage the operations of the laboratory, provide necessary lab equipment and technical personnel to the laboratory, and sublease the laboratory space to the physician group. The company would arrange, through a related organization, the professional services of a pathologist, and, when requested by the physician group, provide billing and collection services. The physician group would own the laboratory, send its specimens to the laboratory, and bill globally for the professional and technical components of the pathology service.

Under the company’s business model, it would establish up to five separate laboratories within the same building at a given location. Each laboratory, commonly referred to as a “condo” laboratory, would have the full amount of equipment necessary to perform pathology services for the particular physician group leasing the space. Each laboratory space would be used exclusively for the tests of a particular physician group. Although the pathologists and technicians would be shared between the five laboratories, they would perform services for a particular physician group only when in that physician group’s laboratory space. This model allows each physician group to satisfy the centralized location requirement of the “in-office ancillary services exception” to the Stark Law.

Although the OIG reviewed the contractual relationships necessary to establish the arrangement, its refusal to grant a favorable opinion did not depend on the agreements. The OIG stated that the proposed arrangement would be problematic under the Anti-Kickback Statute even if each contractual arrangement satisfied the relevant safe harbor. Instead, the OIG based its decision on its concerns over contractual joint ventures listed in its Special Advisory Bulletin from April of 2003.

The OIG takes the position that the Anti-Kickback Statute is potentially violated if a healthcare provider (in this instance, the physician group) outsources the development and management of an ancillary service line to an established provider of that ancillary service line (in this instance, the company). The parties potentially violate the Anti-Kickback Statute if the company allows the physician group(s) to bill for pathology services. In the Advisory Opinion, the OIG identifies a number of “suspect” characteristics of such contractual joint ventures:

- The established healthcare provider is expanding into a new line of business;
- The new line of business depends predominately on the referrals generated by the established healthcare provider's existing patient base;
- The established healthcare provider bears little or no risk associated with the ancillary service line;
- The manager of the ancillary service line is an established provider of the ancillary service;
- The practical effect of the arrangement, viewed in its entirety, is to provide the established provider with the opportunity to capture revenue from referrals of the ancillary service; and

- Restrictive covenants are used to limit competition between the established healthcare provider and the manager of the ancillary service line.

The OIG indicates that the list of suspect characteristics is not intended to be exhaustive and the “[t]he presence or absence of any one of these factors is not determinative of whether a particular arrangement is suspect.”

The OIG noted that the proposed arrangement between the company and the physician groups shared the following characteristics of contractual joint ventures:

- Each physician group would be expanding into an ancillary service line (i.e., pathology services).
- The laboratory would depend solely upon referrals from the physician group.
- The physician group's participation in the laboratory's operations would be minimal and, according to the OIG, the physician group's business and financial risks would be “nonexistent or minimal.”
- Because the company had common parent corporation ownership with an established supplier of pathology services, shared common officers and directors with its “sister corporation”, and had the ability to assign contracts to the affiliated entities, the OIG took the position that it was appropriate to treat the Company as an established provider of pathology services.
- The company's sister corporation, the laboratory, could provide pathology services in its own right and retain all reimbursement for such services. The OIG's position is that, instead of competing for the physician group's business, the company is, basically, offering the physician group the “opportunity to bill” for such pathology services and retaining, through the various fee arrangements, a portion of the physician group's remuneration for pathology services.
- Payment to the company, as well as the physician group's revenue, would vary with referrals from the physician group to its pathology laboratory.
- The company and the physician group would share the economic benefit of the physician group's utilization of its pathology laboratory.

Based upon the similarities between the proposed arrangement and the identified risk factors, the OIG refused to issue a favorable advisory opinion. The OIG found it was “unable to exclude the possibility that the parties' contractual relationship is designed to permit the requestor to do indirectly what it cannot do directly; that is, pay the physician groups a share of the profits from their laboratory referrals.”

The OIG also indicated that, although it understood that the proposed arrangement was structured to comply with the Stark Law, compliance with the Stark Law was not a factor in its analysis of the Anti-Kickback Statute. Further, although beyond the scope of its authority, the OIG indicated that it had concerns as to whether it would be possible to maintain compliance with the Stark Law in the actual operation of the laboratory. At the very least, the OIG indicated that such arrangements would not be subject to monitoring by the physician group and “therefore would be prone to substantial abuse, including, without limitation, the risk of inappropriate utilization and improper claims.”

OIG Approves Cash Donations to Hospice from Foundation Affiliated with Health System

On December 29, 2004, the United States Department of Health and Human Services Office of Inspector General (“OIG”) issued Advisory Opinion 04-18, in which it stated that it would not impose administrative sanctions with respect to proposed donations from a Foundation affiliated with a health system to a local hospice. According to the opinion, a health system formed a charitable foundation in order to provide grants and scholarships to hospitals and other non-profit providers of health services. The foundation proposed to make a donation to a local hospice that provides care to the homeless as well as those with insurance. The OIG stated, “the Foundation has certified that neither the offer nor the amount of the Proposed Donations will be determined in a manner that varies with, or otherwise takes into account in any way, the volume or value of any referrals or other business that the Hospice might generate for the Health System.”

The OIG concluded that the donations are not likely to result in fraud or abuse under the Anti-Kickback Statute. First, patient referrals from the hospice to the health system will be limited “because patients electing Medicare hospice services are required to relinquish their rights to curative care for their terminal illnesses.” Second, the foundation will not restrict in any way the use of the funds by the hospice. Third, the OIG said that the foundation’s donations will be subject to an annual cap and a fixed duration. Thus, based on the “totality of facts and circumstances,” the OIG concluded that it would not impose administrative sanctions under the Anti-Kickback Statute.

HHS Proposes New Medicare E-Prescribing Rules

The United States Department of Health and Human Services (“HHS”) recently issued proposed regulations governing electronic prescriptions under the new Medicare Prescription Drug Benefit, which will take effect on January 1, 2006. The Prescription Drug Benefit is one of the key elements to the Medicare Modernization Act (“MMA”), which was signed into law by President Bush on December 8, 2003. As part of the MMA, Medicare will require drug plans participating in the new prescription drug benefit to support electronic prescribing, or e-prescribing. E-prescribing allows a physician to transmit a prescription electronically to the patient’s choice of pharmacy and also allows physicians and pharmacies to obtain information from drug plans about the patient’s eligibility and medication history. E-prescribing is voluntary for physicians and pharmacies. However, physicians who do E-prescribe will be required to comply with the final regulations. The HHS is encouraging physicians to E-prescribe as a way of improving patient safety and reducing avoidable health care costs by decreasing prescription errors due to physician handwriting and by automating the process of checking for drug interactions and allergies. E-prescribing will also help to ensure that patients and health professionals have the latest medical information when determining the appropriate medications for a patient.

The proposed E-prescription regulations, which are available at 70 Fed. Reg. 6255, adopt standards for the following: transactions between prescribers and dispensers for new prescriptions; prescription refill request and response; prescription change request and response; prescription cancellation request and response; and related messaging and administrative transactions.

HHS is accepting public comments on the proposed regulations through April 5, 2005. The Rogers Law Firm will continue to monitor the proposed regulations and will provide updates accordingly.

OCR Addresses Disclosure of PHI in Judicial and Administrative Proceedings

The Office of Civil Rights (“OCR”) of the United States Department of Health and Human Services recently provided guidance with respect to disclosure of Protected Health Information (“PHI”) in judicial and administrative proceedings under the HIPAA Privacy Rule. The disclosure of PHI in judicial and administrative proceedings has been a significant area of concern in the health care industry since the HIPAA Privacy Rule went into effect in April of 2003. The OCR has now attempted to address these concerns through a series of questions and answers on its website.

As a preliminary foundation, the OCR states that a covered entity which is a party to a legal proceeding may use or disclose PHI for the purpose of litigation as part of its health care operations. The covered entity, however, must make reasonable efforts to limit such uses and disclosures to the minimum necessary to accomplish the intended purpose. A covered entity may rely upon the representation of its attorney that the PHI requested is the minimum necessary for the stated purpose.

The OCR also addressed a covered entity’s disclosure of PHI in a legal proceeding in which the covered entity is **not** a party. The OCR states that if certain conditions are met, a covered entity, which is not a party to the litigation, may disclose PHI in response to a subpoena, discovery request or other lawful process, provided that the covered entity: (1) receives a written statement and accompanying documentation from the party seeking the information that reasonable efforts have been made either to ensure that the individual who is the subject of the information has been notified of the request or to secure a qualified protective order for the information; or (2) makes reasonable efforts to either to provide notice to the individual or to seek a qualified protective order. The requirement to provide sufficient notice to the individual is met when a party provides a written statement and accompanying documentation that demonstrates: (1) the requestor has made a good faith attempt to provide written notice to the individual; (2) the notice included sufficient information about the litigation to permit the individual to raise an objection with the Court; (3) the time for the individual to raise an objection has elapsed; and (4) no objections were filed or all objections filed were resolved and the requestor is consistent with the resolution. Such documentation may include a copy of the notice mailed to the individual that includes instructions for raising an objection with the Court and the deadline for doing so, and a written statement or other documentation demonstrating that no objections were raised or all objections made were resolved and the request is consistent with the resolution. A written statement and accompanying documentation of notice to the individual’s lawyer is considered to be notice to the individual.

The OCR also addressed whether a covered entity must account for disclosures of PHI made during the course of litigation. Upon request, an individual has a right to receive, with certain exceptions, an accounting of disclosures of their PHI made by a covered entity. A covered entity, however, need not account for disclosures of PHI in the course of litigation that are made with the individual’s authorization or as part of a covered entity’s health care operations in circumstances where the covered entity is a party to the litigation. The HIPAA Privacy Rule’s definition of “health care operations” includes the covered entity’s activities of conducting or

arranging for legal services to the extent such activities are related to the covered entity's covered functions (those functions that make the entity a health plan, health care provider or health care clearing house). A covered entity, however, is required to account for disclosures of PHI in circumstances which are: (1) required by law (45 C.F.R. 164.512(a)); (2) made to a health oversight agency; or (3) in response to a subpoena, discovery request or other lawful process in which the covered entity is not a party to the litigation.

IRS Commences Compensation Review Initiative

Representatives of the United States Internal Revenue Service ("IRS") recently confirmed that the agency had commenced its new initiative designed to explore the high compensation paid to individuals associated with tax-exempt organizations. The IRS intends to contact 1,784 exempt organizations and make inquiries regarding the process by which compensation was established for highly compensated employees. (It is believed that the IRS will select tax-exempt organizations whose Form 990 indicates that an employee has received \$1 million dollars or more in compensation.) The initiative was announced last summer by IRS Commissioner Mark Everson, during testimony before the Senate Finance Committee. Commissioner Everson expressed concern that the governing boards of tax-exempt organizations are not exercising sufficient diligence as they set executive compensation. He stated that the initiative is designed to help the IRS become more familiar with the practices that exempt organizations are using to set compensation and how exempt organizations are reporting compensation to the IRS and to the public.

To date, the IRS has mailed approximately half of the contact letters it intends to send to exempt organizations. The IRS expects the balance of these contact letters to be mailed by the middle of March.

This Newsletter is published by The Rogers Law Firm to keep its clients informed of developments in health law. The Newsletter should not be construed or relied upon as legal advice or legal opinion on any specific facts or circumstances. If you have any questions or concerns regarding the articles contained in the Newsletter or would like legal advice or legal opinion concerning a specific matter, please do not hesitate to contact any of the attorneys at The Rogers Law Firm, at (617) 723-1100.