Department of Health and Human Services Office of Inspector General: Draft Supplemental Compliance Program Guidance for Hospitals

On June 8, 2004, the Department of Health and Human Services Office of Inspector General ("OIG") released new draft compliance program guidance for hospitals. The new compliance guidance supplements the original hospital compliance guidance issued in 1998. According to the OIG, the two documents "collectively" represent "a set of guidelines thathospitals should consider when developing and implementing a new compliance program or evaluating an existing one."

Consistent with the original compliance guidance, the new compliance guidance describes the elements of an effective compliance program and identifies areas of legal risk under fraud and abuse laws. The new guidance, however, differs from the original guidance in the following significant respects:

- the discussion of risk areas is more comprehensive and detailed with a new focus on explaining how to analyze a potential compliance concern and where to go for additional government guidance;
- there is a greater emphasis on practices that create risk under federal fraud and abuse statutes (such as the Stark statute, anti-kickback statute and prohibition on inducements to beneficiaries) than on traditional compliance concerns such as coding and cost reporting (which are now relatively well-understood in the industry);
- the discussion of coding and claims submission addresses new concerns created by changes in Medicare reimbursement or policy, particularly the implementation of the hospital outpatient prospective payment system ("OPPS"); and
- there is a new focus on accountability of corporate leadership for compliance programs and on how hospitals should assess the effectiveness of each element of a compliance program.

Fraud and Abuse Risk Areas

The new compliance guidance identifies eight areas of significant concern that involve significant risk as well as certain areas of continuing interest to the hospital community that do not involve significant risk:

- **Submission of Accurate Claims and Information.** The OIG states that the preparation and submission of claims or other requests for payment to federal health care programs remains the "single biggest risk area" for hospitals. The OIG focuses on new risks raised by:
  - OPPS coding (*e.g.*, failing to discount multiple procedures or improperly billing for observation services);
  - admissions and discharges (*e.g.*, same day discharges and admissions);
  - supplemental payment considerations (*e.g.*, abuse of DRG outlier payments or billing for facilities as "provider-based" that do not qualify as such); and

- use of information technology (*e.g.*, the increasingly difficult task ensuring that systems are monitored to ensure accurate coding, billing and transmission of information).

- **The Referral Statutes (Stark and Anti-Kickback Statutes).** The Stark statute receives brief treatment compared to the extensive treatment of the anti-kickback statute. The difference in treatment appears to reflect the differences in the statutes: a violation of the Stark statute exists whenever certain prohibited and unprotected financial relationships exist, while a violation of the anti-kickback statute depends on whether the parties in a financial relationship acted with improper intent.

  - Stark Statute. The OIG emphasizes that hospitals should view the Stark statute as a "threshold statute" because hospitals face significant exposure unless all financial relationships with referring physicians fit squarely within an exception. Hospitals are cautioned to ensure that otherwise permissible relationships with physicians do not fall out of compliance simply because written agreements are allowed to lapse.

  - Anti-Kickback Statute. The OIG provides general instruction on how to analyze an arrangement under the anti-kickback statute. Additional and more specific guidance on analyzing arrangements is provided with respect to seven areas with a potential for abuse that should receive close scrutiny from hospitals: (1) joint ventures, (2) compensation arrangements with physicians, (3) relationships with other health care entities (indicating that that entities as well as health care practitioners can be referral sources), (4) recruitment arrangements, (5) discounts, (6) medical staff credentialing, and (7) malpractice insurance subsidies. These risk areas, with the exception of medical staff credentialing, represent familiar themes. The OIG, in discussing medical staff credentialing, expresses concern that some hospitals may condition privileges on the performance of a certain number of procedures beyond what is necessary to ensure clinical competence. In the discussion of malpractice insurance subsidies, the OIG acknowledges the current malpractice crisis but refuses to permit subsidies across-the-board.

- **Payments to Reduce or Limit Services ("Gainsharing Arrangements").** The OIG reiterates its position that the statutory prohibition on hospital payments made to a physician in order to induce the physician to limit hospital services provided to Medicare and Medicaid beneficiaries is very broad and does not permit "gainsharing arrangements" between hospitals and physicians even when those arrangements serve legitimate business and medical purposes, such as increasing efficiency, reducing waste, and potentially increasing a hospital's profitability. The OIG also expresses concern that gainsharing arrangements could implicate the anti-kickback statute if the arrangement is intended "to influence physicians to 'cherry pick' healthy patients for the hospital offering gainsharing payments and steer sicker (and more costly) patients to hospitals that do not offer gainsharing payments."

- **Emergency Medical Treatment and Labor Act ("EMTALA").** The OIG emphasizes certain EMTALA obligations, such as the obligation of a hospital to accept a patient for transfer if the hospital has specialized capabilities to treat the patient that the transferring hospital does not have and the obligation of a hospital to provide appropriate screening and treatment services within the full capabilities of its staff and facilities including access to specialists who are on call.

- **Substandard Care.** The OIG reminds hospitals of its authority to exclude hospitals from participation in federal health care programs if the hospitals provide substandard or unnecessary medical care to any patient and encourages hospitals to go beyond monitoring compliance with Medicare conditions of participation or JCAHO accreditation standards and develop their own quality of care protocols.

- **Relationships with Federal Health Care Program Beneficiaries.** The OIG cautions hospitals that offering valuable items or services to Medicare and Medicaid beneficiaries to attract their business could implicate the federal prohibition on inducements to beneficiaries. The guidance addresses three practices in particular. First, the OIG encourages hospital scrutiny of gifts and gratuities (reminding hospitals that gifts with a value less than $10 per gift

or $50 per patient in the annual aggregate do not implicate the statute). Second, the OIG also describes the circumstances under which waivers of copayments or deductibles may be permissible. In discussing waivers based on a patient's financial need, the OIG recognizes that financial need may vary based on the patient's circumstances and that hospitals should have flexibility in determining financial need. The OIG states, however, that hospitals should not apply financial need guidelines that allow waivers for patients "not in genuine financial need." Third, the OIG reiterates that the agency is considering a regulatory safe harbor for complimentary local transportation provided by hospitals to patients in their primary service area.

- **HIPAA Privacy and Security Rules.** The OIG reminds hospitals that each hospital must ensure its compliance with all applicable provisions of the privacy rule, including provisions pertaining to required disclosures (including required disclosures to the OIG when the agency is undertaking a compliance investigation or review or enforcement action) and that its privacy procedures are tailored to fit its particular size and needs.
- **Billing Medicare or Medicaid Substantially in Excess of Usual Charges.** The OIG may exclude a hospital that bills Medicare or Medicaid "substantially in excess" of its usual charge or cost absent "good cause" for the higher charge or cost. The OIG, which promulgated proposed regulations on the excessive charge prohibition last year, indicates that the OIG is considering hospital concerns about the impact of its exclusion authority as part of that rulemaking process.

In addition to the eight risk areas, the OIG addresses three areas of general interest: (1) discounts to uninsured patients, (2) preventative health care, and (3) professional courtesy (i.e., practices involving free or discounted services furnished to physicians and their families and staff). Consistent with its position in the recent debate among the hospital industry, the OIG and the Centers for Medicare & Medicaid Services, the OIG states that no OIG authority prohibits or restricts hospitals from offering discounts to uninsured patients who are unable to pay their hospital bills. The OIG also indicates that certain preventative care services -- or incentives to obtain preventative care services -- may be provided under federal fraud and abuse laws if not provided to induce patients to obtain other services reimbursable under federal health care programs. According to the OIG, the key consideration in assessing professional courtesy programs offered by hospitals is whether the recipients of the professional courtesy are selected in a manner that takes into account, directly or indirectly, any recipient's ability to refer to, or otherwise generate business for, the hospital.

Elements of an Effective Compliance Program

Recognizing that many hospitals have implemented compliance programs, the discussion of the elements of an effective compliance program focuses on the significance of corporate leadership and self-assessment in maintaining an effective compliance program. A commitment by corporate leadership to compliance should be evident from active involvement of the leadership in compliance, allocation of adequate resources, a reasonable timetable for implementation of compliance measures, and the identification of a compliance officer and compliance committee vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures. The OIG recommends that, in addition to a detailed set of substantive policies, hospitals develop a general and easily readable statement of ethical and compliance principles (analogous to a constitution) to guide the hospital's operations. In order to assess compliance program effectiveness, the OIG recommends that hospitals should review their compliance programs at least annually. These reviews should not focus entirely on outcome indicators (e.g., billing and coding error rates, identified overpayments, and audit results) because exclusive reliance on these indicators may cause an organization to miss crucial underlying weaknesses. Hospitals should also assess the underlying structure and process of each compliance program element. The compliance guidance offers factors for hospitals to consider in assessing the designation of a compliance officer and compliance committee, reviewing policies and procedures, developing open lines of communication, conducting appropriate training and education, undertaking internal audits and monitoring, responding to detected deficiencies and enforcing disciplinary standards.

The text of the supplemental compliance guidance is in the Federal Register at 69 Fed. Reg. 32012 (June 8, 2004).

Ropes & Gray lawyers are available to provide further assistance with interpreting the compliance guidance as well as implementing or evaluating a hospital compliance program.