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OIG ISSUES GUIDANCE FOR HOSPITAL COMPLIANCE PROGRAMS

On February 11, 1998, the Department of Health and Human Services Office of the Inspector General ("OIG") issued much-anticipated guidelines for hospital corporate compliance programs ("Hospital Guidelines"). The Hospital Guidelines are the second such compliance guidelines issued by the OIG (the first set of guidelines were issued last year for clinical laboratories). The OIG is slated to release other corporate compliance guidelines for industries such as third-party billing companies, HMOs, and DME suppliers. The next set of guidelines, which targets home health agencies, is expected in the next three to four months.

Background

Corporate compliance programs have their basis in the framework promulgated by the United States Sentencing Commission in the Federal Sentencing Guidelines ("DOJ Guidelines"). Issued on November 1, 1991, the Guidelines are mandatory and must be applied by courts upon the conviction of an organization of a federal criminal law (felony or Class A misdemeanor). The DOJ Guidelines employ an elaborate "points" system to determine a range of punishment whereby points are added for "bad" factors and subtracted for "good" factors. One factor that will reduce the point calculation under the DOJ Guidelines is an effective corporate compliance program.

Under the DOJ Guidelines, the mere existence of a corporate compliance program is not enough to mitigate punishment. Rather, the DOJ Guidelines require that the corporate compliance program be "effective." In order to be deemed effective under the DOJ Guidelines, a corporate compliance program at a minimum must address the following seven elements: written standards and procedures; oversight responsibilities; delegation of

authority; employee training; monitoring and auditing; enforcement and discipline; and response and prevention.

The OIG issued a model compliance program for clinical laboratories on February 24, 1997. Based largely on the DOJ Guidelines, these laboratory guidelines represented the OIG's first effort to assist a health care entity (in this case clinical laboratories) in crafting and refining a corporate compliance program. The laboratory guidelines suggested that an effective compliance program include the following eleven elements: (1) written standards of conduct for employees; (2) written policies that address specific areas of potential fraud (e.g., billing); (3) the designation of a chief compliance officer or other appropriate individual to be responsible for the corporate compliance program; (4) education and training programs; (5) audits and other evaluation techniques to monitor compliance; (6) the development of a code of improper/illegal activities and the use of disciplinary action against employees who have violated internal compliance policies or applicable laws or who have engaged in wrongdoing; (7) investigation and remediation of identified systemic and personnel problems; (8) the promotion of compliance as an element in evaluating supervisors and managers; (9) policies addressing the non-employment or retention of sanctioned individuals; (10) a compliance hotline to receive complaints and procedures to protect the anonymity of complainants; and (11) record creation and retention requirements.

The OIG's Compliance Program Guidance for Hospitals

On February 11, the OIG released its Compliance Program Guidance for Hospitals. According to the OIG, the Hospital Guidelines are intended to "assist hospitals... [to] develop effective internal controls that promote adherence to applicable federal and state law, and the program requirements of federal, state, and private health plans." Although the OIG characterizes compliance with the Hospital Guidelines as voluntary, HHS Inspector General June Gibbs Brown has stated that "it is reasonable to expect that every hospital would have something in place" in the future.

While the OIG has said that the adoption of a corporate compliance program is no guarantee that a hospital will not be prosecuted, the existence of a program might

influence the decision whether to administer penalties. In those cases where penalties are warranted, the existence of a compliance program might mitigate the severity of the penalties. According to the OIG, the key to avoiding (or minimizing) penalties is to create an effective corporate compliance program *before* a problem arises.

Unlike the previously released laboratory guidelines, the Hospital Guidelines is not characterized as a "model" for hospitals. Rather, the OIG characterizes the Hospital Guidelines as a set of guidelines for hospitals to consider in implementing a compliance program. The OIG states, however, that elements of the Hospital Guidelines can be used by all hospitals, regardless of size, location, or structure, to establish an effective compliance program. While the OIG is aware that compliance programs can be costly, it asserts that savings likely will be realized in the long run.

Potential Benefits of a Compliance Program

In the OIG's view, the Hospital Guidelines can help advance the prevention of fraud, abuse, and waste in federal, state, and private health plans. In addition to insuring the submission of accurate claims, the Hospital Guidelines may help hospitals reap numerous other benefits. According to the OIG, an effective compliance program helps hospitals fulfill their fundamental care-giving mission to patients and the community, and assists hospitals in identifying weaknesses in internal systems and management. Specific benefits cited by the OIG include:

- ≈ Demonstrating to employees and the community the hospital's strong commitment to honest and responsible provider and corporate conduct;
- ≈ Providing a more accurate view of employee and contractor behavior relating to fraud and abuse;
- ≈ Identifying and preventing criminal and unethical conduct;
- ≈ Tailoring a compliance program to a hospital's specific needs;
- ≈ Improving quality of patient care;
- ≈ Creating a centralized source for distributing

information on health care statutes, regulations, and other program directives related to fraud and abuse and related issues;

- ≈ Developing a methodology that encourages employees to report potential problems;
- ≈ Developing procedures that allow prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, physicians, other health care professionals, and consultants;
- ≈ Initiating immediate and appropriate corrective action; and
- ≈ Minimizing the loss to the government from false claims, and thereby reducing the hospital's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as exclusion.

Core Elements of a Hospital Compliance Program

The Hospital Guidelines draw heavily from the previously released guidelines for clinical laboratories, as well as corporate integrity agreements that the OIG has with numerous health care providers as part of settlements of False Claims Act cases. At a minimum, the OIG states that a comprehensive hospital compliance program should include the following seven elements:

1. The development and distribution of written standards of conduct, as well as written policies and procedures, that promote the hospital's commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as claims development and submission processes, code gaming, and financial relationships with physicians and other health care professionals;
2. The designation of a chief compliance officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility of operating and monitoring the compliance program, and who report directly to the CEO and the governing body;

3. The development and implementation of regular, effective education and training programs for all affected employees;
4. The maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;
5. The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes or regulations, or federal health care program requirements;
6. The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
7. The investigation and remediation of identified systemic problems and the development of policies addressing the nonemployment or nonretention of sanctioned individuals.

The OIG states that the above factors are not all-inclusive, and it emphasized that the Hospital Guidelines may be modified and expanded in the future as the OIG gathers more information and knowledge. According to the OIG, these elements represent a guide, that is, a process that can be used by both large and small hospitals, urban or rural, for-profit or not-for-profit. In the OIG's view, the elements can be tailored to fit the needs and financial realities of a particular hospital.

Areas of Focus

The OIG believes that a hospital's written policies should take into account the regulatory exposure for each function and department of the hospital. Some special areas for the OIG include:

- ≈ False billing;
- ≈ Medically unnecessary services;
- ≈ Upcoding;
- ≈ DRG creep;
- ≈ Outpatient services rendered in connection with

Hospital Guidelines state that steps must be taken promptly to investigate the conduct in question and, if necessary, to take corrective action. According to the OIG, corrective action may include an immediate referral to criminal and/or civil law enforcement authorities, a corrective action plan, a report to the federal government, or the submission of any overpayments.

If a hospital (through its compliance officer, compliance committee, or other management official) discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that misconduct may violate criminal, civil, or administrative law, then the hospital should report the misconduct promptly to the appropriate governmental authority within a "reasonable period," which the Hospital Guidelines indicate is not more than 60 days after determining that there is credible evidence of a violation. For a hospital to limit its damages under the False Claims Act's "not less than double damages" provision, the OIG states that a hospital's report must be provided to the Government within 30 days after the date when the hospital first obtains the information. Moreover, the OIG states that some violations might warrant immediate notification to governmental authorities. Such would be the case if the conduct: (1) is a clear violation of criminal law; (2) has a significant adverse effect on the quality of care provided to program beneficiaries; or (3) indicates evidence of systemic failure to comply with applicable laws, an existing corporate integrity agreement, or other standards of conduct, regardless of the financial impact on federal health care programs.

Medicaid and other publicly sponsored managed care initiatives.

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Practical Application

Given the increased scrutiny the federal government currently pays to false claims, fraud and abuse, and other similar issues, compliance with the Hospital Guidelines may afford hospitals the opportunity to avoid or mitigate criminal and civil penalties under the law. While the Hospital Guidelines serve as a foundation for compliance programs, however, each program must be tailored to the specific needs of a given hospital. Hospitals thus should be wary of approaching compliance with a "one size fits all" mentality. In designing and implementing a compliance program, hospitals would do well to heed the OIG's warning: programs hastily constructed and implemented without ongoing monitoring will likely be ineffective and

could result in greater harm or liability to a hospital than no program at all. In contrast, an *effective* compliance program allows hospitals to improve the quality of patient care, reduce fraud and abuse, and minimize the cost of health care to federal, state, and private health insurers.

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