OIG SUPPLEMENTS HOSPITAL COMPLIANCE PROGRAM GUIDANCE: 
Fraud and Abuse Risks Highlighted

On January 31, 2005, the Office of Inspector General (OIG) of the Department of Health and Human Services published its Supplemental Compliance Program Guidance for Hospitals (“Supplemental Guidance”). As the name suggests, the Supplemental Guidance adds to, rather than replaces, the OIG’s original 1998 Hospital Compliance Program Guidance (“1998 Guidance”). The Supplemental Guidance provides insight into the OIG’s current perception of potential compliance risks for hospitals, particularly in the fraud and abuse arena. The Supplemental Guidance also provides recommendations for hospitals voluntarily to evaluate and revise their compliance programs in an effort to enhance their ethics and business policies.

BACKGROUND

Over the years, the OIG has developed a series of voluntary compliance program guidelines directed at various segments of the health care industry – including clinical laboratories, physicians, and pharmaceutical manufacturers. The OIG’s initial Compliance Program Guidance for hospitals, published on February 23, 1998, was one of the first OIG compliance guidance documents for the health care industry.

In its 1998 Guidance, the OIG identified the benefits that can accrue to an organization that establishes a voluntary compliance program, such as detecting and preventing criminal conduct for which the hospital could be vicariously liable, and enhancing patient care practices and public relations. Additionally, a hospital’s preventative compliance efforts could reduce the criminal penalties the hospital might receive if ever convicted of a health care crime. In fact, the Federal Sentencing Guidelines Manual specifically states: “The prior diligence of an organization in seeking to prevent and detect criminal conduct has a direct bearing on the appropriate penalties and probation terms for the organization if it is convicted and sentenced for a criminal offense.”

The original 1998 Guidance for hospitals addresses the fundamentals for establishing an effective, voluntary compliance program. With little elaboration, the 1998 Guidance provides that, at a minimum, hospital compliance programs should include the following seven elements:

1. The development and distribution of written standards of conduct and written policies and procedures that promote compliance;

2. The designation of a chief compliance officer and other appropriate bodies (e.g., corporate compliance committee), charged with the responsibility of operating and monitoring the compliance program, 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 a complainant 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 employee violators;

(6) The use of audits or other evaluation techniques to monitor compliance and to assist in the reduction of identified problem areas; and

(7) The investigation and remediation of identified systematic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

In developing the written standards of conduct and policies and procedures noted in the first item above, the 1998 Guidance suggests that hospitals take into account the potential areas for regulatory exposure in each of the hospital’s functions and departments. The 1998 Guidance specifically notes some risk areas of particular concern to the OIG, which include: (1) billing for items or services not actually rendered; (2) providing medically unnecessary services; (3) upcoding; (4) “DRG creep”; (5) outpatient services rendered in connection with an inpatient stay; (6) teaching physicians and resident requirements for teaching hospitals; (7) duplicate billing; (8) false cost reports; (9) unbundling; (10) billing for discharge in lieu of transfer; (10) patients’ freedom of choice; (11) credit balances - failure to refund; (12) hospital incentives that violate the Anti-Kickback Statute or other similar federal or state statutes or regulations; (13) joint ventures; (14) financial arrangements between hospitals and hospital-based physicians; (15) Stark physician self-referral law; (16) knowing failure to provide covered services or necessary care to members of the health maintenance organization; and (17) patient dumping. The 1998 Guidance elaborates on outpatient services rendered in connection with inpatient stays, physicians at teaching hospitals, medical necessity of services, cost reports, and a few anti-kickback concerns (bad debt and credit balances).

In response to the need for further explanation of many of the risk areas noted above and significant changes to the way hospitals deliver and are reimbursed for health care services, the OIG solicited public suggestions for revising the 1998 Guidance on June 18, 2002. A draft Supplemental Guidance was issued on June 8, 2004, and the final Supplemental Guidance was published on January 31, 2005.

THE SUPPLEMENTAL GUIDANCE

I. INTRODUCTION

The Supplemental Guidance expands the discussion of several of the risk areas identified in the 1998 Guidance – taking into account changes to the hospital payment systems, the current OIG fraud and abuse enforcement posture, and industry practice. The Supplemental Guidance also identifies factors hospitals may use to evaluate their compliance program components. As with the 1998 Guidance, the recommendations are not mandatory and the OIG warns that the Supplemental Guidance is not to be considered an exhaustive discussion of risk areas or a model compliance program.
II. FRAUD AND ABUSE RISK AREAS

A. Submission of Accurate Claims and Information

OIG considers the preparation and submission of claims for reimbursement from the federal health care programs to be the largest risk area for hospitals. The Supplemental Guidance does not revisit some of the more obvious risks and penalties surrounding claims submission, such as improper coding, upcoding, or billing for unnecessary medical services. Rather, the OIG focuses on what it terms “evolving risks” that it believes are underappreciated in the health care industry. These “evolving risks” include: (1) outpatient procedure coding; (2) admissions and discharges; (3) supplemental payment considerations; and (4) use of information technology. The bulk of the OIG’s discussion references information or guidelines that are available from the OIG and the Centers for Medicare & Medicaid Services (CMS).

1. Outpatient Procedure Coding

Under the Medicare Outpatient Prospective Payment System (OPPS), hospitals are no longer reimbursed based on their charges for services, but are paid based on procedure codes. More specifically, procedures are assigned corresponding Ambulatory Payment Classification (APC) codes and hospitals receive a predetermined amount for each APC. In association with implementing the OPPS system and the use of APCs, CMS developed new rules for outpatient coding. The OIG emphasizes that hospitals should ensure that its coders are qualified and properly trained. Hospitals also are encouraged to review their outpatient documentation practices and to avoid coding with incomplete medical records that do not support the level of service claimed. In addition, the Supplemental Guidance identifies specific risk areas for outpatient procedure coding:

• Billing on an outpatient basis for “inpatient-only” procedures;
• Submitting claims for medically unnecessary services by failing to follow local policies for coverage determinations by the local fiscal intermediary;
• Submitting duplicate claims or failing to follow the National Correct Coding Initiative (NCCI) guidelines. Hospitals are encouraged to ensure that their software includes up-to-date NCCI edit files;
• Submitting incorrect claims for ancillary services based on outdated Charge Description Masters (CDMs). Hospitals are advised to update their CDMs regularly to account for changes in the Healthcare Common Procedure Coding System (HCPCS) codes and the APCs;
• Circumventing the multiple procedure discounting rules. Hospitals are urged to review the OPPS annual rule update to understand the discounting rules;
• Making improper evaluation and management (E/M) code selection;
• Improperly billing for observation services. The OIG explains that, in order to avoid liability, hospitals should become familiar with CMS policies because certain diagnoses have a separate APC for observation while in other situations observation is inappropriate.
2. **Admissions and Discharges**

The method and amount of reimbursement a hospital receives from federal health care programs varies depending upon the patient's condition at the time of admission or discharge. The OIG urges hospitals to update their admission and discharge policies to reflect the most current CMS rules. The OIG identifies the following admission and discharge risk areas:

- Failure to follow same day rules;
- Abuse of partial hospitalization payments;
- Same-day discharges and readmissions;
- Violation of Medicare's post-acute care transfer policy;
- Improper churning of patients by long-term care hospitals co-located in acute care hospitals.

The OIG advises hospitals against the practice of “churning,” or inappropriately transferring patients between a host hospital and the hospital-within-a-hospital. In addition, hospitals should ensure that they are familiar with the OPPS same-day billing rules, the post-acute care transfer policy and affected DRGs, and the hospital services for which there are Medicare per diem payments under the partial hospitalization program. In addition, the Supplemental Guidance recommends that hospitals review their admission and discharge policies to prevent premature discharges, medically unnecessary readmissions of patients, and improper billing and coding.

3. **Supplemental Payment Considerations**

The OIG expresses concern that hospitals may be abusing those limited situations in which a different payment rate or additional payment can be claimed by the hospital. The risk areas identified by the OIG include claims for: the costs of “pass-through” technology and drugs during a transitional period; DRG outlier payments; services furnished by “provider-based” entities; services furnished during clinical trials; organ acquisition costs; cardiac rehabilitation services; and costs related to educational activities.

4. **Use of Information Technology**

Due to hospitals’ increasing reliance on electronic claims submission, electronic prescribing, and information sharing among health care providers, the Supplemental Guidance recommends that hospitals become familiar with the operation of their computer systems and software responsible for coding, billing, or the generation or transmission of information to the federal health care programs.

B. **The Referral Statutes: The Stark Law and Federal Anti-Kickback Statute**

The OIG expands the brief discussion of the federal referral statutes in its initial 1998 Guidance and provides a number of references to applicable authorities, OIG advisories and fraud alerts, and related documents.
1. The Physician Self-Referral ("Stark") Law

For purposes of analyzing a financial relationship under the Stark law, the OIG offers the following three-part inquiry:

1) Is there a referral from a physician for a designated health service? If not, then there is no Stark law issue (although other fraud and abuse laws, such as the Anti-Kickback Statute, may be implicated). If the answer is “yes,” then ask:

2) Does the physician (or an immediate family member) have a financial relationship with the entity furnishing the DHS (e.g., the hospital)? Again, if the answer is no, the Stark law is not implicated. But if the answer is “yes,” then ask:

3) Does the financial relationship fit in an exception? If not, the statute has been violated.

Any financial relationship between the hospital and a physician who refers to the hospital “must squarely meet all of the conditions” set forth in a statutory or regulatory exception to the Stark law. The OIG recommends that, “[t]o avoid a large overpayment, hospitals should ensure frequent and thorough review of their contracting and leasing processes.” The OIG stresses that it is the “actual relationship between the parties, and not merely the paperwork,” that must fit in an exception. Unlike the Anti-Kickback safe harbors, which are voluntary, fitting in an exception is mandatory under the Stark law. As such, the Stark law sets a kind of minimum standard for arrangements between physicians and hospitals – hospitals may view it as a “threshold” statute from a compliance perspective. Accordingly, even if a hospital-physician relationship qualifies for a Stark law exception, a hospital still should review it for compliance with the Anti-Kickback Statute.

2. The Federal Anti-Kickback Statute

Although liability under the federal Anti-Kickback Statute is based on a party’s intent, the OIG believes that certain arrangements or practices may present a significant potential for abuse. In analyzing an arrangement or practice under the Anti-Kickback Statute, the OIG suggests the following two inquiries:

• Does the hospital have any remunerative relationship between itself (or its affiliates or representatives) and persons or entities in a position to generate federal health care program business for the hospital (or its affiliates) directly or indirectly? Persons or entities in a position to generate federal health care program business for a hospital include physicians and other health care professionals, ambulance companies, clinics, hospices, home health agencies, nursing facilities, and other hospitals.

• With respect to any such remunerative relationship, could one purpose of the remuneration be to induce or reward the referral or recommendation

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4 In addition, the OIG’s position is that, under certain circumstances, a knowing violation of the Stark law may also give rise to liability under the False Claims Act.

5 OIG’s position is that hospitals also should be mindful that compliance with the Anti-Kickback Statute is a condition of payment under Medicare and other federal health care programs and, as such, liability may arise under the False Claims Act where the Anti-Kickback Statute violation results in the submission of a claim for payment under a federal health care program.
of business payable in whole or in part by a federal health care program? OIG stresses that, under the Anti-Kickback Statute, neither a legitimate business purpose for the arrangement nor a fair market value payment will legitimize a payment if there is also an illegal purpose (i.e., inducing federal health care program business).

Any arrangement satisfying both tests implicates the Anti-Kickback Statute and requires careful scrutiny by a hospital. The OIG recommends that hospitals ask the following questions, among others, about any potentially problematic arrangements or practices they identify:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase costs to federal health care programs, beneficiaries, or enrollees?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Hospitals that have identified potentially problematic arrangements or practices can take a number of steps to reduce or eliminate the risk of an Anti-Kickback violation. Foremost, the Anti-Kickback Statute and the corresponding regulations establish a number of “safe harbors” for common business arrangements. In assessing compliance with a safe harbor, the OIG examines whether the written contract satisfies all of the safe harbor requirements as well as whether the “actual” arrangement satisfies the requirements. Hospitals should keep in mind that, as noted above, compliance with the Anti-Kickback Statute and the Stark law must be evaluated separately.

Hospitals should closely scrutinize the areas of activity below, as the OIG has identified them as having the potential for abuse. Because physicians are the primary referral source for hospitals, most of the discussion focuses on a hospital’s relationships with physicians. However, hospitals should use these same principles to review their relationships with non-physician referral sources (such as ambulance companies, clinics, and other hospitals) to determine that the relationships do not violate the Anti-Kickback Statute.

a. **Joint Ventures**

The OIG has a long-standing concern about joint venture arrangements between those in a position to refer or generate federal health care program business and those providing items or services reimbursable by federal health care programs.

When scrutinizing joint ventures under the Anti-Kickback Statute, the OIG recommends that hospitals examine factors including: (1) the manner in which joint venture participants are selected and retained; (2) the manner in which the joint venture is structured; and (3) the manner in which the investments are financed and profits are distributed. Whenever possible, hospitals should structure joint ventures to fit squarely in one of the safe harbors for investment interests or the hospital-physician ambulatory surgical center safe harbor.
Joint ventures may take a variety of forms, including a contractual arrangement between two or more parties to cooperate in a common and distinct enterprise providing items or services, thereby creating a “contractual joint venture.” Contractual joint ventures pose the same kinds of risks as equity joint ventures and should be analyzed similarly.

The OIG cautions that, if a hospital is planning to participate, directly or indirectly, in a joint venture involving referring physicians and the venture does not qualify for safe harbor protection, the hospital should scrutinize the venture with care, taking into account the factors noted above, and should consider obtaining advice from an experienced attorney. To reduce the risk of abuse, OIG suggests that hospitals should consider, among other things:

• Barring physicians employed by the hospital or its affiliates from referring to the joint venture;
• Taking steps to ensure that medical staff and other affiliated physicians are not encouraged in any manner to refer to the joint venture;
• Refraining from tracking in any manner the volume of referrals attributable to particular referrals sources; and
• Ensuring that no physician compensation is tied in any manner to the volume or value of referrals to, or other business generated for, the venture.

b. Compensation Arrangements with Physicians

Typical compensation arrangements between hospitals and physicians include medical director agreements, personal or management services agreements, space or equipment leases, and agreements for the provision of billing, nursing, or other staff services. In the Supplemental Guidance, the OIG recommends that hospitals review their physician compensation arrangements and carefully assess the risk of fraud and abuse using factors including those identified by the OIG. Whenever possible, hospitals should structure their compensation arrangements with physicians to fit in a safe harbor. At minimum, hospitals should develop policies and procedures requiring physicians to document, and the hospital to monitor, the services or items provided under compensation arrangements (including, for example, by using written time reports).

The OIG points out that arrangements between hospitals and traditional hospital-based physicians (such as anesthesiologists, radiologists, and pathologists) also can raise Anti-Kickback concerns when, for example, a hospital requires physicians to pay more than the fair market value for services provided to the hospital-based physicians or a hospital compensates physicians less than the fair market value for goods or services provided to the hospital by the physicians.

c. Relationships with Other Health Care Entities

When a hospital is the referral source for other providers or suppliers, it should scrutinize carefully any remuneration flowing to the hospital from the provider or supplier to ensure compliance with the Anti-Kickback Statute, using the principles outlined above. Remuneration may include, for example, free or below-market-value items and services or the relief of a financial obligation. Hospitals should also review their managed care arrangements to ensure compliance with the
Anti-Kickback Statute, evaluating arrangements that do not fit within one of the managed care and risk-sharing safe harbors on a case-by-case basis.

d. Recruitment Arrangements

Safe harbor protection is available for certain recruitment arrangements offered by hospitals to attract primary care physicians and practitioners to health professional shortage areas (HPSAs), as defined in regulation. The OIG notes that the scope of this safe harbor is very limited; in particular, the safe harbor does not protect: (2) recruitment arrangements in areas that are not designated as HPSAs; (2) recruitment of specialists; or (3) joint recruitment with existing physician practices in the area. OIG recommends that, because of the significant risk of fraud and abuse posed by improper recruitment arrangements, hospitals should scrutinize these arrangements, examining factors that include the size and value of the recruitment benefit, the duration of payout of the recruitment benefit, the practice of the existing physician, and the need for the recruitment.

e. Discounts

The Anti-Kickback Statute contains an exception for discounts offered to customers that submit claims to the federal health care programs, so long as the discounts are properly disclosed and accurately reported. The discount safe harbor does not, however, protect a discount offered to one payor but not to the federal health care programs. In negotiating discounts for items and services paid from a hospital’s pocket (such as those reimbursed under the Medicare Part A prospective payment system), the hospital should determine that there is no link or connection, explicit or implicit, between discounts offered or solicited for that business and the hospital’s referral of business billable by the seller directly to Medicare or another federal health care program.

f. Medical Staff Credentialing

Certain medical staff credentialing practices may implicate the Anti-Kickback Statute. Risk areas include conditioning privileges on a particular number of referrals or requiring the performance of a particular number of procedures beyond volumes necessary to ensure clinical proficiency. Whether a particular credentialing policy violates the Anti-Kickback Statute depends on the specific facts and circumstances, including the intent of the parties. The OIG has solicited comments about whether further guidance in this area is appropriate.

g. Malpractice Insurance Subsidies

The OIG has established a safe harbor for medical malpractice premium subsidies provided to obstetrical care practitioners in health professional shortage areas. Depending on the circumstances, premium support may also be structured to fit in other safe harbors. While the OIG acknowledges the current “disruption” (dramatic premium increases, insurers’ withdrawals from certain markets, and/or sudden termination of coverage based upon factors other than the physicians’ claims history) in the medical malpractice liability insurance markets in some geographic areas, it continues to recommend that hospitals review malpractice insurance subsidy arrangements closely to ensure that there is no improper inducement to referral sources. The OIG lists several relevant factors in the
Supplemental Guidance, no one of which is determinative. Parties also should be mindful that these subsidy arrangements also may implicate the Stark law.

C. Payments to Reduce or Limit Services: Gainsharing Arrangements

The Civil Monetary Penalty ("CMP") statute set forth in section 1128A(b)(1) of the Social Security Act (the "Act") prohibits a hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care. In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute. While there is no fixed definition of a "gainsharing" arrangement, the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts.

In addition to this CMP risk, gainsharing arrangements also can implicate the Anti-Kickback Statute if the cost-savings payments are used to influence referrals. Hospitals should consider structuring cost-saving arrangements to fit in the personal services safe harbor. In many cases, though, protection under the personal services safe harbor is not available because gainsharing arrangements typically involve a percentage payment (that is, the aggregate fee will not be set in advance, as required by the safe harbor)

D. Emergency Medical Treatment and Labor Act (EMTALA)

Hospitals should review their obligations under EMTALA to evaluate and treat individuals who come to their emergency departments and, in some circumstances, other facilities. Hospitals should pay particular attention to when an individual must receive a medical screening exam to determine whether that individual is suffering from an emergency medical condition. Thus, hospital policies and procedures should clearly provide how to access the full services of the hospital, and all staff should understand the hospital's obligations to individuals under EMTALA. In particular, on-call physicians need to be educated as to their responsibilities under EMTALA, including the responsibility to accept appropriately transferred individuals from other facilities.

E. Substandard Care

The OIG has the authority to exclude any individual or entity from participation in federal health care programs if the individual or entity provides unnecessary items or services or substandard items or services. Significantly, neither knowledge nor intent is required for this type of exclusion. The exclusion can be based on unnecessary or substandard items or services provided to any patient, even if that patient is not a Medicare or Medicaid beneficiary.

F. Relationships with Federal Health Care Beneficiaries

The CMP law authorizes the OIG to impose CMPs on hospitals (and others) that offer or transfer remuneration to a Medicare or Medicaid beneficiary that the offeror knows or should know is likely to influence the beneficiary to order or receive items or services from a particular provider, practitioner, or supplier for which payment may be made under the Medicare or Medicaid programs. The definition of “remuneration” expressly includes the offer or transfer of items or services for free or other than fair market value, including the waiver of all or part of a Medicare or Medicaid cost-sharing amount. In other words, hospitals may not offer valuable items or services to Medicare or Medicaid beneficiaries to attract their business. As interpreted by the OIG, this prohibition does not apply to the provision of items or services valued at less than $10 per item and $50 per patient in the aggregate on an annual basis.

1. Cost-Sharing Waivers

In general, hospitals are obligated to collect cost-sharing amounts owed by federal health care program beneficiaries. Waiving owed amounts may constitute prohibited remuneration to beneficiaries under the CMP law or the Anti-Kickback Statute. Certain waivers of Part A inpatient cost-sharing amounts may be protected by structuring them to fit in the safe harbor for waivers of beneficiary inpatient coinsurance and deductible amounts. The OIG has proposed a rule to extend this safe harbor to protect waivers of Part B cost-sharing amounts pursuant to agreements with Medicare SELECT plans.

In addition, hospitals (and others) may waive cost-sharing amounts on the basis of a beneficiary’s financial need, so long as the waiver is not routine, not advertised, and made pursuant to a good faith, individualized assessment of the beneficiary’s financial need or after reasonable collection efforts have failed.

The OIG states that hospitals should: (1) use a reasonable set of financial need guidelines that are based on objective criteria and appropriate for the applicable locality and should apply the guidelines uniformly; (2) recheck a patient’s eligibility at reasonable intervals sufficient to ensure that the patient remains in financial need; and (3) take reasonable measures to document their determinations of Medicare beneficiaries’ financial need.

2. Free Transportation

The CMP statute prohibits offering free transportation to Medicare or Medicaid beneficiaries to influence their selection of a particular provider, practitioner, or supplier. Still, hospitals can offer free local transportation of low value (within the $10 per item and $50 annual limits). The OIG is considering developing a regulatory exception for some complimentary local transportation provided to beneficiaries residing in a hospital’s primary service area. The Supplemental Guidance provides temporary guidelines for hospital-based complimentary transportation programs. Other arrangements are subject to a case-by-case review under the statute to ensure that no improper inducement exists.
G. HIPAA Privacy and Security Rules
A hospital’s compliance program should address its obligations under HIPAA Privacy and Security Rules. As of April 14, 2003, most hospitals were required to comply with the HIPAA Privacy Rule. Generally, the HIPAA Privacy Rule addresses the use and disclosure of individually identifiable health information, as well as standards for privacy rights. The final HIPAA Security Rule specifies a series of administrative, technical, and physical security safeguards to assure the confidentiality of electronic protected health information. Hospitals must be compliant with the Security Rule by April 21, 2005.

H. Billing Medicare or Medicaid Substantially in Excess of Usual Charges
The Social Security Act provides for the permissive exclusion from federal health care programs of any provider or supplier that submits a claim based on costs or charges to the Medicare or Medicaid programs that is “substantially in excess” of its usual charge or cost, unless there is “good cause” for the higher charge or cost. The exclusion provision does not require a provider to charge everyone the same price, nor does it require a provider to offer Medicare or Medicaid its “best price.” However, providers cannot routinely charge Medicare or Medicaid substantially more than they usually charge others. Hospitals have raised concerns regarding the impact of the exclusion authority on hospital services, and the OIG is considering those concerns in the context of the rulemaking process.

I. Areas of General Interest
Although in most cases the following areas do not pose significant fraud and abuse risk, the OIG has received numerous inquiries from hospitals and others on these topics. Therefore, it offers guidance to assist hospitals in their review of these arrangements.

1. Discounts to Uninsured Patients
No OIG authority, including the federal Anti-Kickback Statute, prohibits or restricts hospitals from offering discounts to uninsured patients who are unable to pay their hospital bills. Discounts offered to underinsured patients potentially raise a more significant concern under the Anti-Kickback Statute, and hospitals should exercise care to ensure that such discounts are not tied directly or indirectly to the furnishing of items or services payable by a federal health care program.

The OIG has never excluded or attempted to exclude any provider or supplier for offering discounts to uninsured or underinsured patients under its permissive exclusion authority. To provide additional assurance to the industry, however, the OIG recently proposed regulations that would define key terms in the statute and is currently reviewing the public comments to the proposed regulations. Until such time as a final regulation is promulgated or the OIG indicates its intention not to promulgate a final rule, it will continue to be the OIG’s enforcement policy that when calculating their “usual charges”, individuals and entities do not need to consider free or substantially reduced charges to: (1) uninsured patients; or (2) underinsured patients who are self-paying
patients for the items or services furnished. In offering such discounts, a hospital should report full uniform charges, rather than the discounted amounts, on its Medicare cost report and make the fiscal intermediary aware that it has reported its full charges. The Supplemental Guidance also discusses Medicare reimbursement for a portion of a hospital’s “bad debt” (uncollectible Medicare deductible or coinsurance amounts) in connection with indigent or medically indigent patients.

2. **Preventive Care Services**

   The prohibition against beneficiary inducements in the CMP law does not apply to incentives offered to promote the delivery of certain preventive care services if the programs are structured in accordance with the applicable regulatory requirements. Generally, to fit within the preventive care exception, a service must be a prenatal service or post-natal well-baby visit or a specific clinical service described in the current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services that is reimbursed by Medicare or Medicaid. From an Anti-Kickback perspective, the OIG’s chief concern is whether an arrangement to induce patients to obtain preventive care services is intended to induce other business payable by a federal health care program. Relevant factors in making this evaluation include: (1) the nature and scope of the preventive care services; (2) whether the preventive care services are tied directly or indirectly to the provision of other items or services and, if so, the nature and scope of the other services; (3) the basis on which patients are selected to receive the free or discounted services; and (4) whether the patient is able to afford the services.

3. **ProfessionalCourtesy**

   In general, whether a professional courtesy program violates the Anti-Kickback Statute turns on 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. Also relevant is whether the physicians have solicited the professional courtesy in return for referrals. With respect to the Stark law, the key inquiry is whether the arrangement fits in the exception for professional courtesy. In addition, hospitals should evaluate the method by which the courtesy is granted. For example, “insurance only” billing offered to a federal program beneficiary potentially implicates the Anti-Kickback Statute, the False Claims Act, and the CMP provision prohibiting inducements to Medicare and Medicaid beneficiaries.

**III. HOSPITAL COMPLIANCE PROGRAM EFFECTIVENESS**

**A. Code of Conduct and Regular Review of Compliance Program Effectiveness**

   In the Supplemental Guidance, the OIG emphasizes the importance of corporate governance and self-assessment in effectively implementing a hospital compliance program. The Supplemental Guidance provides recommendations on the development of a clear code of conduct and for the regular review of the compliance program effectiveness.
The OIG focuses its discussion on development of an organizational culture that values effective compliance from the top down. To this end, the OIG recommends the adoption of a code of conduct developed by the hospital's management and leadership that should function as the hospital's constitution. The guidance suggests that the code of conduct be a short, easily readable, organizational statement of the fundamental ethical values and principles that articulates a commitment to compliance.

Even after the hospital successfully implements a compliance program, the OIG urges regular review of the program’s elements. In this regard, the OIG revisits the seven elements of a successful compliance program and lists a number of factors a hospital should consider when reviewing the elements of its compliance program. The Supplemental Guidance suggests that relying exclusively on outcomes to assess the compliance program’s effectiveness can overlook underlying structural problems that might perpetuate errors. The OIG highlights the following factors:

1. **Designation of a Compliance Officer and Compliance Committee**
   - Consider the purpose, organization, and resources available to the compliance department;
   - Does the compliance committee represent a cross-section of the hospital, are its members properly trained and is there a working relationship with other key departments?
   - Does the compliance committee have the ability to create ad hoc committees, special task forces and the ability to retain outside counsel?
   - Does the compliance officer and compliance committee have direct access to the hospital’s management and regularly report to the hospital leadership?

2. **Development of Compliance Policies and Procedures, Including Standards of Conduct**
   - Are the written policies and procedures clear, relevant to daily hospital functions and easily accessible to the hospital’s leadership, management, medical staff and employees?
   - Has the hospital developed a risk assessment tool that includes evaluating compliance with federal health care program requirements?
   - Are the policies, procedures and the risk assessment tool reevaluated on a regular basis?

3. **Developing Open Lines of Communication**
   - Are there methods of communicating potential compliance issues that shield informants from retaliation and promote compliance reporting?
   - Are all complaints investigated and shared with the hospital’s governing body?
   - Does the governing body actively address institutional or recurring problems?
4. **Appropriate Training and Education**

The failure to train and educate hospital staff adequately can potentially result in the violation of health care fraud and abuse laws. The OIG recommends that hospitals evaluate their training and education programs by considering the following:

- Does the hospital provide qualified trainers for its staff and is the program up-to-date on recent changes to the federal health care programs?
- Does the training program consider results from hotline reporting, internal audits and investigations, and previous education and training?
- Does the hospital regularly evaluate its training format, impose sanctions for failing to attend training, seek feedback from its staff and conduct post-training testing?
- Has the hospital’s governing body been adequately trained and is the completion of training appropriately documented?

5. **Internal Monitoring and Auditing**

Detailed audit plans help hospitals avoid submitting incorrect claims. The Supplement Guidance offers the following factors for hospitals to evaluate the effectiveness of their internal audit plans:

- Is the audit plan reevaluated regularly and does the plan account for high volume services or concerns identified by the hospitals’ annual risk assessment?
- Does the audit plan include assessment of the billing system, specific error rates of the hospital and all billing documentation?
- Is the audit department’s role clearly established and can it conduct unscheduled reviews or request additional audits or further investigations?

6. **Response to Detected Deficiencies**

When deficiencies are detected, hospitals can help limit losses to the federal health care programs by developing effective corrective action plans. The OIG suggests the following factors for hospitals to evaluate the effectiveness of their response to deficiencies:

- Does the hospital have a response team with representatives from different functional areas in the hospital?
- Do the corrective action procedures promptly and thoroughly investigate the root cause of the problem and does the hospital evaluate the corrective action plans regularly?
- Are violations of law reported to the appropriate enforcement agency and are overpayments identified by the hospital promptly reported and repaid to the fiscal intermediary?
7. Enforcement of Disciplinary Standards

Enforcement of disciplinary standards strengthens the ethical culture of an organization. The OIG recommends that hospitals consider the following factors when evaluating its disciplinary standards:

- Are the disciplinary standards available to all personnel and consistently enforced at each level of the organization?
- Is each instance of disciplinary action enforcement documented?
- Does the hospital regularly check its staff and contractors against the federal health care program exclusion lists?

IV. SELF REPORTING

As with the 1998 Guidance, the Supplemental Guidance states that hospitals should promptly report the existence of misconduct to the appropriate federal and state authorities within a reasonable period, but not more than 60 days, after determining that there is credible evidence of a criminal, civil or administrative law violation. According to the Supplemental Guidance, prompt voluntary reporting will demonstrate the hospital’s good faith and willingness to work with governmental authorities to correct and remedy the problem, and the OIG will consider reporting such conduct a mitigating factor in determining administrative sanctions (such as penalties, assessments, and exclusion) if the hospital becomes the subject of an OIG investigation.

CONCLUSION

Voluntary compliance programs are essential to today’s health care industry. With prosecutions for fraud and abuse at an all-time high, hospitals cannot afford to fail in establishing these types of programs to mitigate the risks of health care violations. Hospitals should take this opportunity to review and revise their compliance programs to ensure a good faith effort to comply with the law. If you need assistance in establishing, revising or auditing your compliance program, please consult one of the Alston & Bird attorneys listed below.
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