

## HEALTH INDUSTRY ALERT

### OIG'S SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE FOR HOSPITALS: HIGHLIGHTS, INSIGHTS AND PRACTICAL RECOMMENDATIONS

On January 31, 2005, the Office of Inspector General of the Department of Health and Human Services (OIG) published the Supplemental Compliance Program Guidance for Hospitals (SCPG) in the Federal Register.<sup>1</sup> Like the original Compliance Program Guidance for Hospitals (CPG) issued in 1998, this guidance is not itself a "model compliance program" but rather, considered collectively with the original CPG, is intended to "offer a set of guidelines that hospitals should consider when developing and implementing a new compliance program or evaluating an existing one." Most notably, the SCPG (1) discusses in extensive detail numerous specific fraud and abuse risk areas upon which hospitals should focus their compliance efforts, (2) emphasizes the critical role played by corporate leadership in compliance efforts and (3) focuses on the need for hospitals continually to evaluate and enhance the effectiveness of their existing compliance programs.

At a January 27, 2005 conference of health care attorneys, Lewis Morris, the OIG chief counsel, offered that the SCPG compiled currently available compliance guidance into one document in a "succinct, well-written and digestible" format. For hospitals with existing compliance programs, the SCPG "may serve as a benchmark or comparison against which to measure ongoing efforts and as a roadmap for updating or refining their compliance plans." Interspersed throughout the SCPG are important clues regarding the OIG's potential enforcement and regulatory priorities. This Alert highlights the most significant aspects of the SCPG, provides some basic insights into the OIG's thinking, and recommends practical steps that hospitals can take to reduce their risks and enhance their compliance efforts.

#### FRAUD AND ABUSE RISK AREAS

The OIG identifies a number of risk areas "that are currently of concern to the enforcement community." Among these are (1) submission of accurate claims and information, (2) the Referral Statutes, (3) payments to reduce or limit services, (4) the Emergency Medical

<sup>1</sup> The SCPG can be found at 70 Fed. Reg. 4858 (Jan. 31, 2005) or on the OIG Web site at <http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>. The original 1998 CPG is also available at <http://oig.hhs.gov/authorities/docs/cpghosp.pdf>.

Treatment and Labor Act (EMTALA), (5) substandard care, (6) relationships with federal health care program beneficiaries, (7) HIPAA privacy and security rules and (8) billing Medicare or Medicaid substantially in excess of usual charges. The OIG also discusses areas of general and continuing interest to the hospital community, but not necessarily matters of substantial risk. Although we encourage hospitals and their compliance officers to review the SCPG in its entirety, as all the risks noted by the OIG are important, we highlight below several of the most significant areas of discussion in the SCPG.

### **SUBMISSION OF ACCURATE CLAIMS AND INFORMATION**

Not surprisingly, the OIG identifies billing of federal health care programs as the “single biggest risk area” for hospitals. The OIG cautions that hospitals should remain diligent regarding the long-standing coding and billing risk areas identified in the original CPG but does not address those in any detail. Rather, the OIG focuses its discussion on what it considers to be “evolving risks” or risks that appear to be “underappreciated” by the industry.

Prominent among these are risks related to billing under the Outpatient Prospective Payment System (OPPS), which the OIG cautions is subject to the same kind of improper and/or false claims procedure coding risks that have previously characterized the inpatient PPS system. Consequently, the OIG admonishes hospitals to “pay close attention to coder training and qualifications.” Finding and maintaining highly trained and qualified coders has represented a long-standing challenge for many hospitals. Yet, it is clear from the OIG’s remarks that it expects hospitals to improve this area of operations and that compliance programs should play a role in this process.

Without interfering with operational management, compliance programs can play a constructive role in this area by doing the following:

- Work with HIM departments to develop coding training programs that promote accurate coding and to identify potential risk areas
- Include coder training and qualifications in annual risk assessments
- Ensure that performance evaluations of coding and HIM department managers incentivize the creation of “professionalized” coding departments.

Although not addressed further in this Alert, the SCPG also identifies several specific risk areas related to OPPS and describes in detail other major areas of risk related to improper claims submission. These include the admission and discharge processes; reporting of “pass-through” items; abuse of outlier payments; and improper claims for provider-based entities, clinical trials, organ acquisition costs, cardiac rehabilitation services and educational activities. Given that it is not practically feasible for hospital compliance programs to monitor effectively every risk area identified by the OIG, hospitals should use the SCPG as a tool to identify issues that should be included in department-level risk assessments. Based on the results of such assessments, hospitals can focus on their most significant potential issues.

### **REFERRAL STATUTES**

Perhaps most striking about the SCPG’s discussion of the Physician Self-Referral Law (the Stark Law) and the Federal Anti-Kickback Statute (Referral Statutes) is the centrality and breadth of the discussion itself, taking up over one third

of the overall guidance. The SCPG does not break any significant new ground, as it generally summarizes existing statutory and regulatory authorities as well as previous OIG policy pronouncements. However, that the OIG has chosen to place such great emphasis on the Referral Statutes in this guidance appears to be significant. This prominence is consistent with the OIG's recent enforcement focus on anti-kickback Civil Monetary Penalties Law (CMPL) actions and the dramatic rise in False Claims Act (FCA) *qui tam* actions predicated on alleged violations of the Referral Statutes. Thus, it appears that the OIG is sending the message that not only should compliance with the Referral Statutes be a priority for hospitals, but hospital compliance programs should play a vital role in ensuring such compliance. As a result, hospitals that have previously viewed their compliance programs narrowly, as being responsible only for Medicare billing and coding compliance, should strongly consider expanding their programs' scope.

**Stark Law.** In its discussion of the Stark Law, the OIG cautions hospitals that the law should be considered a "threshold statute." It stresses that the Stark Law is a strict liability statute that prohibits the submission of, and Medicare payment for, any claim for a designated health service (DHS) pursuant to referrals originating from a physician with whom the hospital has a prohibited financial relationship. Additionally, a "knowing" violation of the Stark Law can subject violators to civil monetary penalties and exclusion from federal health care programs. Moreover, the OIG notes that a Stark Law violation can serve as a predicate for liability under the FCA.

The OIG also provides that hospitals must scrutinize the "actual relationship" between the parties, not merely the contract, and that the relationship must fit squarely into a statutory or regulatory exception. The OIG admonishes that the technical or inadvertent noncompliance exception incorporated into the final Stark II regulations "is not a substitute for vigilant contracting and leasing oversight."

In short, since all inpatient and outpatient hospital services furnished to Medicare and Medicaid patients (including directly furnished services and those paid "under arrangement") are DHS, the SCPG underscores the need for hospitals to review diligently all financial relationships with referring physicians to make certain that such relationships fit squarely into a statutory or regulatory Stark Law exception. Because of the significant exposure for hospitals under the Stark Law, hospitals should implement systems, such as frequent and thorough review of their contracting and leasing processes and processes for making and documenting reasonable determinations of fair market value. And, finally, even if a hospital-physician relationship qualifies for a Stark Law exception, it must still be reviewed for compliance with the Anti-Kickback Statute.

**Federal Anti-Kickback Statute.** At the outset, the OIG reminds hospitals that their compliance with the Anti-Kickback Statute is a condition of payment under Medicare and federal health care programs, and thus noncompliance with it can subject hospitals to potential liability under the FCA. Similar to its statements regarding the Stark Law, the OIG appears to endorse fully the controversial policy of enforcing the Anti-Kickback Statute by "bootstrapping" it under the FCA. Transitioning from enforcement warnings to guidance, the OIG provides a framework of questions for hospitals to pose in their analyses of referral arrangements. Additionally, the OIG counsels hospitals to strive to fit their arrangements into regulatory safe harbors whenever possible.

The SCPG contains a detailed discussion of several risk areas under the Anti-Kickback Statute, including (1) joint ventures, (2) compensation arrangements with physicians, (3) relationships with other entities, (4) recruitment arrangements, (5) discounts, (6) medical staff credentialing, (7) malpractice insurance subsidies and (8) gainsharing. We discuss several of these risk areas below.

**Joint Ventures.** The OIG highlights its “long-standing concern” about joint venture arrangements, which it believes can disguise “payment for past or future referrals to the venture or to one or more of its participants.” Recapping its concerns previously discussed in its 1989 Special Fraud Alert on Joint Venture Arrangements and its 2003 Special Advisory Bulletin on Contractual Joint Ventures, the OIG admonishes hospitals to “scrutinize” potential ventures with care.

**Compensation Arrangements.** The OIG focuses on “fair market value” in its discussion of compensation arrangements with physicians. In addition to providing a detailed list of factors that hospitals should utilize to assess such arrangements for fraud and abuse risks, the OIG particularly cautions hospitals to develop policies and procedures requiring the physician to document and the hospital to monitor the services being provided by the physician under the arrangement. Finally, the OIG underlines that hospitals must also scrutinize their relationships with other entities to which they might refer patients, such as nursing homes or durable medical equipment companies. Thus, hospitals should subject such arrangements to careful review using the same principles they apply to physician arrangements.

**Recruitment Arrangements.** Physician recruiting is singled out by the OIG as an area that “pose[s] substantial fraud and abuse risk.” Hospitals should particularly scrutinize “joint recruiting” arrangements, under which the hospital makes payments directly or indirectly to other entities such as group practices into which a physician is recruited. The OIG emphasizes that such “joint” arrangements are not given safe harbor protection, present a “high risk of fraud and abuse and have been the subject of recent government investigations and prosecutions.”

**Gainsharing.** The OIG highlights gainsharing<sup>2</sup> as a fraud and abuse risk because it runs afoul of the plain language of the CMPL that prohibits a hospital from knowingly making a payment to a physician as an inducement to limit items or services provided to Medicare or Medicaid beneficiaries under the physician’s direct care. The OIG cautions that the CMPL provision is very broad. However, it recognizes that many hospitals engage in or are considering such arrangements because they “can serve legitimate business and medical purposes.” The OIG also cautions that gain-sharing can pose risks under the Anti-Kickback Statute when used to influence referrals; for example, when hospitals provide remuneration to physicians for “cherry-picking” healthy patients in exchange for the hospital offering gain-sharing payments and steering sicker (and more costly) patients to other hospitals not offering such payments.

As noted above, the OIG appears to expect compliance programs to play a key role in ensuring hospital compliance with the Referral Statutes. If properly structured, traditional legal review processes for dealing with the Referral Statutes and compliance program activities can be effectively integrated, without undue duplication or inconsistent treatment. Here are a few practical steps compliance programs can perform to add value to the review process:

- Ensure that financial relationships and the Referral Statutes are accorded appropriate coverage and emphasis in the Code of Conduct, written policies, and general and specialized compliance training

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<sup>2</sup> While the OIG acknowledges that there is no fixed definition of such arrangements, it notes that the term typically refers to various incentive arrangements referred to as gainsharing, where a hospital gives physicians a percentage share of any reduction in the hospital’s costs for patient care attributable in part to the physician’s efforts. Notably, the OIG just issued a favorable Advisory Opinion on a gainsharing arrangement, and more Advisory Opinions on gainsharing are expected to be released in the very near future.

- Disseminate information to referral sources regarding the hospital's policies on the Referral Statutes and key regulatory or enforcement developments (in a manner tailored to the hospital's needs and resources)
- Design compliance monitoring protocols to focus on contract performance (e.g., monitoring whether the medical director is actually providing the services described in the personal services contract)

## **SUBSTANDARD CARE**

It seems particularly noteworthy that the OIG has incorporated into the SCPG a discussion of substandard care as a significant risk area. This incorporation should be read in the context of several recent high-profile enforcement actions against hospitals and physicians that were centered on substandard care allegations, as well as recent reports issued by the Institute of Medicine regarding the prevalence of clinical errors in hospitals. This explicit focus may be a further signal that the OIG (and the government more generally) is opening a new front in its fraud enforcement initiatives. The OIG cautions hospitals to be mindful of its substandard care permissive exclusion authority (section 1128(b)(6)(B) of the Social Security Act). Notably, this authority does not include a knowledge or intent element, and can be invoked for substandard care provided to any patient, not just Medicare and Medicaid beneficiaries.

While the OIG says it recognizes that the vast majority of hospitals are fully committed to providing quality care, it counsels hospitals to ensure that they meet all Medicare conditions of participation, including those related to quality. The OIG recommends that in addition to relying upon JCAHO survey processes, hospitals "should develop their own quality of care protocols and implement mechanisms for evaluating compliance with those protocols." Such protocols should include "overseeing the credentialing and peer review of their medical staffs." Notwithstanding these broad formulations, the OIG does not provide any detail regarding how it expects hospital compliance programs to be involved in such initiatives – an area that has typically been outside the primary concern of most compliance programs.

## **HOSPITAL COMPLIANCE PROGRAM EFFECTIVENESS**

A primary theme of the SCPG under this section is the importance of organizational culture and the responsibility of hospital governing bodies and senior management to instill a culture that values compliance. This focus dovetails with the OIG's recent foray into providing guidance on corporate governance issues, where it has stressed the role of hospital boards and senior management in overseeing and ensuring that hospitals have effective compliance programs. In addition to these corporate governance themes, the OIG emphasizes the need for appropriate structures and processes to create effective internal controls and regular assessment and enhancement of the existing compliance program.

Noting that the 1998 CPG has already provided details regarding the key elements of an effective compliance program, the OIG does not describe those elements in detail here. However, in accordance with its central emphasis on corporate responsibility, it underscores the role of the board and senior management in establishing a formal commitment to compliance expressed through an organizational Code of Conduct. Moreover, organizational leadership must demonstrate such commitment by being actively involved in the program, allocating appropriate resources to it, and vesting a compliance officer and committee with sufficient autonomy, authority and accountability to maintain an

effective program. According to the OIG, the hospital “should endeavor to develop a culture that values compliance from the top down and fosters compliance from the bottom up.”

Although some experts have previously recognized that an effective compliance program includes regular assessments of the program itself, the OIG has now made that expectation explicit. The OIG expects such review to take place annually. The OIG also cautions hospitals not to rely solely on outcome indicators such as billing and coding error rates as the measuring stick of effectiveness, as such focus “may cause an organization to miss crucial underlying weaknesses.” Thus, hospitals should also measure the “underlying structure and process of each compliance program element.” The OIG lists a number of factors that should be considered under each element. These factors are, in large part, restatements of attributes of compliance program elements that have previously appeared in OIG guidances as well as “best practice” standards developed and published by industry associations focused on compliance.

As hospitals look to evaluate and enhance their existing compliance programs, we recommend that they incorporate the following steps, among others:

- Ensure that the senior leadership commitment expected by the OIG is manifested through concrete actions (e.g., the CEO’s appearance at annual compliance training sessions; inclusion of compliance program commitment as a performance evaluation criteria for senior managers; and public recognition of employees who are champions of compliance within the organization (if such recognition is acceptable to the employee))
- Utilize internal audit or other appropriate departments outside the compliance function (if available) to conduct annual reviews of the compliance program itself and supplement such reviews with a periodic assessment by an outside third party.

By publishing this supplemental guidance, the OIG has raised the bar for hospitals, their senior leadership and their compliance programs. We advise hospitals to use the SCPG to prioritize and focus their compliance efforts consistent with their own risk profile and organizational needs.

## CONTACT INFORMATION

If you need assistance with the implementation, review or evaluation of your compliance program or practices; are interested in hearing about other compliance advisory services that we can provide; or have questions about the SCPG or this Alert, please contact:

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