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Health Care Bulletin

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August, 2000

OIG RELEASES DRAFT COMPLIANCE GUIDANCE FOR SINGLE PHYSICIANS AND SMALL PRACTICES

On June 7th, the Department of Health and Human Services ("DHHS") Office of Inspector General ("OIG") issued draft guidance aimed towards helping physicians in solo or small group practices to conduct effective voluntary compliance measures to prevent fraud and abuse in government health programs. The draft guidelines open new options for solo or small group practices that wish to establish effective compliance programs in accordance with OIG guidelines but are unable to afford to implement full-blown compliance plans. The OIG expects that all physician practices, regardless of size, will have appropriate compliance policies in place and that these policies must be disseminated to all employees.

This new compliance guidance presents basic procedural and structural guidelines to assist physicians in designing a compliance program, but it is not intended by the OIG to be an actual program for physician practices to implement verbatim.

The draft guidelines also address the concerns of physicians that governmental agencies are not recognizing the difference between fraudulent and merely erroneous claims. The draft guidance emphasizes that OIG uses the standard for fraudulent claims as defined in the False Claims Act and the Civil Money Penalty Act, under which only offenses committed with actual knowledge of the falsity of the claim, or reckless disregard or ignorance of the falsity of the claim, are covered. In the words of the OIG, "[P]hysicians are not subject to civil or criminal penalties for innocent errors, or even negligence."

Seven Basic Compliance Elements

The draft guidelines are similar to other previously published OIG guidelines, such as those for clinical laboratories, hospitals, home

health agencies, third-party billing agencies, durable medical equipment suppliers and managed care organizations. The draft guidelines are based on the seven elements set forth in the Federal Sentencing Guidelines but have been modified to address a solo or small practice's unique needs with respect to staffing and financial constraints. All compliance plans must incorporate and address the seven elements in order to be considered effective. The essential elements are:

- ≈ establishing compliance standards through the development of a code of conduct and written policies and procedures;
- ≈ assigning compliance monitoring efforts to a designated compliance officer or contact;
- ≈ conducting comprehensive training and education on practice ethics and policies and procedures;
- ≈ conducting internal monitoring and auditing focusing on high-risk billing and coding issues through performance of periodic audits;
- ≈ developing accessible lines of communication, such as encouraging discussions at staff meetings regarding fraudulent or erroneous conduct issues, creating a community compliance bulletin board, or making clear to employees that the compliance officer is available at any time to discuss compliance-related issues, to keep practice employees updated regarding compliance activities;
- ≈ enforcing disciplinary standards by ensuring employees are aware that compliance is treated seriously and that violators will be dealt with consistently and uniformly; and
- ≈ responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate government entities.

The OIG concedes that full implementation of each element by all physician practices may not be feasible, yet smaller practices are encouraged to address the elements in a manner that best suits their individual practices. Larger practices, however, are encouraged to refer to both the guidance for small practices and the guidance addressing third-party medical billing companies and clinical laboratories to develop a compliance program that fully meets their needs. The OIG also recommends that physician practices collaborate by participating in the compliance programs of other health organizations, such as those offered by the hospitals or other

settings in which the physician practices.

The OIG made specific adjustments to its previously published compliance guidelines for other Federal health program participants in connection with most of these essential elements to accommodate the characteristics of small physician group practices. For example:

- ⌘ The written policies of the physician practice should explain in simple language how the compliance measures will be incorporated into the practice's standard operating procedures. If scarcity of resources in developing such policies is a legitimate issue, the OIG recommends that the physician practice focus first on the risk areas most likely to affect their particular practice.
- ⌘ The position of compliance officer for a physician practice need not be a fulltime position, however, the draft guidelines indicate that the individual should be sufficiently independent in the position so as to protect against any conflicts of interest that may arise from performing compliance duties. The draft guidelines also posit that a physician practice may properly designate more than one employee to handle compliance-related activities. In addition, it is also possible for the compliance responsibilities to be outsourced. It is important, however, that if a physician practice chooses this option, the compliance officer should have sufficient interaction with the practice to be able to serve effectively as the compliance officer.
- ⌘ The draft guidelines emphasize that an open line of communication is necessary to allow proper implementation of an effective compliance program. At the same time, however, the guidelines acknowledge that the nature of a small physician practice dictates that such communication and information exchanges need to be conducted through a less formalized process than that which has been envisioned by prior OIG guidance. The draft guidelines suggest that a clear "open door" policy between the physicians and compliance personnel and practice employees can aid in developing effective lines of communication. The OIG recognizes in the guidelines that protecting anonymity may not be feasible in some small practice settings, yet the guidelines emphasize the importance that all employees, when seeking answers to questions or reporting potential instances of fraudulent or erroneous conduct, should know to whom to turn for assistance in the matters and should be able to do so without fear of retribution.

Identification of Specific Physician Risk Areas

Throughout the draft guidelines, the OIG emphasizes that physician practices should determine what types of fraud and erroneous billing practices most threaten their individual practice. To make this assessment, it is important for a practice to determine risk areas where the practice may be vulnerable. To that end, the OIG attempts to assist physician practices by highlighting the following risk areas: (1) coding and billing; (2) reasonable and necessary services; (3) documentation; and (4) improper inducements, kickbacks and self-referrals. This list is by no means exhaustive; rather, it is intended to be used as a starting point for reviewing potential risk areas for a physician practice.

About Vedder Price

Vedder, Price, Kaufman & Kammholz is a national, full-service law firm with approximately 190 attorneys in Chicago, New York and New Jersey.

The Health Care Group

Vedder Price provides a broad range of services to its health care clients, including:

- ⌘ Federal and state regulatory counseling on tax-exemption, Medicare/Medicaid, antitrust, fraud and abuse/Stark legislation, Certificate of Need, licensure, corporate practice of medicine and other issues;
- ⌘ Development of managed care organizations and other strategic health care arrangements;
- ⌘ Structuring of corporate networks, mergers, affiliations and acquisitions, including purchases and sales of practices and institutions;
- ⌘ Comprehensive counseling to professional health care associations and medical specialty societies;
- ⌘ Counseling in connection with implementation of strategic initiatives by health care entities, such as primary care satellite programs, physician recruitment and retention initiatives, and program development in emerging areas such as home health and outpatient

The draft guidelines also recommend that a practice use a baseline audit to examine the claim development and submission process, from patient intake through claim submission and payment, and identify elements within this process that may contribute to noncompliance or that may need additional attention. The involvement of the physician's legal counsel in the planning and conduct of such audits is very important in order to maintain the appropriate focus, the proper interpretation of the information obtained and the preservation of any legal privileges protecting the involuntary disclosure of such information. After the initial baseline audit, periodic audits are urged to ensure that the compliance program is being followed. These periodic audits should include:

- ⌘ confirmation that the physician practice has been using specific codes, as some codes are too general for reasonable and necessary services;
- ⌘ a check for data entry errors;
- ⌘ confirmation that all orders are written and signed by a physician;
- ⌘ a check for reasonable and necessary services performed, confirmation that all tests ordered by physicians were actually performed and documented and that only those tests were billed; and
- ⌘ a review of assignment codes and modifiers to the claims.

The guidelines offer the following warning signs of conduct which a compliance program must immediately address: (1) high rates of rejected and/or suspended claims; and (2) the placement of a practice on prepayment review by the carrier.

Responding to Detected Offenses and Developing Corrective Action Plans

Once a physician practice detects an offense, the OIG strongly suggests that it take all reasonable steps to respond to the offense and to prevent similar offenses. A full internal investigation of all reports of detected violations should occur. It is important that the compliance officer consult with legal counsel and conduct a thorough review of the situation and, if a violation is found, take decisive steps to remedy the problem and make a determination of the necessity for or the extent of disclosure to payors and/or governmental agencies.

mental health;

☞ Tax-exempt and taxable financing (both as borrowers' and underwriters' counsel); and

☞ Development of innovative responses to Medicaid and other publicly sponsored managed care initiatives.

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Even though the OIG indicates that the adoption of a compliance program is not mandatory at this time, it has repeatedly emphasized the importance of doing so. The OIG believes there are numerous benefits to be gained by implementing an effective compliance program. These benefits include:

- ☞ improved medical record documentation;
- ☞ improved education for practice employees;
- ☞ reduction in the denial of claims;
- ☞ more streamlined practice operations through better communication and more comprehensive policies;
- ☞ the avoidance of potential liability arising from noncompliance; and
- ☞ reduced exposure to penalties.

Vedder Price Health Law attorneys have experience in assisting physicians in the implementation and operation of effective compliance plans tailored to the unique characteristics of each individual practice.

A copy of the complete draft guidelines can be obtained on the DHHS web site at

<http://www.dhhs.gov/progorg/oig/modcomp/cpgphysiciandraft.htm>.

- ☞ Return to the [Health Care](#) index.
- ☞ Return to the Vedder Price [Publications Page](#).
- ☞ Return to: [Top of Page](#).

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[Top of Page](#)

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