COMPLIANCE WITH LAWS AND REGULATIONS FOR HEALTHCARE ORGANIZATIONS

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ISSUE ANALYSIS 98-1

COMPLIANCE WITH LAWS AND REGULATIONS FOR HEALTHCARE ORGANIZATIONS

I. INTRODUCTION

This is the third Issue Analysis of the Healthcare Financial Management Association’s Principles and Practices (P&P) Board. The P&P Board writes an Issue Analysis in response to the need for practical information on emerging issues in healthcare financial management. In order to expedite information to the industry, the P&P Board will prepare an Issue Analysis. An Issue Analysis is factual but not authoritative. It is not sent out for public comment and provides the healthcare industry short-term assistance on emerging issues. The purpose of P&P Board Issue Analysis 98-1, Compliance with Laws and Regulations for Healthcare Organizations, is to help healthcare financial managers understand their responsibility to implement and maintain an effective internal control system to ensure compliance with laws and regulations.

II. BACKGROUND

The Attorney General has named healthcare fraud the number two priority of the Department of Justice, second only to violent crime. The federal government has made clear its intent to detect and prosecute anyone who commits healthcare fraud and abuse. It is important that all healthcare executives recognize that they, and their organizations, can be held criminally liable for the acts of employees, even if an employee was acting on his or her own and without the permission of management.

The Auditing Standards Board (ASB) has recently issued a number of statements addressing internal control, including Statement on Auditing Standards (SAS) No. 78, Consideration of Internal Control in a Financial Statement Audit: An Amendment to SAS No. 55. SAS No. 55, Consideration of Internal Control Structure in a Financial Statement Audit, discusses internal con-
control as part of an audit of historical financial statements. The SAS No. 78 amendments to SAS No. 55 recognize the definition and description of internal control contained in Internal Control — An Integrated Framework, published by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO Report).

The Committee of Sponsoring Organizations (COSO) includes members from the AICPA, the Financial Executives Institute, the Institute of Management Accountants, the Institute of Internal Auditors, and the American Accounting Association. The COSO Report, issued in 1992, defines three types of internal control: (1) external financial reporting, (2) compliance with laws, regulations, contracts, and grants, and (3) operations. It also provides criteria for evaluating the effectiveness of internal control over financial reporting. The COSO Report emphasizes that management is responsible for designing and maintaining effective internal control for each of the three types.

In addition to SAS No. 78, the ASB recently issued SAS No. 82, Consideration of Fraud in a Financial Statement Audit. This new standard articulates the independent auditor’s responsibility to plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether caused by error or fraud. The ASB issued SAS No. 82 to enhance auditor performance by providing auditors with additional operational guidance on the consideration of material fraud in conducting a financial statement audit. The new standard requires auditors to assess certain risk factors relating to fraudulent financial reporting and the misappropriation of assets. As a result, management should be prepared to answer additional in-depth questions about their organization’s operating environment and internal control. The AICPA Audit and Accounting Guide Health Care Organizations acknowledges that compliance with laws and regulations requires knowledge that may be beyond the professional competency of the healthcare financial manager and generally would need to be based on the advice of a qualified expert, particularly concerning medical necessity and clinical coding.

III. PURPOSE

Given the increased interest and scrutiny by the federal government and the increased emphasis on internal control resulting from the COSO Report and the ASB pronouncements, the Principles and Practices (P&P) Board has written this issue analysis to help healthcare financial managers understand their responsibility to implement and maintain an effective internal control system to ensure compliance with laws and regulations. This issue analysis provides financial managers with an understanding of the increase in federal activities related to fraud and abuse and the role a corporate compliance plan can play in protecting a healthcare organization.

IV. MANAGEMENT’S RESPONSIBILITY

SAS No. 78 revises the definition of internal control contained in SAS No. 55 to recognize the definition and description contained in the COSO Report. As described in SAS No. 78, “Internal control is a process — effected by an entity’s board of directors, management and other personnel — designed to provide reasonable assurance regarding the achievement of objectives in the following categories: reliability of financial reporting, effectiveness and efficiency of operations, and compliance with applicable laws and regulations.” This definition differs from that contained in SAS No. 55 because, in addition to specifically identifying three categories of objectives, it emphasizes the fact that internal control is a function of the board, management, and other personnel within the organization. SAS No. 78, which is effective for audits of financial statements for periods beginning on or after January 1, 1997, and COSO place the responsibility for internal control squarely on management’s shoulders. SAS No. 78 identifies the five interrelated components of internal control as:

- **Control environment** sets the tone of an organization, influencing the control consciousness of its people. It is the foundation for all other components of internal control, providing discipline and structure.
- **Risk assessment** is the entity’s identification and analysis of relevant risks to achievement of its objectives, forming a basis for determining how the risks should be managed.
- **Control activities** are the policies and procedures that help ensure that management directives are carried out.
- **Information and communication** are the identification, capture, and exchange of information in a form and time frame that enable people to carry out their responsibilities.
- **Monitoring** is a process that assesses the quality of internal control performance over time.

The Appendix of SAS No. 78 discusses these components in detail.

V. CURRENT OPERATING ENVIRONMENT

Healthcare providers are responsible for complying with a myriad of laws and regulations addressing patient billing, cost reporting, physician transactions, occupational health and safety, and fair labor standards, to name just a few. Allegations of violations of laws and regulations are widespread. Some government estimates indicate that healthcare fraud and abuse accounts for as much as 11 percent of total federal healthcare spending in this country. As a result, federal and state government interest in combating fraudulent and abusive practices is now widespread. High-profile settlements involving many
types of providers and settlements into the hundreds of millions of dollars have provided additional incentives for the government to continue its scrutiny of the healthcare industry.

A. The Federal False Claims Act

Any person found to be knowingly involved in submitting a false or fraudulent claim to the federal government is liable for a civil penalty of $5,000 to $10,000, plus three times the amount of damages. This is the essence of the federal False Claims Act (FCA). While Congress enacted this law during the Civil War era to stop defense contractors from defrauding the federal government, the plain language of the law expands its reach beyond defense. Healthcare providers participating in federal programs such as Medicare, Medicaid, and CHAMPUS, submit claims for payment to the federal government. Therefore, healthcare providers run the risk of violating the FCA if they submit a claim for payment that they knew was fraudulent. The up-to-$10,000 fine per false claim, applied to the relatively large number of claims a healthcare provider submits, is a significant factor in the large size of recent FCA settlements.

Healthcare providers contend that in view of the complexity and changing nature of numerous laws and regulations, and seemingly unclear or conflicting billing instructions, many claims considered fraudulent by the government are, in fact, billing errors. The issue of knowing that a claim is fraudulent is important. While the government does not have to prove that an individual intended to defraud the government, it does have to prove that the individual: 1) had actual knowledge of the information; 2) acted in deliberate ignorance of the truth of the information; or 3) acted in reckless disregard of the truth or falsity of the information.

B. Operation Restore Trust

Initiated on May 3, 1995, Operation Restore Trust (ORT) was a pilot program to combat healthcare fraud, waste, and abuse. In ORT, the Department of Health and Human Services (HHS) assembled an interdisciplinary project team of federal and state government and private sector representatives to target Medicare abuse and misuse in California, Florida, New York, Texas, and Illinois. These states account for 40 percent of the nation’s Medicare and Medicaid beneficiaries. The team focused on home health care, nursing home care, hospice, and durable medical equipment, four of the fastest growing areas in Medicare. Three agencies within HHS—the Office of Inspector General (OIG), the Health Care Financing Administration (HCFA), and the Administration on Aging—are involved, along with the Department of Justice (DOJ).

The activities in ORT included:

- Financial audits by OIG and HCFA;
- Criminal investigations and referrals by OIG to appropriate law enforcement officials;
- Civil and administrative sanctions and recovery actions by OIG and other appropriate law enforcement officials;
- Surveys and inspections of long-term care facilities by HCFA and state officials in search of fraudulent activities;
- Studies and recommendations by OIG and HCFA for program adjustments to prevent fraud and reduce waste and abuse; and
- Issuance of special fraud alerts (see summary of recent fraud alerts in Appendix B) to notify the public and the healthcare community about schemes by fraudulent providers of home health services, nursing care, and medical equipment and supplies.

On May 20, 1997, the HHS Secretary announced the next phase of ORT, which expands investigations into 12 additional states: Arizona, Colorado, Georgia, Louisiana, Massachusetts, Missouri, New Jersey, Ohio, Pennsylvania, Tennessee, Virginia, and Washington. The Administration also intends to add new target provider groups. Eventually, the Secretary said, the investigation techniques developed by ORT will be applied in all 50 states and throughout the Medicare and Medicaid programs. Other areas of OIG concern are highlighted in the OIG’s work plan (see Appendix A to access the OIG internet website to obtain a copy of the work plan).

C. Qui Tam issues

A person may bring a civil action called a qui tam action against an entity for a violation of the FCA. Anyone who knows a fraudulent claim was submitted may sue on behalf of the government, and the government may either accept the whistleblower’s claim and proceed to prosecute it or elect not to proceed. If the government proceeds with the action and is successful, the whistleblower, or relator, receives between 15 and 20 percent of the settlement amount, plus other reasonable expenses. If the government elects not to proceed, the relator has the right to continue to pursue the action. If the suit is successful, the relator receives between 25 and 30 percent of the settlement, plus expenses.

D. Health Insurance Portability and Accountability Act of 1996

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted in August 1996. While most press accounts of the Act focused on its portability provisions, its accountability provisions were extensive. HIPAA further expands the fraud and abuse initiatives begun by the Clinton administration under ORT. A discussion of the pertinent fraud and abuse provisions of HIPAA follows.

1. Federal criminal law

Prior to HIPAA, activities involving healthcare fraud were subject to criminal sanctions only through nonhealthcare criminal statutes,
such as the False Claims Act. HIPAA, however, now incorporates certain healthcare fraud activities into the criminal statutes. For example, anyone who knowingly and willfully defrauds a healthcare benefit program can face fines and from 20 years to life imprisonment, or both, depending upon the severity of the violation. A healthcare benefit program is defined as a “public or private plan or contract, affecting commerce, under which any medical benefits, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item or service for which payment may be made under the plan or contract.” Specific provisions were also added to the criminal statutes for material false statements, embezzlement or theft, and money laundering concerning a healthcare benefit program. Other penalties include the freezing or forfeiture of assets.

2. Civil monetary penalties

Effective January 1, 1997, a civil monetary penalty (CMP) may be imposed on a healthcare organization if an individual submits, or causes the submission of, a false or fraudulent claim for any federal healthcare program, not just the Medicare and Medicaid programs. The penalties were increased to three times the amount claimed for the service, and the fine is $10,000 for each item or involved service. HIPAA adds three actions to the existing list of actions subject to a CMP: 1) the submission of a claim based on a code that will result in a greater payment than should be applicable (upcoding); 2) the submission of a claim for items or services that are not medically necessary; and 3) offering remuneration to beneficiaries to influence them to use a particular provider, practitioner, or supplier for anything that is reimbursable by Medicare or Medicaid.

3. Fraud and abuse control program

HIPAA created a national Fraud and Abuse Control Program to coordinate federal, state, and local law enforcement efforts to combat healthcare fraud and abuse. Activities under the program’s auspices include conducting investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care. This data must be shared with representatives of public and private third party payers. The program will also coordinate the issuance of safe harbors, fraud alerts, and advisory opinions.

4. Healthcare fraud and abuse control account

There is now a separate healthcare fraud and abuse control account within the Hospital Insurance Trust Fund. The fund is the repository for monies derived from the coordinated fraud and abuse control program, including criminal fines, CMPs, and assessments. Each year, the HHS Secretary and the Attorney General must submit a report to Congress identifying the amounts appropriated to the trust fund and the sources of these amounts, plus the amounts expended with justification for the expenditures.

E. Balanced Budget Act of 1997

The Balanced Budget Act of 1997 (BBA), intended to balance the federal budget within a five-year period, was enacted on August 5, 1997. The BBA includes changes for providers that directly affect healthcare finance professionals. Along with significant Medicare and Medicaid payment system changes and spending reductions, the BBA contains numerous fraud-fighting provisions.

1. Mandatory exclusions

The BBA includes a new mandatory exclusion authority if a provider is convicted of a criminal offense — 10 years for a second criminal conviction and permanent exclusion for a third conviction known as “three strikes and you’re out.” Previously, the law called for a five-year exclusion for a criminal conviction, and did not address repeat offenders.

2. New civil money penalties

A new civil money penalty (CMP) was created to penalize anyone who arranges or contracts for Medicare-covered items and services with an individual or entity that the person knew or should have known was excluded from the program. A health plan also faces a $25,000 CMP if it fails to report an adverse action taken against a healthcare provider, supplier, or practitioner as required by the national healthcare fraud and abuse data collection program created under previous health insurance reform law.

3. Antikickback provisions

Congress increased the CMP for violations of the antikickback statute to $50,000 for each violation, plus treble damages. This provision was also changed so that a CMP may be imposed if any portion of the remuneration is intended to induce a beneficiary to use a specific participating provider, regardless of whether a portion of the remuneration “was offered, paid, solicited, or received for a lawful purpose.” This could have substantial repercussions for healthcare providers now that a CMP may be imposed for a minor violation of the statute.

F. Taxpayer Bill of Rights 2 (Intermediate Sanctions Law)

A not-for-profit organization may lose its tax-exempt status under section 501(c)(3) of the Internal Revenue Code if it operates for the private benefit of
others, is controlled by private parties, or if any part of the organization's net earnings inures to the benefit of private shareholders or individuals. Repercussions from the loss of 501(c)(3) status include the liability for federal, state, and local income tax, and, in many jurisdictions, liability for property taxes; and the loss of access to capital through tax-exempt bond financing. Additionally, the immediate taxation of interest on outstanding tax-exempt bonds, the triggering of automatic call or other provisions, and ensuing actions by bondholders would be costly.

Before the enactment of the Taxpayer Bill of Rights 2 in July 1996, the IRS had only one statutory remedy to exercise when a charitable entity engaged in a transaction that violated its exemption: the revocation of the organization's tax-exempt status. The IRS seldom revokes tax-exempt status because this tends to penalize the beneficiaries of the tax-exempt organizations. The IRS can now assess personal tax sanctions, known as intermediate sanctions, against individual managers, accountants, and attorneys who are party to transactions that result in excess benefits. Examples of this include transactions with physicians, compensation received by, or revenue-sharing arrangements with, a disqualified person in amounts deemed in excess of fair value. A disqualified person is defined to include anyone in a position to exercise substantial influence over an organization.

Regulations governing the imposition of intermediate tax sanctions have not been finalized. Currently, there is much debate about how the IRS will assess transactions between tax-exempt organizations and persons deemed disqualified. A report of the House Ways and Means Committee suggests that the IRS apply existing tax standards to decide the reasonableness of compensation and fair market value of benefits in transactions involving tax-exempt organizations and corporate insiders. The committee's report states that a participant in a transaction is entitled to a “rebuttable presumption of reasonableness” with respect to the compensation arrangement with a disqualified person when the arrangement is approved by an independent board of directors or trustees. Financial managers of tax-exempt healthcare organizations should review and adopt the criteria that create a presumption of reasonableness. The House Ways and Means Committee report also states that intermediate sanctions penalty excise taxes may be imposed instead of, or in addition to, revocation of an organization's tax-exempt status.

G. Other Laws and Regulations

This section addresses only a few areas subject to recent enforcement or legislative activity. Failure to adhere to the many other federal, state, and local laws and regulations could, as well, expose a provider to prosecution or administrative actions. A penalty or exclusion by one federal agency or program prompts the notification of other federal agencies of the action and increases the possibility of additional investigations.

VI. CORPORATE COMPLIANCE PLANS

Due to the increasing complexity of the operating environment, it has become significantly more important for healthcare providers to have in place internal control processes directed toward compliance. Management and governing boards can fulfill a substantial portion of their responsibility to implement and maintain internal control processes that provide reasonable assurance of compliance with laws and regulations through the adoption, implementation, and ongoing operation of a corporate compliance plan. Corporate compliance plans ensure that corporate policies, practices, and culture foster the understanding of, and compliance with, applicable legal requirements. A corporate compliance plan should be an integral part of every healthcare provider's internal control processes.

A. Federal Sentencing Guidelines

The Federal Sentencing Guidelines, developed by the United States Sentencing Commission, provide for the moderation of sentences when the convicted defendant is an organization with an effective corporate compliance plan in place at the time of the offending. The Federal Sentencing Guidelines' application note 3(k) states:

"An 'effective program to prevent and detect violations of law' means a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct. Failure to prevent or detect the instant offense, by itself, does not mean that the program was not effective. The hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct by its employees and other agents. Due diligence requires at a minimum that the organization must have taken the following steps:

(1) The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct.

(2) Specific individual(s) within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures.

(3) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in illegal activities.

(4) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, e.g., by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required."
“(5) The organization must have taken reasonable steps to achieve compliance with its standards, e.g., by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the entity without fear of retribution.

“(6) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the discipline that will be appropriate will be case specific.

“(7) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses— including any necessary modifications to its program to prevent and detect violations of law.”

The above, sometimes known as the seven minimum elements of an effective compliance plan, stress that a plan need not be perfect so long as it demonstrates due diligence. Consequently, a plan should be an active, evolving process and not simply a static document.

B. Purpose of a Corporate Compliance Plan

The Federal Sentencing Guidelines and the concept of corporate compliance plans are not new. Defense contractors have had such programs for many years. A significant problem exists in the application of these matters to the healthcare industry. Even if a healthcare provider receives the mandated reduction in fines because they have an effective compliance plan, the fact that the organization was convicted of a healthcare program related offense will still result in automatic exclusion from all federal healthcare programs. Also, individual members of management may still be prosecuted and subjected to fines and/or imprisonment. All recent settlement agreements have included mandatory, government-imposed compliance plans.

The purpose of a corporate compliance plan is: first, to prevent violations of the law; second, to detect violations of the law; and third, to document the provider’s efforts in this regard in the event violations are not detected. In addition to the moderation of sentences, an active, functioning corporate compliance plan provides the following benefits:

- Provides an introspective look at the organization’s business process and culture;
- Establishes a structure to disseminate legal and policy changes quickly and with the confidence that the communication will go beyond just lawyers and top management;
- Establishes a structure to maximize the legally enforceable privacy of an organization’s documents and communications using one of the few constitutional privileges still available to corporations;
- Improves the speed and quality of responses to lawsuits, investigations, and other emergencies, which often occur with little or no warning;
- Reduces the likelihood of civil and criminal wrongdoing;
- Documents the organization’s good intentions and improves its position to negotiate reduced penalties if violations occur;
- Reduces the risk of prosecution and conviction, which reduces the chance of mandatory exclusion from the Medicare and Medicaid programs;
- Reduces the risk of a government imposed compliance plan.

C. Compliance Program Guidance

The OIG has responded to healthcare industry requests for specific guidance related to the elements of a compliance plan. The OIG issued a model laboratory plan in February 1997 and guidance for hospitals in February 1998 that detail the OIG’s minimum expectations of plans but are not fill-in-the-blanks documents. The OIG expects each provider to develop a plan customized to the particular provider’s operations. Compliance program guidance for home health agencies is expected to be released in the summer of 1998. The OIG intends to issue similar compliance program guidance for other industry providers and suppliers including medical billing companies, managed care organizations, and pharmaceutical companies.

The information contained in this issue analysis is believed to be current as of the date issued. Readers are cautioned that changes to laws and regulations are likely. Validity of the information may decrease in proportion to the time lapse from the issue date.
VII. APPENDIX A

INTERNET SITES

This listing provides the healthcare financial manager with available resources to aid in the implementation of an effective compliance program. While this listing is comprehensive, it is not intended to be all inclusive.

Healthcare Financial Management Association (HFMA) Home Page
http://www.hfma.org

Government Internet Sites

1. Federal Sentencing Commission Home Page
   http://www.usse.gov

2. Health Care Financing Administration (HCFA) Home Page
   http://www.hcfa.gov

3. Department of Health and Human Services (HHS) Home Page
   http://www.os.dhhs.gov

4. HHS Office of Inspector General (OIG) Home Page
   http://www.dhhs.gov/progorg/oig

5. Internal Revenue Service (IRS) Home Page

6. Department of Justice (DOJ) Home Page
   http://www.usdoj.gov

Other Association Internet Sites

1. American Institute of Certified Public Accountants (AICPA) Home Page
   http://www.aicpa.org

   http://www.healthlawyers.org

3. American Hospital Association (AHA) Home Page
   http://www.aha.org

4. Association of American Medical Colleges (AAMC) Home Page
   http://www.aamc.org

VIII. APPENDIX B

MEDICARE FRAUD ALERTS, SPECIAL FRAUD ALERTS, AND MEDICARE ADVISORY BULLETINS

The Department of Health and Human Services Office of Inspector General (OIG) periodically issues fraud alerts, advisory bulletins, and advisory opinions setting forth activities believed to raise legal and enforcement issues. Compliance programs should require appropriate personnel to carefully consider all fraud alerts, advisory bulletins, and advisory opinions. The following list summarizes fraud alerts and advisory bulletins presently released by the government. For a current list, refer to the OIG website at http://www.dhhs.gov/progorg/oig.

Medicare Fraud Alerts

OIG97-02 Myocardial Perfusion Imaging
The OIG found that a physician improperly billed Medicare for myocardial perfusion imaging tests (CPT codes 78460 and 78461) performed in his office, when he did not have the equipment needed to perform the test and was not licensed to maintain nuclear medicine or radioactive material.

OIG97-01 Laboratory Billing
The OIG found that hospitals working with consulting firms, whose fees were based on a percentage of increased lab revenue, were more likely to submit false claims. The firms promised to increase hospital revenue by fragmenting lab billings in return for a percentage of the first year’s increase in revenue. The OIG asserted that these arrangements were ripe for upcoding, unbundling, and other increases in costs to Medicare.

Special Fraud Alerts

March 1998 Fraud and Abuse in Nursing Home Arrangements with Hospices
The OIG has observed instances of potential kickbacks between hospices and nursing homes to influence the referral of patients. An example of illegal remuneration is if a hospice pays a nursing home for a dually eligible beneficiary’s room and board at a rate that exceeds what the nursing home would have received if the patient was not enrolled in the hospice. Under the anti-kickback statute, it is illegal to knowingly and willfully solicit, receive, offer, or pay anything of value to induce referrals of items or services payable by a federal healthcare program.

OIG96-18 Nursing Facility Benefits
The OIG has found practitioners of medical specialties have misrepresented the nature of services provided to Medicare and Medicaid beneficiaries, because these programs have stringent coverage limits for some specialties, including podiatry, audiology, and optometry. This special fraud alert out-
lines common schemes that entail the falsifying of bills and medical records to misrepresent the services or extent of services provided.

OIG95-09 Medical Supplies at Nursing Facilities
False or fraudulent claims include claims for items that were never provided or were not provided as claimed, duplicate claims submitted for the same item, and claims for items that the supplier knows are not medically necessary. Improper claims have been submitted for supplies and equipment that are reflected in the facility's Medicare cost report under Medicare Part A and also billed by the supplier to Medicare Part B.

OIG95-08 Home Health Care
False and fraudulent claims include claims for services that were never provided, duplicate claims submitted for the same service, and claims for services to ineligible patients. The alert also covers Medicare cost reports for reimbursement of administrative overhead and other general costs, as well as kickbacks in exchange for the referral of reimbursable home health services and the marketing of uncovered or unneeded home care services.

October 1994 Clinical Lab Services
Some labs have offered inducements to physicians to use their services, including providing phlebotomy services to physicians, discounting some end-stage renal disease (ESRD) testing in order to gain directly reimbursable ESRD testing; and waiving charges to managed care patients in order to retain fee-for-service patients.

August 1994 Prescription Drug Marketing Schemes
It is illegal to offer physicians supplies or patients valuable, nonmedical benefits in exchange for selecting specific prescription drug brands. Such activities include product conversion programs, where pharmacies fill prescriptions with a specified company's brand; frequent flier campaigns, where physicians are given frequent flier miles in exchange for patient information; and research grants, where physicians are paid for minimal information about patients using the company's brand.

May 1992 Hospital Incentives to Physicians
It is illegal for hospitals to provide financial incentives to physicians for their referrals. Incentives include payments, the use of free or discounted office space or equipment, free or discounted billing, nursing, or other staff services; free training for office staff; guaranteed income, low interest or interest free loans; payment for travel and conference expenses; payment for continuing education; insurance coverage; and payment for services requiring little work.

OIG91-23 Routine Waiver of Coinsurance
It is illegal to waive copayments or deductibles under Medicare Part B. The special fraud alert explains an exception to the rule if the waiver is based on a patient's genuine financial hardship. This exception may not be used routinely.

August 1989 Joint Venture Arrangements
The OIG addresses arrangements between those in a position to refer business, such as physicians, and those providing items or services for which Medicare or Medicaid pays, including clinical diagnostic laboratory services, durable medical equipment, and other diagnostic services.

Medicare Advisory Bulletins
Hospice Benefits
Some hospice providers have been found to improperly maximize Medicare reimbursement by knowingly engaging in the following efforts:

- Incorrect determinations of a person's life expectancy for the purposes of meeting hospice eligibility requirements;
- Marketing/sales strategies that offer incomplete or inadequate information to induce beneficiaries to elect hospice and thereby waive other treatment benefits; or
- Encouraging hospice beneficiaries to temporarily revoke their election of hospice during a period when costly services covered by the hospice plan of care are needed.

HMO enrollment, provision of services, and disenrollment of Medicare beneficiaries
This advisory bulletin explains to Medicare program beneficiaries their rights to medical services in an HMO. Areas covered:

- Definition of Medicare contracting HMOs;
- Enrollment and disenrollment rights;
- Provision of medical services; and
- How to make complaints.
# IX. APPENDIX C

## PRELIMINARY ASSESSMENT TOOL

This preliminary assessment tool is intended to help healthcare financial managers gain a better understanding of their organization's compliance systems. This tool should be used as a baseline to highlight the elements of a compliance program and should be applied within the specific context of your organization. Once completed, it may focus on areas to assist you in managing significant risks.

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<th># ISSUE</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>Compliance Commitment and Standards</td>
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<td>1. Do you have a formal compliance plan approved by your governing board?</td>
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<td>2. Have you reviewed the OIG's Compliance Program Guidelines for applicability to your organization?</td>
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<td>2a. Do your written policies conform with those recommended by the OIG?</td>
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<td>3. Are mechanisms in place to monitor relevant federal and state regulations and legislation?</td>
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<td>4. Have you used this preliminary assessment tool with affiliated entities that you control?</td>
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<td>5. Prior to treatment, do you have procedures to collect necessary information and documentation from a patient?</td>
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<td>5a. Is this information and documentation readily accessible?</td>
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<td>6. Does your record retention policy ensure that all records and documentation required by federal or state law or the compliance program are created and maintained for the required period of time?</td>
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<td>6a. Is there a system in place to ensure that access to records and documentation is limited to appropriate parties?</td>
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<td>7. Do you charge consistently the same amount for the same service for all patients regardless of payer and location of service?</td>
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<td>7a. Are correct site-of-service codes recorded on billing forms?</td>
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<th># ISSUE</th>
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<td>8. Are providers performing and documenting all services, including advice, to patients?</td>
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<td>9. Do control procedures provide reasonable assurance that services performed are recorded and billed?</td>
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<td>10. Are all individual charges (including those provided within clinical pathways and laboratory panel tests) supported by signed physician orders?</td>
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<td>11. Does the medical record documentation support the reasonableness of the charge and document the results of diagnostic tests?</td>
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<td>12. When providing services to a Medicare beneficiary who is an inpatient at another facility, is the other facility billed appropriately?</td>
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<tr>
<td>13. Is there a system in place to ensure that adjustments to patient accounts (bad debt, discount, capitation, etc.) are authorized and performed only by designated individuals?</td>
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<tr>
<td>14. Are there standard procedures to process refunds in a timely manner?</td>
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<tr>
<td>14a. Are overpayments obtained from Medicare or other federally funded healthcare programs promptly returned to the appropriate fiscal intermediary, carrier, or other entity that made the erroneous payment?</td>
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<td>14b. Are refunds processed in a timely manner, approved by the appropriate management personnel, and routinely monitored by management?</td>
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<tr>
<td>14c. Are unclaimed patient refunds monitored and reported in accordance with federal and state requirements?</td>
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<tr>
<td>15. Are bulletins and fraud alerts from your carrier/fiscal intermediary reviewed when received to determine whether coding modifications, instructions, or clarifications are mandated?</td>
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<tr>
<td>15a. Are the specified coding changes made on a timely basis?</td>
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<tr>
<td>15b. Are fiscal intermediary instructions confirmed in writing and maintained?</td>
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<tr>
<td>#</td>
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<td>Yes</td>
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<td>16.</td>
<td>Are there established and enforced policies for collecting copayments, deductibles, and other amounts for which patients are responsible?</td>
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<td>17.</td>
<td>Are courtesy discount policies set in compliance with anti-kickback statutes?</td>
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<td>18.</td>
<td>Are charges bundled where appropriate?</td>
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<td>19.</td>
<td>Is there a system in place to ensure that claims are recognized by primary insurer before secondary insurers are billed (such as required by MSP [Medicare as secondary payer] requirements)?</td>
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<td>20.</td>
<td>Is there a comprehensive list of all financial relationships, with potential referral sources, such as:</td>
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<tr>
<td>20a.</td>
<td>payments to physicians for specified services such as medical directorships?</td>
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<tr>
<td>20b.</td>
<td>consulting services and physician recruitment?</td>
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<tr>
<td>20c.</td>
<td>leases of office space and/or equipment to or from referral sources?</td>
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<tr>
<td>20d.</td>
<td>provision of free goods and/or services?</td>
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<tr>
<td>20e.</td>
<td>cross-referral arrangements with other healthcare providers?</td>
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<td>20f.</td>
<td>arrangements with marketing representatives?</td>
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<tr>
<td>21.</td>
<td>Are all arrangements (leases, provision of billing or other services, compensation, etc.) reviewed periodically for appropriateness and compliance with applicable laws and regulations?</td>
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<tr>
<td>22.</td>
<td>Have these relationships been reviewed for compliance with safe harbor regulations?</td>
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<tr>
<td>23.</td>
<td>Is there a system to ensure against receipt of gifts, rebates, services, or anything of value from vendors?</td>
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<td>24.</td>
<td>Are all referrals and consultations properly documented?</td>
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<tr>
<td>25.</td>
<td>Are any services provided for free or at a discounted rate to any referral source?</td>
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<tr>
<td>25a.</td>
<td>Is the appropriateness of providing the free or discounted service documented?</td>
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<tr>
<td>26.</td>
<td>Is there a system in place to ensure all cost reports are filed accurately?</td>
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</tbody>
</table>

**Compliance Officer**

<table>
<thead>
<tr>
<th>#</th>
<th>ISSUE</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>27.</td>
<td>Is a high level employee designated as the compliance officer for responsibility of operating the compliance plan?</td>
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<tr>
<td>27a.</td>
<td>Is there a compliance committee, comprised of individuals with varying perspectives in the organization, established to advise the compliance officer?</td>
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**Employment and Education**

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<thead>
<tr>
<th>#</th>
<th>ISSUE</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>28.</td>
<td>Is the Board's support of and commitment to corporate compliance communicated to all employees?</td>
<td></td>
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<td>29.</td>
<td>Do the hiring procedures outline the institution's policy on background investigations (such as the use of the National Practitioner Data Bank or Cumulative Sanction Report)?</td>
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<td>30.</td>
<td>Does the policy comply with regulations to avoid hiring or retaining sanctioned individuals?</td>
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<td>31.</td>
<td>Upon completion of employee orientations, do you require a signed statement of the code of conduct? Is it renewed annually? (Sample code of conduct: &quot;I understand I have the responsibility to report any possible compliance issues related to my job responsibilities that come to my attention.&quot;)</td>
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<td>32.</td>
<td>Is there annual compliance training?</td>
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<td>33.</td>
<td>Are job descriptions for personnel current, relevant, and comprehensive?</td>
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**Hotline**

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<tr>
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<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>34.</td>
<td>Are there mechanisms and procedures for employees to report possible compliance issues, up to and including an anonymous hotline?</td>
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**Standards Enforced**

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<th>ISSUE</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td>35.</td>
<td>Are there disciplinary policies for noncompliance and mechanisms for accountability? Are employees informed of these policies in the code of conduct and training?</td>
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</tbody>
</table>
X. SELECT BIBLIOGRAPHY


Acknowledgments: The participants in the 1997 HFMA Compliance Conference provided valuable input into the development of this preliminary assessment tool.
1997-98
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