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CENTERS FOR MEDICARE & MEDICAID SERVICES

COMPLIANCE PROGRAM

GUIDANCE

FOR

MEDICARE

FEE-FOR-SERVICE

CONTRACTORS

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TABLE OF CONTENTS

INTRODUCTION	3
ELEMENTS OF A COMPLIANCE PROGRAM	4
1. WRITTEN POLICES AND PROCEDURES	4
a. Standards of Conduct	4
b. Written Compliance Policies and Procedures	5
c. Retention of Records and Information Systems	5
d. Compliance as an Element of Performance Plan	5
2. DESIGNATION OF A COMPLIANCE OFFICER AND A COMPLIANCE COMMITTEE	6
a. Compliance Officer	6
b. Compliance Committee	7
3. CONDUCTING EFFECTIVE TRAINING AND EDUCATION	8
a. Formal Training Programs	8
b. Informal On-going Compliance Training	9
4. DEVELOPING EFFECTIVE LINES OF COMMUNICATION	9
a. Hotline or Other System for Reporting Suspected Noncompliance	9
b. Routine Communication and Access to the Compliance Officer	10
5. AUDITING AND MONITORING	10
a. Auditing	10
b. Monitoring	10
c. Risk Areas	11
6. ENFORCEMENT THROUGH PUBLICIZED DISCIPLINARY GUIDELINES AND POLICIES DEALING WITH INELIGIBLE PERSONS	11
a. Consistent Enforcement of Disciplinary Policies	11
b. Employment of, and Contracting with, Ineligible Persons	12
7. RESPONDING TO DETECTED OFFENSES, DEVELOPING CORRECTIVE ACTION INITIATIVES AND REPORTING TO GOVERNMENT AUTHORITIES	12
a. Responding to Offenses and Developing Corrective Action	12
b. Reporting to the Government	13

INTRODUCTION

The Centers for Medicare & Medicaid Services (CMS), an agency of the Department of Health and Human Services (HHS), has developed this compliance program guidance for Medicare fee-for-service Contractors¹. CMS believes that compliance efforts are fundamentally designed to establish a culture within an organization that promotes the prevention, detection and resolution of instances of conduct that do not conform to federal and state law, or to federal healthcare program requirements. This compliance program guidance is intended to assist Medicare fee-for-service Contractors in developing and implementing effective compliance programs that promote adherence to, and allow for, the efficient monitoring of compliance with all applicable statutory, regulatory and Medicare program requirements. CMS, in its ongoing effort to work collaboratively with the Medicare fee-for-service Contractors, has developed these compliance guidelines as a demonstration of CMS' commitment to compliance.

This document offers critical guidance for those who are attempting to develop and implement an effective compliance program, as well as a benchmark for those who already have a compliance program in place but wish to improve its effectiveness. An effective compliance program should both articulate and demonstrate the Contractor's commitment to ethical and legal business conduct. The governing body of the organization, including the board of directors, chief executive officer and senior management, are tasked with the responsibility to provide ethical leadership and to ensure that adequate systems are in place to facilitate ethical and legal conduct. Thus, an effective compliance program should guide these managers in the ethical operation of the business and create a culture of compliance.

Implementing and maintaining an effective compliance program requires a substantial commitment of time, energy and resources. CMS recognizes, however, that each Contractor must tailor its compliance program to its own business model, including the size of the entity. The development and implementation of a compliance program is voluntary, but CMS believes that an effective compliance program is a cost-effective investment. It should be noted, however, that CMS is not specifically authorizing funding for any of the recommendations contained in this guidance.

A compliance program that is superficial or a program that is hastily developed and implemented will most likely fail to be effective. It is critical for the Medicare fee-for-service Contractor to assess its own organization and determine its needs with regard to compliance with applicable federal and state statutes and federal healthcare program requirements. Thus, CMS encourages Medicare fee-for-service Contractors to read this guidance with the whole organization in mind.

¹ As used in this guidance, "Medicare fee-for-service Contractors" includes Medicare Part A fiscal intermediaries, Medicare Part B carriers, and durable medical equipment regional carriers (DMERC). For purposes of this guidance, those Blue Cross Blue Shield organizations that serve as subcontractors under the Blue Cross Blue Shield Association Medicare Part A fiscal intermediary primary contract are also considered Medicare fee-for-service Contractors.

This document should not be viewed as an exclusive iteration of the advisable components of a compliance program. This document presents CMS' suggestions on how a Medicare fee-for-service Contractor can establish internal controls and monitor company conduct to reduce the risk of unlawful or improper activities. Although this document presents basic structural and procedural guidance for developing a Medicare fee-for-service compliance program, it is not in itself a compliance program. Accordingly, this compliance guidance document should not be substituted for nor used in lieu of a well thought-out and implemented compliance program tailored to the unique business aspects of the company.

In developing this compliance program guidance, CMS has relied primarily on the following sources of information: on-site reviews of existing compliance programs implemented by Medicare fee-for-service Contractors conducted by CMS compliance teams; the Federal Sentencing Guidelines promulgated by the United States Sentencing Commission²; similar guidance documents prepared by HHS' Office of Inspector General (OIG) for other business segments of the healthcare industry; and existing contemporary literature in the field of compliance.

A compliance program is not a panacea guaranteed to eliminate the risk that fraud, waste, abuse or inefficiency will occur. Nevertheless, CMS believes that the establishment of an effective compliance program will protect the Medicare Trust Fund by significantly reducing the risk of unlawful or improper conduct, and will likely lead to other programmatic efficiencies.

This compliance guidance document is structured in seven sections that follow the seven steps determined by the United States Sentencing Commission to be the minimum requirements for an effective compliance program³.

ELEMENTS OF A COMPLIANCE PROGRAM

1. WRITTEN POLICES AND PROCEDURES

a. Standards of Conduct

The Contractor should have written standards of conduct that clearly state the Contractor's commitment to comply with all applicable statutory, regulatory and Medicare program requirements. The standards of conduct should be written in an easy to read format and distributed to all employees. All employees should be required to certify that they have read, understand

² In order to receive "credit" for good corporate behavior, the Federal Sentencing Guidelines require that organizational defendants exercise due diligence in the design and implementation of a compliance program intended to detect and deter fraud, waste and abuse. The Federal Sentencing Guidelines Manual at §8A1.2, Application Note (k), sets forth seven steps that any compliance program must incorporate in order to demonstrate the due diligence element. These seven steps have been included in the various guidelines developed by the OIG and other compliance program authorities, and are believed to be the minimum requirement for an effective compliance program.

³ Id.

and agree to comply with the standards⁴. The standards of conduct may be set forth in a separate Medicare-specific stand-alone document or as a supplement to a corporate code of conduct.

b. Written Compliance Policies and Procedures

The Contractor should have comprehensive written compliance policies and procedures, developed under the direction of the Compliance Officer (CO) and Compliance Committee, which direct the operation of the compliance program. The policies and procedures may be Medicare-specific stand-alone documents or may be drafted as Medicare supplements to corporate policies and procedures.

The written compliance policies and procedures should include, at a minimum, the following elements:

- Duties and responsibilities of the CO and Compliance Committee
- How and when employees will be trained
- Procedures for how employee reports of non-compliance will be handled
- Guidelines on how the compliance department will interact with the internal audit department
- Guidelines on how the compliance department will interact with the legal department
- Guidelines on how the compliance department will interact with the Human Resources (HR) department
- Duties and responsibilities of management in promoting compliance among employees and responding to reports of non-compliance
- Ensuring that prospective employees receive appropriate background screening and agree to abide by the Contractor's code of conduct
- Conducting periodic reviews, at least annually, of the code of conduct and the compliance policies and procedures

c. Retention of Records and Information Systems

The Contractor should have a policy that describes the retention schedule for Medicare documents and records in accordance with CMS requirements. Documents identified by the CMS General Counsel's office, the Department of Justice or the Office of Inspector General as being related to an investigation or other litigation should be retained in accordance with the requests of those offices.

d. Compliance as an Element of Performance Plan

The Contractor should make adherence to the code of conduct, timely reporting and proper handling of compliance violations and attendance at compliance training an element of employee and manager performance

⁴ A Contractor should consider publishing the standards of conduct in other languages, such as Spanish, to accommodate those workers who speak English as a second language.

evaluations. The Contractor should make promotion of the compliance program among employees and appropriate handling of reports of non-compliance elements of a manager's annual performance evaluation. We believe that all reports of non-compliance should be directed to the compliance department, even if it is the Contractor's policy to allow a manager to initially attempt to resolve an issue.

The Organizational Sentencing Guidelines require that there be a compliance component in an employee's evaluation. There should be positive incentives for compliance enforcement as well as disciplinary actions or penalties for failure to conform to the Contractor's compliance program. For example, employees, supervisors or managers could be rewarded for making suggestions to improve the compliance program or for reporting compliance violations.

2. DESIGNATION OF A COMPLIANCE OFFICER AND A COMPLIANCE COMMITTEE

a. Compliance Officer

The Contractor should designate a CO whose primary responsibility is to oversee the implementation and maintenance of the compliance program. The CO should have adequate authority and independence within the organizational structure in order to make reports directly to the board of directors and/or to senior management concerning actual or potential cases of non-compliance. The CO must also report directly to corporate governance on the effectiveness and other operational aspects of the compliance program. The CO's responsibilities should encompass a broad range of duties including but not limited to the investigation of alleged misconduct, the development of policies and rules, training officers, directors and staff, maintaining the compliance reporting mechanism and closely coordinating with the internal audit function.

A full-time Medicare specific compliance officer should be the desired objective. However, because of cost efficiencies or other reasons, certain contractors may want their corporate compliance officer to also serve as the Medicare compliance officer. The corporate compliance officer's position description should state, with particularity, the Medicare duties and responsibilities. In such a dual role situation, the Contractor should ensure that there is a lower level person delegated to oversee day-to-day Medicare compliance operations.

CMS believes it is a best practice to separate the CO function from the General Counsel function. We do, however, understand that other models do exist. In "An Integrated Approach to Corporate Compliance: A Resource for Health Care Boards of Directors", (July 2004) a publication issued jointly by the American Health Lawyers Association and DHHS's Office of Counsel to the Inspector General, three models are described as

acceptable. The model CMS prefers is where there is total separation of the General Counsel and CO functions. A second model combines the General Counsel and CO into one. A third model separates the General Counsel and CO functions, but the CO reports directly to the General Counsel. This latter model appears to violate the amended Organizational Sentencing Guidelines that require direct reporting by the CO to corporate governance, unless the CO is provided with such authority.

The Contractor should give consideration to the possibility that by placing the CO under the authority of the General Counsel, the relationship could present a potential conflict of interest. For example, the General Counsel is ethically obligated to vigorously represent, defend and maintain the confidences of the company, particularly in those instances where alleged fraud or misconduct have occurred. On the other hand, the CO is duty-bound to report on and correct alleged fraud and other misconduct, and in certain instances to advise the government of such non-compliance.

CMS believes that the CO should be the company's "watch dog." In order to maintain the CO's independence and protect the CO from threats or retaliation by corporate management, we believe the CO should be exempt from state at-will employment rules or work under an employment contract. We understand that a Contractor may want to establish other procedures to protect the CO. For example, a Contractor could require that prior to taking any disciplinary action against the CO, up to and including possible termination, that the board of directors conduct an inquiry into the matter and give its assent to any disciplinary action.

The Contractor should locate the compliance department in a secure, but accessible area, within its facility. This is essential in order that the compliance department be able to receive confidential communications from employees and to conduct internal investigations.

b. Compliance Committee

The Contractor should establish a compliance committee of the Board of Directors and an Executive compliance committee that advises the CO and assists in the implementation of the compliance program. We are aware that in some Contractors the Board's audit committee oversees compliance matters. We believe that as a matter of good corporate governance that the Board committee, which oversees compliance, should be comprised of a majority of outside directors and that the quorum rule for the committee to conduct business should require that outside directors constitute a majority. It should be noted that the Organizational Sentencing Guidelines have recently been revised to place more responsibility on corporate boards to oversee compliance and ethical matters. Thus, the Board's ratio of inside/outside directors, as well as the quorum rule, may become critical

factors in determining whether the Board is effectively exercising its compliance oversight responsibilities.

We believe that while the Board's compliance committee provides essential oversight of the compliance program, a compliance committee below the Board level would be able to quickly identify and raise internal issues of which the Board committee may not be aware. This committee could be denominated an "Executive Compliance Committee" or a "Medicare Compliance Committee." This committee would provide guidance and information to the CO but should not have the authority to block or interfere with any actions taken or proposed to be taken by the CO. This compliance committee could be comprised of the heads of the major departments within the Contractor, such as Provider Audit, Claims, Human Resources and the General Counsel, as well as any other departments that may be high risk areas. The CO should chair the committee. The Executive compliance committee should meet more frequently than the Board's committee.

3. CONDUCTING EFFECTIVE TRAINING AND EDUCATION

a. Formal Training Programs

The Contractor should provide general compliance training to all employees, officers, managers, supervisors, Board members and long-term temporary employees⁵ that effectively communicates the requirements of the compliance program, including the company's code of conduct and applicable Medicare statutory, regulatory and contractual requirements. Contractors should also determine under what circumstances it may be appropriate to train non-employee agents and contractors. Employees, officers, managers, supervisors and Board members should be required to attend compliance training sessions and to sign certifications that they have completed the appropriate sessions.

The initial compliance training for new employees should occur at or near the date of hire. The Contractor should provide annual refresher compliance training that highlights compliance program changes or other new developments. The refresher training should re-emphasize Medicare statutory, regulatory and contractual requirements and the Contractor's code of conduct. We believe that the training should, when appropriate, use actual compliance scenarios and/or investigations of non-compliance as examples of risks that employees and managers may encounter. When using actual scenarios, care should be taken to protect the privacy of the individuals involved.

⁵ In a recent corporate integrity agreement, the OIG defined a long term temporary employee as anyone who worked for the employer more than 160 hours. We think that the OIG's guidance is instructive but Contractors should exercise discretion in determining how many hours of work would subject a long term temporary employee to compliance training.

Contractors should consider using tests or other mechanisms to determine the trainees' comprehension of the training concepts presented. Trainees should also be provided a mechanism, such as evaluation forms, in order to provide feed-back regarding the effectiveness of the trainer and how to improve future training sessions.

If a Contractor emphasizes "chain of command" as the first line of compliance reporting, special compliance training should be provided to supervisors and managers that focuses on encouraging employees to report instances of non-compliance and the proper handling of employee complaints. Specialized compliance training should also be provided to employees and supervisors in specific, higher risk business areas. See section 5.C. of this document for examples of risk areas.

b. Informal On-going Compliance Training

The Contractor should employ additional, less formal means for communicating its compliance message such as posters, newsletters and Intranet communications. The CO should be responsible for the content of the compliance messages and materials distributed to employees and managers.

4. DEVELOPING EFFECTIVE LINES OF COMMUNICATION

a. Hotline or Other System for Reporting Suspected Noncompliance

The Contractor should have mechanisms in place for employees and others to report suspected or actual acts of non-compliance. The Contractor may designate that reports can be made to managers, supervisors, the CO or the compliance staff. Reports may be made by way of telephone, face-to-face, e-mail or written contact. A separate mechanism, such as a toll-free hotline, must be employed to permit anonymous reporting of non-compliance. The hotline message should emphasize that the complainant will be protected from retaliation or retribution when making a good faith report of non-compliance. The hotline should have the capability of allowing complainants to anonymously check on the status of their complaint. If a Contractor uses a single hotline number for Medicare and non-Medicare complaints, it should use a Medicare specific voice-mail box for Medicare complaints. In some cases, a "drop-box" may be a useful additional mechanism for both anonymous and direct written reports.

The Compliance Department should be made aware of all reports of actual or potential non-compliance that involve the Contractor's government operations, regardless of the means by which the report is made or who is responsible for the investigation. For example, in "chain of command" reporting where a manager may be the first to receive a non-compliance report, the Compliance Department should be made aware of the incident so

that the CO can consider similar reports from other components, the data can be added to any trend analysis or the occurrence can be included in general reports to the Board of Directors.

The Contractor's compliance department should maintain a detailed log of all reports of actual or potential non-compliance. The Contractor must create an environment in which employees feel free to report concerns or incidents of wrongdoing without fear of retaliation or retribution, when making a good faith report of non-compliance.

b. Routine Communication and Access to the Compliance Officer

The Contractor should have a general "open door" policy for employee access to the CO and the Compliance Department staff. Staff should be advised that the CO's duties include answering routine questions regarding compliance or ethics issues.

5. AUDITING AND MONITORING

a. Auditing

The Contractor should have a comprehensive internal audit system to ensure that the Contractor is in compliance with the range of contractual and other CMS requirements in critical operations areas. The internal auditors should be independent from the Contractor's management team and competent to identify potential issues within the critical review areas. The auditors should have access to existing audit resources, relevant personnel and all relevant operational areas. Written reports should be provided to the CO, the Compliance Committee and appropriate senior management. The reports should contain findings, recommendations and proposed corrective actions that are discussed with the CO and senior management.

The Contractor should ensure that regular, periodic evaluations of its compliance program occur to determine the program's overall effectiveness. This periodic evaluation of program effectiveness may be performed internally, either by the CO or other internal source - or by an external organization. These periodic evaluations should be performed at least annually, or more frequently, as appropriate.

b. Monitoring

The Contractor should have a means of following up on recommendations and corrective action plans to ensure that they have been implemented. The Contractor should develop an Exit Interview Questionnaire that includes questions regarding whether the exiting employee observed any violations of the compliance program, including the code of conduct, as well as any violations of applicable statutes, regulations and Medicare program requirements during the employee's tenure with the Contractor. The

Compliance Department should review any positive responses to questions regarding compliance violations.

c. *Risk Areas*

During the last few years, the OIG, through settlement of civil False Claims Act cases, and the prosecution of criminal activity, has compiled a list of areas that are typically vulnerable to fraud or other misconduct. Accordingly, the Contractor should consider tailoring its auditing and monitoring activities with these vulnerabilities in mind. The following list is for illustrative purposes only and should not be considered exhaustive.

- Falsification of documents in support of audits
- Inflation of the number of claims processed for CPEP audits
- Trust funds used to pay private side costs
- Altered documents to increase CPEP scores
- False or improperly adjusted cost reports
- Hiding on-going processing errors
- Failure to process claims properly and then submitting false reports
- Falsification of data entered into the System Tacking and reimbursement database

6. ENFORCEMENT THROUGH PUBLICIZED DISCIPLINARY GUIDELINES AND POLICIES DEALING WITH INELIGIBLE PERSONS

a. *Consistent Enforcement of Disciplinary Policies*

The Contractor should maintain written policies that apply appropriate disciplinary sanctions on those officers, managers, supervisors, and employees who fail to comply with the applicable statutory and Medicare program requirements, and with the Contractor's written standards of conduct. These policies should include not only sanctions for actual non-compliance, but also for failure to detect non-compliance when routine observation or due diligence should have provided adequate clues or put one on notice. In addition, sanctions should be imposed for failure to report actual or suspected non-compliance.

The policies should specify that certain violations, such as intentional misconduct or retaliating against an employee who reports a violation, carry more stringent disciplinary sanctions. We believe that certain behavior cannot be tolerated in the work-place. Thus, the Contractor should consider listing those offenses that would carry the termination sanction without progressive discipline. In all cases, disciplinary action should be applied on a case-by-case basis and in a consistent manner.

Contractors may want to identify a list of factors that will be considered before disciplinary action will be imposed. Such factors may include degree of intent, amount of financial harm to the company or the

government or whether the wrongdoing was a single incident or lasted over a long period of time.

b. Employment of, and Contracting with, Ineligible Persons

The Contractor should have written policies and procedures requiring a reasonable and prudent background investigation to determine whether prospective employees and prospective non-employee subcontractors or agents were ever criminally convicted, suspended, debarred or excluded from participation in a federal program.

Contractors should determine whether background checks should be applied just to the subcontractor as an entity or whether it should apply to the principals, officers, directors and employees of the subcontractor, or any subset thereof. In making that determination Contractors should consider the nature of the work a subcontractor or agent will be performing against the business risk associated with such work. When a subcontractor is being considered for work identified as high risk, it would be a prudent business practice to determine whether that partner subjects its own employees to reasonable and prudent background checks.

When subcontractors are frequently used, the Contractor should consider requiring the subcontractor to have a compliance program in place and require it to conduct necessary background and suspension/debarment checks on its own employees. The Contractor could require the subcontractor to routinely provide reports of these activities to the Contractor's CO.

The Contractor should also conduct periodic reviews of current employees and/or subcontractors and agents to determine whether any have been suspended or debarred, or are under criminal investigation or indictment. If an employee or non-employee agent or subcontractor is found to be ineligible, the Contractor should have a written policy requiring the removal of the employee from direct responsibility for, or involvement with, the Medicare program, or for the termination of the subcontract, as appropriate.

7. RESPONDING TO DETECTED OFFENSES, DEVELOPING CORRECTIVE ACTION INITIATIVES AND REPORTING TO GOVERNMENT AUTHORITIES

a. Responding to Offenses and Developing Corrective Action

The Contractor should ensure that the CO has a means by which to determine the type and extent of the investigation required following receipt of a report of non-compliance. The Contractor should handle reports of potential non-compliance in a consistent manner. The Contractor should have written policies and procedures to ensure that investigations of suspected non-compliance are handled appropriately and that the necessary

corrective action is taken. The Contractor should establish written policies and procedures that, at a minimum, cover the following areas:

- A plan that addresses how internal investigations should be conducted
- A time limit for closing an investigation
- Options for corrective action after determining that an act of non-compliance has occurred including disciplinary action, a review of existing policies and procedures and possible training of employees
- When to have an investigation performed by an outside, independent investigator
- How and when to refer an act of non-compliance to CMS or law enforcement authorities

The Contractor should ensure that internal investigation case files are consistently documented to show, at a minimum, the substance and date of the complaint, investigative actions taken, a narrative description of the resolution of the matter and the date of closure. Internal investigation case files should be maintained in a secure area. If other departments are to be involved in the investigation, the CO should still maintain oversight and final closing authority over the matter. The Contractor should ensure that persons performing the internal investigations have been adequately trained in performing such investigations. Corrective action should be developed in consultation with the CO and periodic audits of any revised procedures should be conducted to ensure that the revisions are effective.

b. Reporting to the Government

Where potential fraud or False Claims Act liability is not involved, the Contractor should use normal contract administration channels to report and resolve non-compliance with Medicare program requirements. However, where the CO has credible evidence of misconduct from any source and has reason to believe that the misconduct may violate criminal, civil or administrative law relating to the Medicare program, then the Contractor should report the misconduct to the OIG and CMS within 30 days of discovering the misconduct. The contractor should have written procedures on how and when misconduct will be referred to CMS or law enforcement authorities.