
CMS Manual System

Pub. 100-16 Medicare Managed Care Manual

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 110

Date: January 11, 2013

SUBJECT: Compliance Guidelines Program

I. SUMMARY OF CHANGES: “The sponsor’s governing body is responsible for Medicare compliance program oversight, not a parent company’s governing body” has been deleted. This change clarifies CMS’ Compliance Program Guidelines policy and ensures consistency between the language found in Section 50.2.1 of Chapter 21 with previously approved language already found in Section 50.2.3 of Chapter 21.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 11, 2013

IMPLEMENTATION DATE: January 11, 2013

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	21/ 50.2/ 50.2.1/Compliance Officer

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

50.2.1 – Compliance Officer

(Chapter 9 – Rev. 16, Issued: 01-11-13, Effective: 01-11-13; Implementation: 01-11-13)

(Chapter 21 – Rev.110, Issued:01-11-13, Effective:01-11-13; Implementation:01-11-13)

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The compliance officer position should be full-time. The sponsor is not required to have a separate compliance officer (“Medicare Compliance Officer”) dedicated only to its Medicare Parts C and D business, although CMS strongly recommends a dedicated Medicare compliance officer. Sponsors must assess the scope of the existing compliance officer’s responsibilities, the size of the organization, and the organization’s resources when determining whether a single compliance officer can effectively implement the Medicare compliance program and the sponsor’s commercial or other governmental business.

The compliance officer must be an employee of the sponsor (preferred) or of its parent company or corporate affiliate. Sponsors may not delegate the compliance officer position or compliance program functions to first tier or downstream entities. When the compliance officer is not employed by the sponsor itself, but by the sponsor’s parent company or corporate affiliate, the sponsor must ensure that the compliance officer has detailed involvement in and familiarity with the sponsor’s operational and compliance activities.

The sponsor must ensure that reports from the compliance officer reach the sponsor’s senior-most leader (typically the CEO or President). The direct reporting relationship between the compliance officer and the senior-most leadership refers to the direct reporting of information, not necessarily to a supervisory reporting relationship. This can be accomplished through a dotted line or matrix reporting.

The compliance officer must have express authority to provide unfiltered, in-person reports to the sponsor’s senior-most leader. The compliance officer’s reports should not be routed to the CEO or President through operational management such as the COO, CFO, GC (General Counsel) or other executives responsible for operational areas. For example, the compliance officer’s report to the CEO should not be filtered through the CFO. However, the compliance officer’s reports may be relayed to the sponsor’s senior-most leader through divisional Presidents. For example, the compliance officer may report directly to the President of the division that houses the Medicare program, who then reports to the CEO of the sponsor on the status and activities of the Medicare compliance program.

The compliance officer’s reports to the sponsor’s governing body must be made through the compliance infrastructure. The compliance officer must have express authority to provide unfiltered, in-person reports to the sponsor’s governing body at his/her discretion.

The Medicare compliance officer may report compliance issues directly to the corporate compliance officer and/or the compliance committee, who then provide compliance reports directly to the sponsor’s governing body. The compliance officer, in his/her discretion, need not await approval of the sponsor’s governing body to implement needed compliance actions and

activities, provided that those actions and activities, as appropriate, are reported to the governing body or governing body committee at its next scheduled meeting. It is a best practice for sponsors who have both a corporate compliance officer and a Medicare compliance officer to allow the Medicare compliance officer to regularly attend meetings of the sponsor's governing body and to make in-person reports to the sponsor's governing body. A related best practice is to allow the compliance officer to meet in Executive Session with the governing body.

The compliance officer should be independent. The compliance officer should not serve in both compliance and operational areas (e.g., where the compliance officer is also the CFO, COO or GC). This leads to self-policing in the operational area(s) in which he/she serves, which is a conflict of interest.

Because the compliance officer must be free to raise compliance issues without fear of retaliation, it is a best practice to require governing body approval before the compliance officer can be terminated from employment.

The compliance officer is responsible for the implementation of the compliance program. The compliance officer defines the program structure, educational requirements, reporting, and complaint mechanisms, response and correction procedures, and compliance expectations of all personnel and FDRs.

The compliance officer should have training and/or experience working with MA, MA-PD or PDP programs and, with regulatory authorities. It is a best practice for the compliance officer to be a member of senior management.

Duties of the compliance officer may include, but are not limited to:

- Ensuring that Medicare compliance reports are provided regularly to the sponsor's corporate compliance officer (if any), governing body, CEO, and compliance committee. Reports should include the status of the sponsor's Medicare compliance program implementation, the identification and resolution of suspected, detected or reported instances of noncompliance, and the sponsor's compliance oversight and audit activities;
- Being aware of daily business activity by interacting with the operational units of the sponsor;
- Creating and coordinating, by appropriate delegation, if desired, educational training programs to ensure that the sponsor's officers, governing body, managers, employees, FDRs, and other individuals working in the Medicare program are knowledgeable about the sponsor's compliance program, its written Standards of Conduct, compliance policies and procedures, and all applicable statutory and regulatory requirements;
- Developing and implementing methods and programs that encourage managers and employees to report Medicare program noncompliance and potential FWA without fear of retaliation;

- Maintaining the compliance reporting mechanism and closely coordinating with the internal audit department and the SIU, where applicable;
- Responding to reports of potential FWA, including the coordination of internal investigations with the SIU or internal audit department and the development of appropriate corrective or disciplinary actions, if necessary. To that end, the compliance officer should have the flexibility to design and coordinate internal investigations;
- Ensuring that the DHHS OIG and Government Services Administration (“GSA”) exclusion lists have been checked with respect to all employees, governing body members, and FDRs monthly and coordinating any resulting personnel issues with the sponsor’s Human Resources, Security, Legal or other departments as appropriate;
- Maintaining documentation for each report of potential noncompliance or potential FWA received from any source, through any reporting method (e.g., hotline, mail, or in-person);
- Overseeing the development and monitoring of the implementation of corrective action plans;
- Coordinating potential fraud investigations/referrals with the SIU, where applicable, and the appropriate NBI MEDIC. This includes facilitating any documentation or procedural requests that the NBI MEDIC makes of the sponsor.

Similarly, the compliance officer should collaborate with other sponsors, State Medicaid programs, Medicaid Fraud Control Units (MCFUs), commercial payers, and other organizations, where appropriate, when a potential FWA issue is discovered that involves multiple parties; and

- The compliance officer should have the authority to:
 - Interview or delegate the responsibility to interview the sponsor’s employees and other relevant individuals regarding compliance issues;
 - Review company contracts and other documents pertinent to the Medicare program;
 - Review or delegate the responsibility to review the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements;
 - Independently seek advice from legal counsel;
 - Report potential FWA to CMS, its designee or law enforcement;
 - Conduct and/or direct audits and investigations of any FDRs;
 - Conduct and/or direct audits of any area or function involved with Medicare Parts C or D plans; and

- Recommend policy, procedure, and process changes.