

## COMPLIANCE AND BUSINESS INTEGRITY (CBI) PROGRAM STANDARDS

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook is issued to establish standards for the implementation of CBI programs at all organizational levels.
- 2. SUMMARY OF MAJOR CHANGES:** This is a new VHA Handbook outlining the standards for the compliance program.
- 3. RELATED DIRECTIVE:** VHA Directive 1030.
- 4. RESPONSIBLE OFFICE.** The Compliance and Business Integrity Office (10B3) is responsible for the contents of this Handbook. Questions may be referred to (202) 501-1831.
- 5. RECISSIONS.** None.
- 6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working day of November 2015.

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**CONTENTS**

**COMPLIANCE AND BUSINESS INTEGRITY (CBI) PROGRAM STANDARDS**

<b>PARAGRAPH</b>	<b>PAGE</b>
1. Purpose .....	1
2. Background .....	1
3. Definitions .....	2
4. Scope .....	3
5. Responsibilities of the Chief CBI Officer .....	4
6. Responsibilities of the Veterans Integrated Service Network (VISN) Director .....	4
7. Responsibilities of the Medical Center Director .....	4
8. Compliance Program Standards for Implementation at VHA VISNs and Medical Facilities ..	4
a. Written Policies and Procedures .....	4
b. Designation of a CBI Officer .....	5
c. Establishment of a CBI Committee .....	5
d. Risk Management .....	6
e. Training and Education .....	6
f. Open Lines of Communication .....	7
g. Enforcement and Discipline .....	7
h. Auditing and Monitoring .....	7
i. Investigation and Response .....	8
j. Annual Review of CBI Program Effectiveness .....	9
9. References .....	9

## COMPLIANCE AND BUSINESS INTEGRITY (CBI) PROGRAM STANDARDS

### 1. PURPOSE

This Veterans Health Administration (VHA) Handbook establishes standards for the implementation of Compliance and Business Integrity (CBI) programs at all organizational levels.

### 2. BACKGROUND

a. Formal compliance programs have been implemented across a wide spectrum of business and governmental organizations for several decades. These programs are designed to prevent, detect, and mitigate fraud, waste, and abuse along with organizational risk in a systematic fashion.

b. Over time, Federal oversight and regulatory organizations have published guidance for industry use in implementing effective compliance programs. The United States Sentencing Commission (USSC), in publishing its first Federal Sentencing Guidelines for Organizations in 1991 (updated in 2004 and 2010), provided remedy for potential penalties if an organization had implemented an effective compliance program. In doing so, they provided a basic framework for effective industry compliance programs.

c. Compliance programs in the health care industry began in the late 1980s as a result of increased regulatory authority of the Department of Health and Human Services (HHS) Office of Inspector General (OIG). While implementing the programs, many organizations looked to the Sentencing Guidelines for the appropriate systems to employ. The HHS OIG provided guidance specific to the health care field in the form of Compliance Program Guidance publications, and released guidance for hospitals in 1998, with additional supplemental guidance issued in 2005 (see subpars. 9b and 9c).

d. The Compliance Program Guidance for Hospitals identified core practices that must be in place for a compliance program to be successful. This guidance was embraced by the health care community and is now deemed so basic to compliance programs as to be necessary for any organization. These core practices were defined around seven elements, later augmented by risk assessment and an annual review of program effectiveness; they are:

- (1) Written Policies and Procedures (see subpar. 8a).
- (2) Designation of a Compliance Officer and Compliance Committee (see subpars. 8b and 8c).
- (3) Risk Assessment (see subpar. 8c).
- (4) Training and Education (see subpar. 8d).
- (5) Open Lines of Communication (see subpar. 8e).

- (6) Enforcement and Discipline (see subpar. 8f).
- (7) Auditing and Monitoring (see subpar. 8g).
- (8) Investigation and Response (see subpar. 8h).
- (9) Annual Review of Compliance Program Effectiveness (see subpar. 8i).

e. Another key characteristic of effective compliance programs, codified in industry guidance, is the presence of a strong ethical culture. The HHS OIG Supplemental Compliance Program Guidance for Hospitals and the revised USSC Sentencing Guidelines both clearly link the ethical culture of an organization to effective compliance programs. Empirical research in the compliance and ethics arena demonstrates the importance of an ethical organizational culture to compliance program outcomes.

f. VHA's formal CBI Program was established in 1999 in response to new Federal regulations which allowed Department of Veterans Affairs (VA) medical facilities to retain the collections they received from first and third-party billings. In designing the program, CBI adopted the HHS OIG Guidance and the United States (U.S.) Federal Sentencing Guidelines as the benchmarks against which the program would be built.

g. The health care compliance industry recognizes the need to retain records of key actions and outcomes of the compliance program. Retention of records allows the organization to protect the integrity of its compliance program and demonstrate its effectiveness to internal and external reviewers. VHA's CBI programs at all levels are expected to maintain records for these and other purposes.

### 3. DEFINITIONS

a. **Business Unit.** The business unit is the entity that is performing the operational functions in question. For instance, where billing issues are concerned, the business unit would be the medical facility or Consolidated Patient Account Center (CPAC) billing department; where accuracy of insurance information is a cause of concern, the business units are likely the patient intake and insurance verification departments.

b. **CBI Helpline.** VHA maintains a CBI Helpline to receive questions and reports of potential noncompliance, and to implement procedures to protect a caller's anonymity when requested. The CBI Helpline is a reporting opportunity which is separate from the VA OIG Hotline or the Medical Inspector Hotline. Compliance inquiries may be directly reported to a supervisor, other management, or the facility or Veterans Integrated Service Network (VISN) CBI Officer.

c. **Compliance Inquiry Reporting and Tracking System (CIRTS).** CIRTS is a database and document management system maintained by the VHA CBI Office to provide a tool which

collects data arising from calls made to the Helpline, and compliance inquiries conducted by CBI Officers at the VISNs and VA medical facilities.

d. **Causation and Corrective Action Plan.** A causation and corrective action plan is specific to an identified risk or CBI revenue and purchased care organizational failure. Its purpose is to identify the cause of the risk or failure, and to lay out the specific steps the organization will take to minimize the likelihood of a risk actually occurring, or to halt the compliance failure and implement prevention mechanisms to ensure the failure does not resurface. *NOTE: The VHA CBI Office has developed a standard causation and corrective action plan, which can be found at: [http://vaww.cbi.va.gov/metrics\\_list.asp](http://vaww.cbi.va.gov/metrics_list.asp). This is an internal web site and is unavailable to the public.*

e. **Excluded Parties List System (EPLS).** EPLS provides a single comprehensive list of individuals and firms excluded by Federal government agencies from receiving federal contracts or federally approved subcontracts and from certain types of federal financial and non-financial assistance and benefits. The EPLS is used to keep agencies abreast of administrative, as well as, statutory exclusions taken throughout the Federal Government. Actions may be taken under the Federal Acquisition Regulation (FAR) or supplements thereto, under specific agency regulations or under the Government-wide Nonprocurement Suspension and Debarment Common Rule ([68 Federal Register \(FR\) 66533](#)), or other specific statutory authority.

f. **Internal Controls.** Internal controls are an integral component of management that provide reasonable assurance that the following objectives are being achieved: effectiveness and efficiency of operations, reliability of transactions affecting financial reporting and of the reports which result, and compliance with applicable laws and regulations.

g. **List of Excluded Individuals and Entities (LEIE).** The HHS OIG LEIE database provides information to the health care industry, patients, and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid, and all Federal health care programs.

h. **Organization.** In this Handbook, “organization” refers to a VISN office, VA medical facility, or any other VHA entity that maintains a CBI program charged with overseeing revenue or purchased care activities.

#### 4. SCOPE

a. CBI provides internal oversight of VHA’s revenue and purchased care programs to:

- (1) Uphold compliance with applicable laws and standards;
- (2) Foster the highest standards of business integrity and quality;
- (3) Support the early detection and prevention of non-compliance practices; and
- (4) Demonstrate VHA’s commitment to accountability and stewardship.

b. In this way CBI upholds VA's mission to serve and honor the men and women who are America's Veterans by strengthening VHA's business infrastructure to better support the delivery of high quality, compassionate, patient-centered care to Veterans.

c. VHA organizations must implement their CBI program in accordance with the standards set forth in this Handbook (see par. 7).

## **5. RESPONSIBILITIES OF THE CHIEF CBI OFFICER**

The Chief CBI Officer is responsible for:

- a. Establishing the CBI Program Standards and updating them as appropriate.
- b. Routinely assessing field implementation of the standards.
- c. Providing a report, at least annually, to the Business Compliance Committee (BCC) as to the results of field assessments.

## **6. RESPONSIBILITIES OF THE VETERANS INTEGRATED SERVICE NETWORK (VISN) DIRECTOR**

The VISN Director is responsible for ensuring implementation of these program standards within the VISN office and at VA medical facilities located within the VISN.

## **7. RESPONSIBILITIES OF THE MEDICAL FACILITY DIRECTOR**

The VA medical facility Director is responsible for ensuring implementation of these program standards within the VA medical facility no later than December 31, 2010.

## **8. COMPLIANCE PROGRAM STANDARDS FOR IMPLEMENTATION AT VHA VISNs AND MEDICAL FACILITIES**

### **a. Written Policies and Procedures**

(1) The organization must demonstrate that:

(a) Written compliance policies and procedures are consistent with those established by VHA and reflect industry standards and practices; and

(b) Policies and procedures are accessible and communicated, when both initiated and updated, through a variety of communication and management forums to all employees, volunteers, contractors, and other business compliance stakeholders.

(2) Organizational policies and procedures must, at minimum, identify that the core compliance elements are implemented through the CBI Program. These must be approved and signed by the organization's senior most executive.

b. **Designation of a CBI Officer.** The organization must employ a dedicated, full time CBI Officer, charged with responsibility of day-to-day operations of the CBI Program, who reports directly to and is supervised by the organization's senior most executive.

(1) The organization must ensure that:

(a) Resources (e.g., budgetary resources for training and education materials and staff) are dedicated to support the CBI program; and

(b) The senior-most executive and executive committees are routinely updated on the elements of the organization's CBI Program.

(2) The designated CBI Officer must have the access and authority to review all documents, patient records, and other information that are relevant to CBI activities, including, but not limited to, claim submissions, financial reports, external review reports, purchased care reports, communication from first and third-party payors, quality reports, privacy records, reports of investigations, and arrangements with other parties.

(3) The organization CBI Officer is responsible for:

(a) Providing training and education to organizational leadership and to the members of the CBI Committee (see subpar. 8e).

(b) Promoting the standards in cooperation with Regional Counsel and the local-designated ethics officer (see subpar. 8g(3)).

(c) Reviewing internal controls in place within any business unit in question, and making a determination as to the unit's adequacy in preventing CBI revenue and purchased care operational failures (see subpar 8h).

(d) Including an assessment of internal controls in any audit report provided to leadership.

(e) Authoring a report for the senior-most executive and the CBI Committee, after the annual review of effectiveness has been concluded, including a description of how future CBI program activities will mitigate current compliance risks and failures (see subpar. 8j(2)).

c. **Establishment of a CBI Committee.** A CBI Committee must be formally established through organizational policy to advise leadership of compliance activities.

(1) At a minimum, membership must include the senior-most officers responsible for the revenue cycle and purchased care operations, Health Information Management (HIM), the Chief Financial Officer, and may include other services with operational responsibility for CBI program elements, such as Human Resources, Quality Management, and other services as needed.

(2) The CBI Officer serves as either Chair or Co-Chair of the committee.

(3) At a minimum, the CBI Committee must demonstrate:

(a) Active involvement in the organization's risk management process to identify, assess, respond, prioritize, mitigate, monitor, document, and bring business compliance risks to closure specific to its business environment.

(b) That there are risk-driven internal controls in place throughout the organization to monitor CBI program activities (e.g., coding accuracy and CBI Metrics) and these controls are reviewed by the CBI Committee on a periodic basis.

(c) Promotion of the CBI Program and reporting mechanisms for potential violations. This includes use of CIRTS, the CBI HelpLine and other reporting mechanisms.

(d) Routine review and reporting of the results of CBI Program activities to organizational leadership.

(e) Active involvement in the review and recommendation of CBI Program plans and corrective action plans for approval by the organization's senior-most executive.

d. **Risk Management.** The organization must:

(1) Implement a standardized risk management process to periodically (annually at a minimum) identify, assess, prioritize, respond to, mitigate, monitor and document CBI business compliance risks associated with the revenue cycle and purchased care activities. The primary objective of CBI risk management is to bring CBI business compliance risks to closure in a prioritized manner consistent with VA and VHA mission, vision, and goals.

(2) Demonstrate correlation of identified business compliance risks with response and mitigation activities, such as: training and education plans and monitoring and auditing plans.

(3) Implement a quarterly review process with the local CBI Committee to communicate and document the status of business compliance risk resolution, i.e., the status of risk mitigation and monitoring activities.

e. **Training and Education**

(1) The organization must:

(a) Demonstrate a formal, written training and education plan to include: basic compliance awareness training, annual refresher retraining, job-specific training for employees of the organization related to specific positions that affect revenue cycle, CPAC, purchased care activities, LEIE, CIRTS, and the CBI HelpLine. This formal plan is developed by the CBI Committee and must be endorsed by organizational leadership.

(b) Establish policies and procedures outlining the specific number of training and education activities each employee must complete in order to achieve CBI program outcomes.

(2) The CBI Officer must have access to training records documented in VA Learning Management System (LMS) and elsewhere.

(3) All training and education activities are to be delivered on a fiscal year basis by qualified personnel, consultants, or products purchased from compliance industry resources.

f. **Open Lines of Communication.** The organization must:

(1) Use CIRTIS to track and trend reported organizational compliance failures in accordance with established VHA Handbooks, VHA Directives, policies and procedures.

(2) Demonstrate adherence to HHS OIG Guidance regarding the anonymity of the reporting individual; although certain circumstances may present themselves which make anonymity unfeasible.

(3) Demonstrate, consistent with the NO FEAR Act, (see [http://vaww4.va.gov/orm/NOFEAR\\_Select.asp](http://vaww4.va.gov/orm/NOFEAR_Select.asp), *NOTE: This is an internal web site and is not available to the public.*) that any individual who makes a report in good faith is not subjected to retaliation or punitive action by any organizational entity or employee.

g. **Enforcement and Discipline.** The organization must demonstrate:

(1) Adherence to the prohibition of employment of individuals contained in the LEIE, as defined in Title 42 United States Code (U.S.C.) 1320a-7b(f) and prohibition of remuneration to entities on the EPLS.

(2) Equitable enforcement of disciplinary procedures at all levels of the organization.

(3) Employees have been trained, provided access to and understand their roles and responsibilities under the “Standards of Ethical Conduct for Employees of the Executive Branch”. In VHA, these standards are supported and carried out by the Designated Agency Ethics Officials (DAEO), the General and Regional Counsels. The CBI Officer is however expected to promote the standards in cooperation with Regional Counsel and the local designated ethics officer.

h. **Auditing and Monitoring.** According to industry standards, internal controls and quality monitoring is the responsibility of business units actually carrying out the business activity. For instance, internal controls focused on ensuring proper and accurate insurance capture should be carried out by Insurance Identification and Verification staff. This Handbook does not attempt to require such activity as it only addresses the requirements of the CBI Program. It is the CBI Officer’s duty as part of periodic audits to review those internal controls in place within the business unit in question, and to make a determination as to their adequacy in preventing CBI, revenue, and purchased care operational failures. Any audit report provided to leadership must include such an assessment (see subpar. 8b(3)).

(1) The organization must demonstrate:

(a) Formal, written plans for auditing and monitoring business activities which have been identified as actual or potential sources of compliance failures, revenue, and purchased care operational failures, or by the organization's risk assessment. Auditing and monitoring plans must be endorsed by both the CBI Committee and organization leadership. Auditing will be completed in accordance with industry standards and appropriate VHA guidance provided in VHA Handbooks, VHA Directives, and policies.

(b) That when an audit or established monitor finds that practices are inconsistent with VHA standards and policies, a CBI causation and corrective action plan is developed and implemented.

(2) All auditing must:

(a) Be completed in accordance with industry standards and appropriate VHA guidance provided in VHA Handbooks, VHA Directives, and policies.

(b) Demonstrate a review of internal controls (monitoring) within the business units to determine if internal controls are implemented and effective in maintaining adequate performance.

(3) When CBI activities identify a compliance failure, the organization must demonstrate that a retrospective review was conducted to determine the origin of the failure.

i. **Investigation and Response.** The organization must demonstrate:

(1) Formal and informal investigation processes and procedures in accordance with applicable VHA Handbooks, VA Directives, and policies.

(a) If it is determined that a failure found during CBI program activities was caused by improper procedures, misunderstanding of the rules, or systemic problems, the organization must demonstrate prompt steps are taken to correct the problem.

(b) When CBI program activities identify that failures were not detected in a timely manner due to inadequate, or a lack of internal controls, appropriate modifications to those internal controls must be implemented.

1. Identified or potential issues of fraud, waste and abuse need to be immediately referred to the VA OIG. Other violations of law not related to fraud, waste, or abuse must be referred to the VA police.

2. Any investigation by organization staff outside of these parties may taint the eventual investigation. Therefore, the OIG and Police have properly directed VHA employees to

immediately refer suspect activity and not to conduct any internal investigation or fact-finding prior to the referral.

(2) Processes and procedures for monitoring and auditing following the organizational failure to determine if corrective actions were appropriate.

(3) That findings of investigation and response activities, along with the associated causation or corrective action plan, are reviewed and approved by the both the CBI Committee and the senior-most executive.

j. **Annual Review of CBI Program Effectiveness**

(1) The organization must demonstrate a written review of the effectiveness of the CBI program on a fiscal year basis.

(2) After the review of effectiveness has been concluded, the CBI Officer must author a report for the senior-most executive and the CBI Committee detailing: the performance of the program, including all work completed; the results of the risk assessment; and the contents of the program's various planning documents. This report is to include a description of how future CBI program activities will mitigate current compliance risks and failures.

## **9. REFERENCES**

a. VHA Directive 1030, Compliance and Business Integrity (CBI) Program, and associated Handbooks.

b. HHS OIG Compliance Program Guidance for Hospitals, 63 Federal Register (FR) 8987 (February 23, 1998).

c. HHS OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858 (January 31, 2005).

d. Public Law 107-174, Notification and Federal Employee Antidiscrimination and Retaliation Act of 2002, also known as the NO FEAR Act.

e. Standards for Internal Control in the Federal Government; Government Accountability Office (GAO); November 1, 1999; available at: <http://www.gao.gov/special.pubs/ai00021p.pdf>.

f. Standards of Ethical Conduct for Employees of the Executive Branch at: [http://www.usoge.gov/ethics\\_docs/publications/reference\\_publications/rfsoc\\_02.pdf](http://www.usoge.gov/ethics_docs/publications/reference_publications/rfsoc_02.pdf)

g. United States Sentencing Commission, Sentencing Guidelines, Chapter 8, Sentencing of Organizations at: <http://www.ussc.gov/2004guid/CHAP8.pdf>

h. VA Handbook 0700, Administrative Investigations, located at: [http://www1.va.gov/vapubs/viewPublication.asp?Pub\\_ID=82&FType=2](http://www1.va.gov/vapubs/viewPublication.asp?Pub_ID=82&FType=2)