



COMPLIANCE: AUDITING AND MONITORING

Purpose:

To outline and evaluate the process of performing audits and/or monitoring to measure compliance and assist in process improvement.

Scope:

The procedure outlined in this document is a guide for audits conducted by or on behalf of the Boulder Community Health ("BCH") Compliance Department and applies to risk assessment, ad hoc, external, and research audits.

Policy Statements:

- BCH takes reasonable steps to achieve compliance with applicable laws and with the Hospital's compliance standards by utilizing auditing and monitoring practices to detect criminal or other improper conduct by BCH staff.
- The Compliance Officer is responsible for overseeing that auditing and monitoring are properly executed, documented, and evidenced to ensure effective training and quality review of work performed.
- Legal counsel is consulted, as necessary, with respect to audit and monitoring activities.
- All audit and monitoring activities are conducted in such a manner as to maintain any appropriate legal privileges, including the attorney-client, work product, quality management and self-evaluative privileges, as applicable.
- The results of all audit and monitoring functions are provided to the Compliance Officer, who shall report such results to the Compliance Committee, Executive Compliance Committee, Chief Executive Officer, and Board of Directors on a regular basis, but no less frequently than annually.
- In the event any audit or review reveals potential violations or areas for improvement, the Compliance Officer takes any appropriate action in accordance with BCH's policies, including without limitation, conducting an investigation, advising enforcement and discipline if warranted, development of a corrective action plan, modification of the BCH's standards and policies if necessary, and to the extent feasible, reporting to applicable government agencies, including submission of any overpayments made to BCH within 60 days of being identified, if applicable.

Procedural Guideline Statements:

1. Oversight
 - a. The Compliance Officer:
 - i. Recommends and facilitates auditing and monitoring of identified risk areas related to compliance with laws and regulations, as well as organizational policies, procedures, and the Code of Conduct;
 - ii. Verifies completion of compliance audits and any corrective action measures

- arising from them.
- b. The members of the Compliance Department:
 - i. Have unrestricted access to all system records relevant to the audit.
 - c. Conduct auditing and monitoring of identified risk areas related to compliance on an ongoing or as needed basis and may review the following (including but not limited to):
 - i. Policies and procedures
 - ii. Internal controls
 - iii. Data integrity
 - iv. Financial statements
 - v. Research IRB applications, correspondence, and documentation
 - vi. Patient records in all systems
 - d. Provide management with analyses, recommendations, counsel and information concerning the activities reviewed.
 - e. Do not develop or install procedures, prepare records, make management decisions, manage or oversee implementation of the action plan, or engage in any other activity that could be reasonably construed to compromise the Auditor's independence.
 - f. The internal audit plan will be presented to the Compliance Committee, Executive Compliance Committee, CEO, and the Audit Committee of the Board of Directors on an annual basis.
2. Confidentiality
- a. Confidential information acquired by the Compliance Department through the relationship as a BCH staff member is considered to be privileged and must be held in strictest confidence. It is to be used solely for BCH purposes and not as a basis for personal gain by the Auditor.
 - b. Confidential information is transmitted only to those persons who need the information to discharge their duties as staff or governmental and contracted Auditors.
 - c. All reports are filed in the Compliance Department with limited access control.
3. Records Retention
- a. Auditing and Monitoring reports are maintained in compliance with the BCH records retention policy.
4. Audit Selection
- a. The Compliance Department develops a schedule of activities and departments to be audited annually and presents it to the Compliance Committee, Executive Compliance Committee, and the Audit Committee of the Board of Directors. This schedule includes both risk assessment audits and known ad hoc audits.
5. Risk Assessment
- a. An annual compliance risk assessment will be conducted, incorporating any issues identified through the regular course of business, external alerts (e.g., annual OIG work plan), and internal reporting channels.
 - b. The Compliance Department will also solicit input from the administrative leaders at BCH for high risk areas of the organization.
 - c. The Compliance Department will establish a system for staying current on risk areas identified by the OIG, CMS, the Colorado department of HCPF, Joint Commission, FDA, DHHS, and other regulatory entities, as well as by organizations serving similar

- populations, such as the Colorado Hospital Association. An analysis of these potential risks is included in the annual risk identification and prioritization process.
- d. The Compliance Department evaluates the scope of an audit request, availability of resources, and timing of the next regularly scheduled audit. The audits with regulatory risk have the highest priority.
6. Annual Audit Work Plan
 - a. Once the list of risks has been developed, they will be ranked according to probability of occurrence and potential impact or consequences. The Compliance Department will develop an annual audit work plan that places the greatest emphasis on addressing areas of highest risk.
 - b. The plan includes the following:
 - i. Specific areas of the Hospital's operations which will be audited or reviewed during the year.
 - ii. The persons or entities responsible for conducting the audit or review.
 - iii. Audits and reviews may be conducted internally or by persons or entities outside the hospital that have knowledge of health care compliance requirements in the specific area. The Compliance Department will assume that all outside auditors have entered into appropriate contracts with the organization including Business Associate Agreements (BAA).
 - iv. Internal audits may be performed with approval and under direction of the CO.
 7. Audit Process
 - a. Audit Planning: Preliminary communication with key stakeholders, regarding the audit scope and timing, should take place prior to the initiation of the audit.
 - b. Opening Conference: As needed, the Auditor will direct an opening conference which provides the Auditor(s) with the opportunity to work with all key players and department management to further define the scope of the upcoming audit, learn where to find pertinent information for the audit, and in general explain the specific audit program to the stakeholders.
 - c. The Auditor will invite to the audit opening meeting the audit requestor, any appropriate staff members, and the appropriate department manager or director. The vice president for the area will also be notified of the audit.
 - d. The anticipated duration of the audit will be discussed in this meeting.
 - e. For Audit preparation the Auditor(s):
 - i. Gather information and conduct interviews, as necessary, to gain an understanding of the operation or system under review.
 - ii. Research pertinent policies, procedures, guidelines, regulations or industry standards to assess the level of compliance of the processes being reviewed.
 - iii. Prepare an audit program which outlines the objectives, scope, procedures, staff involved, and references the work papers.
 - iv. Create work papers, which effectively document the fieldwork performed and serve as the connecting link between the audit assignment, the Auditor's fieldwork, and the final report. The Auditor will provide sufficient evidence to support the findings.
 - f. Turn-around time for directors to comply with audit requests for data should be as follows:

- i. Urgent regulatory requirement, external request, subpoena, etc.: immediately to 48 hours
 - ii. Monitoring audit: 5-10 business days.
 - iii. The director or vice president of their area will be notified if information requested from the department under review is not delivered to Compliance within 10 business days.
 - iv. In extenuating circumstances the director may request and the Auditor may grant a reasonable extension on an exception basis.
 - g. Reporting: After the data has been analyzed the Auditor writes a report that clearly express the objectives, scope, sampling methodology, procedures, and findings of the audit.
 - i. The report will identify areas of non-compliance and improvement opportunities and be delivered to the department manager and/or director and the vice president responsible for that area. If the audit has been prepared pursuant to the attorney client privilege, it will be delivered to internal or outside counsel who will distribute it internally as appropriate.
 - h. Any findings requiring immediate action will be shared with the management team as they are found. This report may be verbal and does not remove the obligation of a final written report for the audited process or department.
 - i. The Auditor will communicate milestone reports to the department management throughout the review process.
8. Audit Close Meeting and Action Plan Generation
 - a. After all the data has been analyzed and a report has been generated, the Auditor will present the findings and recommendations expressed in the report to:
 - i. the audit requestor
 - ii. any appropriate staff members
 - iii. appropriate department manager or director
 - b. The department leaders will be responsible documenting management response for any recommendations for improvement.
 - c. The Auditor will negotiate a reasonable timeframe for completion of the action plan.
 - d. The Auditor will continue his/her review of audit recommendations noted in the action plan until satisfactory solutions have been found for reported deficiencies.
 - e. The audit will be considered closed when the final report has been issued and an agreed upon action plan has been created by the department.
 - f. It is the responsibility of the department to execute the action plan and notify compliance upon completion.
9. Overpayments: If an internal audit determines that there was an overpayment, the Auditor will immediately notify the Compliance Officer who will work, as practicable, to refund the overpayment within 60 days of the date it was identified.
10. Monitoring and Follow-up
 - a. The Compliance Department monitors risk areas when deemed necessary.
 - b. The follow-up may be informal observations, monitoring of specific data elements or in some instances, may take the form of a subsequent audit.
 - c. The nature of the follow-up is dictated by the seriousness and complexity of the deficiencies noted.

- d. Monitoring may also include assessment of the compliance program. The Compliance Officer and Committee may utilize, as necessary, any additional means of assessing the effectiveness of the Hospital's Compliance program, including the use of outside auditors and consultants.

Definitions:

1. **Ad Hoc Audits:** Any audits that occur in the regular course of business. Conditions that may trigger an ad hoc audit include:
 - a. Processes that are inconsistent with policies and procedures
 - b. Unexpected financial or statistical results
 - c. A request from Senior Leadership, a department's manager, or director
2. **Compliance Officer ("CO"):** The individual in charge of overseeing and managing compliance issues within BCH, ensuring that it is complying with regulatory requirements, and that BCH and its employees are complying with internal policies and procedures.
3. **External Audits:** Audits that are initiated by an external party, including commercial and government payers or their representatives (ex: HCPF, OIG, CMS).
4. **Internal Audits ("IA"):** Audits/reviews designed to determine a department's or staff member's level of compliance with legal and regulatory guidelines and/or compliance with an internal policy or standard operating objective.
5. **Identified:** An overpayment is considered identified when the nature and basis for the overpayment are known to the hospital and the patient accounts that are out of compliance resulting in the overpayment have been recognized.
6. **Monitoring:** On-going statistical or other reporting to promote and review compliance after the audit process has been completed.
7. **Planned Audits:** Any audit that is planned with assigned resources. These audits may include audits that result from performing a Risk Assessment.
8. **Research Audits:** A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory requirement(s). (ICH E6 1.6)
9. **Risk Assessment:** Analysis and prioritization of risk areas. Usually the highest risk areas will be assigned resources to conduct an audit. A risk assessment is generally performed separately for Research vs. General Compliance issues.
10. **Work Papers:** Supporting documentation that substantiates a claim or finding in the audit report. Audit work papers should be prepared to achieve four main objectives:
 - a. Document the planning, performance, and review of audit work.
 - b. Provide the principal support for audit communication such as observations, conclusions, and the final report.
 - c. Facilitate third-party reviews and re-performance requirements.
 - d. Provide a basis for evaluating the internal audit activity's quality control program.
 - e. Audit work papers remain the property of BCH.

Resources:

[The Institute of Internal Auditors Website \(www.theiia.org\)](http://www.theiia.org)

References:

[Code of Conduct](#)

[Compliance: Program Structure and Responsibilities](#)

[Compliance: Reporting Issues and Concerns](#)

[Compliance: Education and Training](#)

[Compliance: Investigations and Response to Compliance Issues](#)

[Government Authorities: Cooperation With](#)

[Government Investigation: Employee Response](#)

Key Words:

Content Reviewers:

Audit Committee of the Board of Directors

Compliance Committee

Executive Compliance Committee

Approved By:

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