

(ATTACHMENT III-A)
Compliance Program - Sample Case File Documentation Requested

Please note this document is being provided in conjunction with Attachment III (*Compliance Program Data and Documentation Requests*). It is intended to provide sponsors with the documentation that will be requested for each of the sample cases by CMS during the on-site audit.

Instructions:

CMS will evaluate the sponsor's submission in response to the *Compliance Program Data and Document Requests* (Attachment III), and will identify sample cases on-site for the sponsor to provide to the audit team. The sponsor must include in the sample request response all documentation below for each sample case, unless otherwise noted. Sponsor must submit all requested documentation electronically via the Secure File Transfer Protocol (SFTP), by the deadline established by the Compliance Team Lead. All hard-copy documentation originals that are not available electronically must be scanned to create an electronic copy, with the electronic copy provided to CMS via the SFTP.

With the exception of the documents requested for Element I (Written Policies, Procedures and Standards of Conduct), the documentation listed under each sample request is provided as examples of what your organization may provide as evidence of compliance for the respective element.

Compliance Program Effectiveness

- I. Element I - Written Policies, Procedures and Standards of Conduct;**
- Element III - Effective Training and Education;**
- Element VI - Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks**

Sample Requested: Employee Records/ Governing Body Records

- (a) For each identified employee/volunteer/Board of Director Member, please provide documentation e.g. sign-in sheets, employee attestations, electronic certifications of completion, etc.) that confirms:
 - Standards of Conduct/Code of Conduct distributed to employee/volunteer/Board member, along with date of distribution;
 - Most recent general compliance training and/or education
 - Most recent (including date)fraud, waste and abuse (“FWA”) training (including date)
 - Screening against the OIG and GSA exclusion lists (including date(s))

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II. Compliance Officer, Compliance Committee, Governing Body

No sample- this element is satisfied through original universe request and Element I- Employee Records/ Governing Body Records.

III. Effective Training and Education

No sample- this element is satisfied through Element I- Employee Records/ Governing Body Records sample and First Tier Entity Records sample.

IV. Effective Lines of Communication

Sample Requested: Log of Reported Non-Compliance Incidents (including but not limited to hotline calls)

(a) For each report of noncompliance or hotline call, provide the following (when applicable):

- Description of the issue reported;
- Specific steps taken to address the complaint ;
- Summary of findings;
- If applicable, report of findings to management and/or the compliance committee;
- Date of resolution of issue (if not resolved, please note);
- If applicable, dates and descriptions of actions taken to determine that the issue is permanently resolved; and
- If applicable, final resolution of complaint and how it was reported to impacted operational areas within the organization.

V. Enforcement of Well-Publicized Disciplinary Standards

No sample- this element is satisfied through original universe request.

VI. Effective System for Routine Monitoring, Auditing, and Identification of Compliance Risks

Sample Requested: Monitoring and Auditing Activities

(a) For each identified monitoring/ auditing activity, provide the following (when applicable):

- Full monitoring and/or audit report;
- Issues identified from the monitoring and/or audit activity;
- Corrective actions taken as a result of the monitoring and/or audit and date when corrective action implemented;
- If applicable, report of findings to management and/or the compliance committee;

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- Names and titles of those who were responsible for ensuring corrective actions were implemented :
- Dates and results of monitoring corrective action for effectiveness and names and titles of individuals who requested monitoring and who received the results.
- If applicable, tracking of current status of corrective action or remediation plan .

Sample Requested: First Tier Entity Records

For each identified first tier entity, provide the following documentation, including the date of receipt (e.g. signed certifications, attestations, training logs, etc.):

(a) Training, Education and Exclusion List Checking

- Evidence that general compliance training was timely provided to your FDRs.
- Evidence that sampled non-deemed first tier entities' employees received timely FWA training.
- Evidence that you provided FWA training or training materials to the non-deemed first tier entity for its employees' timely FWA training or otherwise ensured that the first tier entity completed the CMS FWA training module through the Medicare Learning Network (MLN) (Required).
- Evidence that you require the sampled first tier entities to maintain records for ten years of the training of their employees, including the following details: time, attendance, topic, certificate of completion, if applicable and test scores, if any.
- Evidence that sampled first tier entities' employees were timely checked against the OIG/GSA exclusion lists.

(b) Effective Communication

- Evidence that your compliance/FWA reporting mechanism(s) are accessible to your FDRs. Evidence that you have publicized your compliance/FWA reporting mechanism(s) to your FDRs
- Evidence that your sampled FDRs' employees have been notified of the no-retaliation policy for reporting potential FWA.
- Evidence that either you or the sampled first tier entities have communicated to their employees the obligation to report compliance concerns and potential FWA.

(c) Disciplinary Standards

- Evidence that you have publicized your disciplinary standards to your FDRs, including the duty and expectation to report.

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(d) Monitoring/ Auditing Records

- Evidence of monitoring of the sampled first tier entities (please provide full report as available)
- Evidence of auditing of the sampled first tier entities (please provide full report as available)
- Evidence that you audited the sampled first tier entities to determine whether they are monitoring / auditing their downstream entities' compliance with Medicare regulations and requirements.
- Issues identified from monitoring
- Issues identified from auditing
- If applicable, issue tracked through completion
- Corrective actions taken as a result of the monitoring and/or audit and date started and completed
- If applicable, report to senior management and/or the compliance committee
- If applicable, names and titles of person responsible for the corrective action
- If applicable, names and titles of individuals requesting the monitoring and /or audit
- Names and titles of individuals receiving the results
- If applicable, the risk analysis that demonstrated the need for the monitoring and/or audit

VII. Procedures and Systems for Promptly Responding to Compliance Issues

Sample Requested: Incidents of Non-compliance and FWA

(a) Investigations into Compliance Issues: For each investigation identified, provide the following (when applicable):

- Investigative report;
- Conclusions of investigation;
- Issues discovered from the investigation;
- Root cause of the issue(s) that led to non-compliance, or FWA ;
- Description and dates of all actions taken by the organization as a result of the investigation;
- Date investigation completed;
- Communications to the Board, Senior Management, and/or the compliance committee or others within organization the results, issues discovered, root cause(s), and corrective actions taken from the investigation; and

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- Communications to the Account manager (AM) , the summary of the non-compliance & FWA issues, the results, issues discovered, root cause(s), and corrective actions taken from the investigations.
 - Date(s) of subsequent monitoring to confirm effective correction.
 - Root cause of incident
 - Date(s) of investigation;
 - Summary of findings
 - Description of response to incident (e.g. reported to NBI MEDIC, corrective action implemented)
 - Date of response to incident (e.g. date reported, date corrective action implemented)
- (b) Incidents of Misconduct (if applicable)
- All related documentation that demonstrates incident was investigated internally at your organization
 - If applicable, the incident was referred to the National Benefit Integrity (NBI) MEDIC, or to law enforcement
 - If applicable, current status of the referrals to NBI MEDIC or law enforcement