

**Pharmaceutical and Device Manufacturer
Compliance Program Elements**

Date:

Compliance Program Function

Status

Complete
In Progress
Not Complete

1 Compliance Committee

- a. A Compliance Committee Charter is in place
- b. The Compliance Committee has authority to address compliance issues
- c. The Compliance Committee maintains minutes of its meetings
- d. The Compliance Committee members are properly trained in compliance

2 Compliance Officer

- a. The Compliance Officer job description is approved and updated
- b. The Compliance Officer is responsible for implementing policies and procedures and for the operation of the Compliance Program
- c. The Compliance Officer reports to the CEO and has authority to investigate compliance issues
- d. The Compliance Officer provides periodic updates to the Board of Directors or the Board-level Committee responsible for compliance
- e. Compliance Officer reports to the Board/Board Committee are documented in minutes

3 Code of Conduct

- a. The Code of Conduct is approved by the Board of Directors
- b. The Code of Conduct is distributed to all employees and contractors
- c. Adherence to the Code of Conduct is included as an element of employee performance evaluations
- d. The Code of Conduct includes a commitment to compliance, employee expectations, and the right of employees to use the confidential disclosure program and the commitment to non-retaliation
- e. Employees have returned a form confirming they have received, read, understand, and will abide by the Code of Conduct
- f. Completed employee attestation forms have been audited
- g. The Code of Conduct has been reviewed and updated as necessary

4 Compliance Policies

- a. Compliance Program policies are in place that define the operation and structure of the Compliance Program
- b. A Compliance Program Charter has been adopted by the Board of Directors
- c. Compliance Program policies have been reviewed and updated on a regular basis
- d. Policies have been developed to address specific compliance risk areas
- e. Specific risk area policies are reviewed and updated to ensure that all relevant risk areas are covered
- f. Risk area policies are announced and made available to employees

5 Compliance Training

- a. Employees have attended general compliance training
- b. General compliance training includes information about the Compliance Program, Code of Conduct, Non-Retaliation policy, hotline, and employee obligations under the Compliance Program
- c. New employees are provided compliance training after commencing employment
- d. General compliance training is provided on an annual or more frequent basis
- e. Documentation of completion of general compliance training is maintained and audited
- f. Training for risk areas is provided to specific employees based on responsibilities
- g. Documentation of risk area training is maintained and audited

6 Hotline

- a. A confidential reporting mechanism is operational
- b. The hotline number is communicated to all employees
- c. Hotline calls are reported and investigated
- d. A non-retaliation policy has been adopted by the Board
- e. Evidence of employee willingness to use the hotline is maintained by the compliance officer

7 Sanction Screening

- a. A process exists to screen employees, contractors, consultants to ensure eligibility to participate in Federal health care programs ("eligibility")
- b. New potential employees are screened for eligibility
- c. A process exists to remove ineligible employees from business operations related to Federal health care programs
- d. Employee files have been audited to confirm sanction screening has been completed
- e. A sanction screening policy documents the requirements to confirm eligibility of employees, contractors, and consultants

8 Investigation, Response & Discipline

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- a. Documentation exists of the process to receive reports of suspected non-compliance.
- b. A process exists to investigate reports of suspected non-compliance
- c. The Compliance Officer maintains a log of all reports of suspected non-compliance
- d. The Compliance Officer maintains documentation of efforts made to address and remediate any identified non-compliance
- e. Discipline for non-compliance with the Code of Conduct is applied consistently and uniformly
- f. Discipline for noncompliance is documented in employee personnel files

9 Ongoing Monitoring & Auditing

- a. A process exists to annually assess compliance risks
- b. Risk areas are identified and documented
- c. Audits of risk areas are performed to assess compliance
- d. Corrective action plans to improve compliance efforts are developed and implemented

10 Sunshine Act Reporting

- a. A process exists to track and record payments required to be reported under the Sunshine Act and applicable state laws
- b. Sunshine reports are timely submitted and in the required format and accepted by CMS and applicable states
- c. Payments to consultants are documented by contract
- d. Payments are audited to ensure the reported payment matches the contract and the actual payment
- e. Investment interests are recorded and supported by documentation of the initial value, current value, and the consideration for the investment interest