

The Key Components of an Organizational Compliance Program

David W. Tate, Esq.

<http://davidtate.us>; tateatty@yahoo.com

The following are key organizational compliance program component areas. Of course, each component must also have subparts, and program standards and procedures must be developed to meet the needs of the specific organization for potential different substantive areas such as the foreign corrupt practices act; governmental billings and receipts; fraud; HR and the ADA; accounting; disclosures; environmental; quality assurance (such as with respect to products, materials, services or care); bribes/kickbacks; and other areas of potential liability and risk exposure.

- High-level personnel of the organization (tone at the top) must ensure that the organization has an effective compliance and ethics program. A specific individual, or individuals, within high-level personnel shall be assigned overall responsibility for the compliance and ethics program. The term "high-level personnel of the organization" means individuals who have substantial control over the organization or who have a substantial role in the making of policy within the organization. The term includes: a director; an executive officer; an individual in charge of a major business or functional unit of the organization, such as sales, administration, or finance; and an individual with a substantial ownership interest.
- The organization's governing authority, i.e., the Board or other highest-level governing body (tone at the top) shall be knowledgeable about the content and operation of the compliance and ethics program and shall exercise oversight with respect to implementation and effectiveness.
- A specific individual, or individuals, within the organization shall be delegated day-to-day operational responsibility for the compliance and ethics program, and shall report periodically to high-level personnel and to the governing authority, or an appropriate subgroup of the governing authority, on the effectiveness of the compliance and ethics program. The person or persons to whom responsibility is delegated shall be given adequate resources, appropriate authority, and direct access to the governing authority or an appropriate subgroup of the governing authority.
- Delineate lines of reporting and authority that are designed to effectively accomplish the goals and objectives of the compliance and ethics program.
- Design the compliance and ethics program standards and procedures to prevent and detect criminal conduct.
- Implement the standards and procedures.
- Promote and incentivize the compliance and ethics program consistently throughout the organization, and promote an organizational culture of ethical conduct and compliance with laws, regulations and rules. Periodically communicate the program's standards and procedures, and other aspects of the compliance and ethics program, to the members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents. The term "substantial authority personnel" means individuals who within the scope of their

authority exercise a substantial measure of discretion in acting on behalf of an organization. The term includes high-level personnel of the organization, individuals who exercise substantial supervisory authority (e.g., a plant manager, a sales manager), and any other individuals who, although not a part of an organization's management, nevertheless exercise substantial discretion when acting within the scope of their authority (e.g., an individual with authority in an organization to negotiate or set price levels or an individual authorized to negotiate or approve significant contracts).

- Monitor the program to ensure that it is being followed to prevent and detect criminal conduct. Review and improve the program when needed.
- Periodically audit and evaluate the effectiveness of the standards and procedures to prevent and detect criminal conduct. Review and improve the program when needed.
- Periodically assess and reassess the risk of criminal conduct and take appropriate steps to design, implement, or modify each requirement in the program to reduce the risk of criminal conduct identified through this process.
- Have and enforce an effective progressive disciplinary system to encourage compliance with the goals and objectives of the compliance and ethics program.
- Enforce the compliance and ethics program's standards and procedures consistently throughout the organization including appropriate disciplinary measures for engaging in criminal conduct and for failing to take reasonable steps to prevent or detect criminal conduct.
- Implement policies and procedures to facilitate prompt appropriate organizational reaction to possible unlawful conduct, and potential damage mitigation, control and remedy.
- After potential or actual criminal conduct has been detected, take necessary steps to promptly and appropriately respond to and investigate the conduct and to prevent further similar conduct, including making any necessary modifications to the organization's compliance and ethics program.
- Have and publicize a system, which includes mechanisms that allow for anonymity or confidentiality, whereby the organization's employees and agents may report or seek guidance regarding potential or actual criminal conduct without fear of retaliation.

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