

COMMON COMPLIANCE PROGRAM DEFINITIONS

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In building an effective Compliance Program, the starting point is to define what it is and what it should accomplish. The following provide key definitions related to compliance that may be useful for Compliance Officers.

1. **Compliance** is the action or fact of complying with a set of internal or external rules. Internal rules may be in the Code of Conduct, controls, and policy documents. External rules would include laws, regulations, standards, or third-party contractual obligations.
2. **Compliance Programs** are generally defined as the ongoing process of meeting or exceeding the legal, ethical, and professional standards applicable to an organization; and includes their written guidance and actions to prevent and detect violations of laws, regulations, and other standards that could give rise to liability. The framework for compliance programs is the seven standard elements of a compliance program established by the U.S. Sentencing Commission and adopted by the OIG in their compliance guidance.
3. **Compliance Plans** are statements of intent and proposed actions for doing or achieving compliance objectives. It is contrasted with a compliance program that relates to actions taken in furtherance of the plan, along with the results of actions taken.
4. **Effective Compliance Programs** have been defined many ways by different authorities, however it might be summed up as a program that reduces the likelihood or minimizes actions that could give rise to legal or regulatory penalties and potential civil litigation. The DOJ Guidelines used by prosecutors in assessing compliance program effectiveness focus on whether a compliance program is: “well designed”; “being applied earnestly and in good faith”; and “works in practice.”
5. **Seven Standard Element of Compliance Programs** are standard by which programs are evaluated and was first defined in the United States Sentencing Commission “Guidelines for Organizations” and have been adopted by the DHHS OIG in Compliance Program Guidance documents. They include: (1) Implementing written policies and procedures and Code of Conduct, (2) Designating a compliance officer and compliance committee, (3) Conducting effective training and education, (4) Developing effective lines of communication (e.g., Hotline), (5) Conducting internal monitoring and auditing, (6) Enforcing standards through well-publicized disciplinary guidelines; and (7) Responding promptly to detected problems and undertaking corrective action.
6. **OIG Compliance Program Guidance** have been issued since 1997 as a means by which to promote development of voluntary compliance programs for various sectors of the health care industry, including hospitals, nursing homes, third-party billers, and durable medical

equipment suppliers. All their guidance is built around the standard seven elements of an effective compliance program.

For answers to Frequently Asked Questions about compliance see